wrong to assume that one could materially affect the revenue streams of corporations without affecting the rate of return a corporation is able or expected to earn.

Although final consumer price was the question at issue in the several court and regulatory cases mentioned above, attention was directed toward rates of return in regulated industries. Questions of "adequacy," "excessiveness," and "equity" of final price were answered by examination of profit. Under assumptions of profit maximizing behavior questions of adequacy, excessiveness, and even equity are evaluated in terms of the rate of return and risk environment.

In studying adequacy and excessiveness of rates of return and risks, the courts and agencies have generally found that the government is not free to change merely the rates of return of the industries whose prices it seeks to establish. Unless the government is willing to make certain guarantees of minimum returns to these new "semiregulated" industries, it will leave the risk environment unchanged, while usually lowering the rate of return by lower product prices. Such action would result in a marked reduction in the flow of capital to these corporations and, therefore, in a necessary curtailment of the normal flow of goods and services to the public.

In summary then, any discussion of prices and excessiveness of prices in the pharmaceutical industry should be focused on the underlying issues of profitability of this industry, and even more importantly on the relation of this industry's profit level to the risks inherent in its operation. If prices are to be challenged or if suggestions are to be made by the Government for new price mechanism, the industry should be in a position to deal with such matters on grounds that are truly pertinent. What follows in this report is a theoretical and statistical development of risk/return relationships in American industry which can be used to place the entire issue of possible price regulation for drugs in the perspective of:

(1) the Pharmaceutical Industry's position in our economy; and
(2) the relationship of its profit level to its risk environment.

III. Proposed Theory of Risk and Return [3]

Our objective in general terms has been to determine the relationship, if any, between the levels of profitability and varying degrees of risk experienced in American industry. The first variable, rate of profitability (or return) is relatively easy to measure conceptually. As will be explained in Section IV, we have used a number of book value and market value financial statistics to measure it. Problems of insuring inter-company accounting comparability were minimized by our use of the Compustat data, in whose preparation pains were taken to insure comparability.

The concept of risk, however, is a more troublesome problem involving semantics. Risk is basically a subjective phenomenon and not as susceptible to precise or direct measures. What we have done, therefore is to theorize that certain objectively measurable concepts are related to, and to some extent describe, risk. Our next step was, by statistical techniques, to correlate rates of return with these objective risk measures.[4]

Two types of problems can arise. First of all, because of some logical error or assumption contrary to fact, there may be no correspondence between the concept of risk and our objective measures. Our sole technique for dealing with this possibility has been to express as explicitly as we can the steps in our logic and our assumptions so that they may be critically examined.

The second type of problem is that we can find a relationship which turns out to be spurious, i.e., some statistical fluke. This type of problem is easier to deal with, at least conceptually. It is discussed in our analysis of the statistical results below.

The basic unit of concern in our risk/return analysis must be the individual corporation. It is within the individual corporation that the balance between

[3] Parts of this section are based on the illustrations given by Paul Cootner and Daniel Holland in their study of Risk and Return for the American Telephone and Telegraph Company (M.I.T. DSR Project No. 9565).

[4] Economists and financial analysts have long proclaimed the existence of a "risk premium." By this phrase they usually mean that prospective investors must be offered above average expectations of return (premium returns) in order to induce them to invest in projects having above average uncertainty (risk). Hence, the higher yield on a corporate debenture than on a government bond is believed to be caused by adding the appropriate risk premium to the government's (riskless) interest rate.

expected returns and expected risks is struck. However, this is not meant to suggest that the only or best source of information about risk expectation by entrepreneurs is historical statistics developed on a company by company basis. Surely management forms its risk expectations on the basis of experience; but not solely on the experience of its own firm. Likewise, entrepreneurs considering entry into an industry will assess the general riskiness of the industry by examining the range of corporations active (or previously active) in that industry. It is therefore, not unreasonable to seek a measure of *expected* risks based on historical industrial experiences.

It is our contention that returns among industry groups cannot be compared unless one has a measure of industry risks. The logic of our model of inter-industry risk/return comparisons follows from our beliefs about the inherent forces which create risky or uncertain situations within individual industries and, consequently, within companies.

For the concept of an "industry" to have any validity in risk/return comparisons it must be demonstrated that there exists sufficient similarities among various companies so that they may be meaningfully divided in industry groupings.

A listing of the various phenomenon that might contribute to inter-industry difference in basic riskiness would certainly include the following:

(1) Differences in the ease of entry of new firms into the industry or the ease of construction of new capacity in the industry.

(2) Differences in the income elasticity of demands for the final products of the industry. (This would affect the response of the industry to general, economic activity.)

(3) Differences in price flexibility in the industry.

(4) Differences in the stability of major sources of raw materials.

(5) Differences in storability and durability of products and raw materials.

(6) Differences in exposure to foreign competition.

(7) Differences in competition among existing prospective, or potential new products.

Another major cause of differences in inter-industry risk character derives from differences in technological and research and development bases of industries' products. Differences in innovative processes and product obsolescence rates are prime examples.

These considerations and others led us to stratify a number of companies into various industry groups. As will be seen below, our research has indicated that a fairly definite pattern of risk/return relationships does emerge from the industry grouping based on SIC stratification.

The reasoning of our model is as follows:

Assume an investor is seeking to enter an industry, i.e., to set up an economic concern in that industry *or* reinvest capital in a going concern in that industry, in such items as plant expansion, product development, etc. The investor being reasonably experienced with the economic, financial and production problems of the industry, believes that he can expect to do as well as anyone else operating in that industry. He also knows that he is not omniscient, so that while he hopes *on occasion* to be more far-sighted, imaginative or effective than his competitors, he also knows that he is likely to be outwitted, or to outwit himself, or to run into a number of natural calamities as often as the reverse. His view, in that case, of the risks inherent in operating in the industry probably arise from observing the impact of errors and advantages upon the rates of return of the companies already engaged in the industry. If the impact, on profitability, of some above or below average behavior is severe the risk of entry will be large. If, on the other hand, no reasonably likely error (or action of a competitor) could push him far from the average return he might assume there was low risk. Thus, at least in theory, a concept of risk evolves and as such is subject to statistical testing. (Cf. Cootner and Holland p. 42).

In order to perform these statstical tests it was necessary to construct a quantitive measure of the industry risk (or uncertainty). We selected measures of the dispersion of individual companies' rates of return about their industry's average rate of return for a given year. An industry which is characterized by relatively high dispersion of rates of return presents the prospective investor with much greater uncertainty as to the return he will achieve should he invest in that industry, than does an industry with low dispersion. Because our theory of return is essentially a long-run theory, we averaged over the period studies

(1950–1965) each industry's annual rate of return and dispersion. In this way our measures should not have been unduly influenced by abnormal years.[5]

(It will be readily noted by economists that in measuring risk as the average intercompany dispersion (or variance) we are, at the same time, staying with and breaking with standard economic tradition. The word risk is generally used by economists to represent certain aspects of the utility functions persons are presumed to maximize in their decision making processes. Specifically, the second moment of the expected utility function is considered the risk element[6] which one usually tries to minimize, while trying to maximize the first moment of the utility function. It is, therefore, natural to measure risk as some type of variance (i.e., mathematical second moment); in so doing we are in keeping with tradition. However, the expected utility function concerns itself with *ex ante* risk. There is no strong reason to believe that temporal variance is a good measure of this quantity. In fact, when dealing with autocorrelated time series (as economic series almost always seem to be) we reject the usual reliance on individual company temporal variance.)

The inter-company dispersion of returns measures one aspect of industry riskiness. We call it the *interspacial*[7] component and view it as somewhat analogous with the uncertainty of any one company's market share in a nonregulated industry. There also exists an *intertemperal* component to industry riskiness. This component is analogous with the *non-predictable* element of year to year changes in individual company or industry profitability. So defined it is very difficult to measure because most economic times series are highly autocorrelated. We have developed some more general intertemporal dispersion measures and have used them, as far as possible, in our analyses.

Our statistical tests on interspacial dispersion turned out to be significant and are discussed in full below. There are, however, a number of theoretical problems which warrant discussion at this point. A few are easily disposed of. One is the problem of industry definition. The theory depends *critically* upon the idea of similarity between the companies assigned to an industry group. The industry groupings we chose are as homogeneous as the SIC based Compustat tape would allow. One may choose the precise industry composition in differing ways and thus, because the number value of our basic measure of risk is so *critically dependent* on the industry grouping, we believe that it was essential to test the sensitivity of our measure to different industry groupings. It is reassuring to report that the results were essentially unchanged when we employed a small number of quite narrow and homogeneous industries.[7]

A similar problem arises because of the widely different sizes of the firms that are rightfully grouped in any industry and the fact that the firms used in our analyses (because of the selectivity of the Compustat tapes) tended to be the larger and more successful firms in each category. We, at this point, do not have sufficient data to investigate the effect that this may have on our results but have sufficient reason to believe that the inclusion of smaller firms would strengthen the relationship we have found.

IV. Definitions of Return

In studying the relation between risk and return it is, of course, necessary to construct quantitative measures of both variables. The measure of risk has been defined in the previous section as the average interspacial deviation of company rates of return about the industry's rate of return. As can be seen from the mathematical deviation presented in Appendix A, the general definition of our risk measure does not depend at all on the specific definition of the rate of return. However, care must be taken in defining return, for the logic upon which the measure of risk is based maintains its economic validity if, and only if, the return calculated is a true, overall economic rate of return.

Rates of return can be measured either at "book value" or at "market value." Book value returns relate the yearly income flow as reported on the company P&L statement to stock Balance Sheet items, such as total assets. Although book value figures are subject to many imperfections, in the long run they are the best indicator of real[8] economic return to invested resources. For a company

[5] Appendix A presents a detailed mathematical derivation of our measure of risk and contrasts it with other measures that have been proposed.
[6] C. J. H. Markowitz, *Portfolio Selection*, New York: Wiley, 1959.
[7] May also be called cross-sectional or intercompany.
[8] Throughout this paper "real" is used in its economic sense, meaning tangible or physical rather than intangible.

which employed the same level of assets in an industry for an entire year and whose assets were financed solely by common equity, the ideal book rate of return would be:

Net Income—Total Assets

However, such a company is quite unusual, for most American corporations employ a seasonally changing level of assets, which are financed in varying degrees by both debt and equity capital. Therefore, measuring total assets at any point in time (and, consequently, at a particular season), one would find some industries with a higher than average level of assets while others would be below average due to seasonal factors. Further, net income for highly levered firms would represent a much smaller portion of the total return to the invested resources, than would it for an all equity financed company which had no fixed charges to pay.

To overcome these objections we have developed the concept of total return to total permanently investable funds. Total return is defined as "Net Income plus Fixed Charges," while total permanently investable funds is "Total Assets minus Current Liabilities." It will be immediately recognized that our asset base measure—"Total Investable Funds" is the familiar Total Capitalization (Common and Preferred Equity plus Long Term Debt) while our total return measure is the sum of the returns to both the equity and debt capital suppliers. We prefer to use the more general terms for they allow us to consider financial as well as industrial industries in the analyses.

To summarize then, in order to adjust for industry differences in peak-seasons and financing we have defined the book value rate of return as:

$$B = \frac{\text{Net Income} + \text{Fixed Charges}}{\text{Total Asset} - \text{Current Liabilities}}$$

For comparisons we have also considered other commonly used but, for our analysis, less meaningful measures of book return. They are:

$$B' = \frac{\text{Net Income}}{\text{Common Equity}}$$

and:

$$B'' = \frac{\text{Net Income}}{\text{Total Assets}}$$

B′ is objectionable because it considers neither the totality of assets invested in the enterprise nor the totality of return. As indicated above, B″ is a misleading measure when comparing industries with different degrees of leverage.

Before defining our measure of market value rate of return it is important to emphasize one point. When we relate book return to enterpreneurial risks, we are asking whether resources are being efficiently allocated in the real economy. However, when we relate market returns to market risks we are concerned with the efficiency of the capital markets as allocators of financial instruments. A company may be experiencing monopoly returns (returns higher than justified by risk) on its book assets (i.e., monopoly real returns) while the holder of its equity instruments would receive a "normal" return if the monopoly profits were capitalized when the stock was issued. Although, the relationship between market return and risk does not directly bear on the question of efficient resource allocation it is of interest to us. The testing of the relationship offers an addition-

al test on the viability of our measure of risk and provides insight into the industries deemed risky by the market. If stock values are ultimately tied to real economic phenomena, then the potential market risks should be related to real economic risks.

Market rate of return is here viewed as the total income received by a purchaser of all the securities of a company related to his purhase price, on the assumption that he sells his holding at the end of a single year. (Other time spans can reasonably be considered.) Therefore,

$$M = \frac{\text{Fixed Charges} + \text{Dividends} + \text{Change in Market Value}}{\text{Initial Market Value}}$$

where

Initial Market Value = Total Market Value of all debt and equity issues at beginning of year one,

and

Change in Market Value = Terminal Market Value less Initial Market Value.

Fixed Charges and Dividends are those actually paid (or payable) by the corporation which the purchaser would receive (or accrue) in the course of the year.

For obvious reasons we could not obtain market values for debt instruments and used Compustat book values for both debt and preferred equity. Common equity is evaluated as the total market value of the common shares outstanding. This compromise with the ideal definition does not seem to be of great significance because of the relative unimportance of preferred stock and the relative stability of most corporate bonds.

V. Statistical Analyses [9]

The model used to test the industry risk/return relation was of the form:

$$\text{(I) Industry Return} = a + b_2 \text{ (Industry Risk)}$$

The major question we sought to answer concerned the sign and statistical significance of "b_2" in the above equation. That is, if "b_2" is positive and significantly greater than zero we have demonstrated our hypothesized relationship between industry return and our measure of risk—a relationship implying that high returns are associated with high risks during the period studied.

Model I was fitted on both book (B) and market (M) rates of return. It is not necessary to study the detailed statistical analyses appearing in Appendix D to appreciate the relationship we have found. A simple graph can tell most of the story.

Considering book return and risk first, we have plotted in Figure 1 (average book return) on the vertical axis and Risk (average inter-company variance) on the horizontal axis. For each of the 59 industries studied we have plotted one point identifying its 15 year average risk/return position. The fact that the pattern of points form an upward sloping line demonstrates the posited relationship between risk and return.

[9] The following description of the results of our regression analyses is intended only to summarize the general findings. It is not a substitute for Appendix D which reports in detail the various models tested.

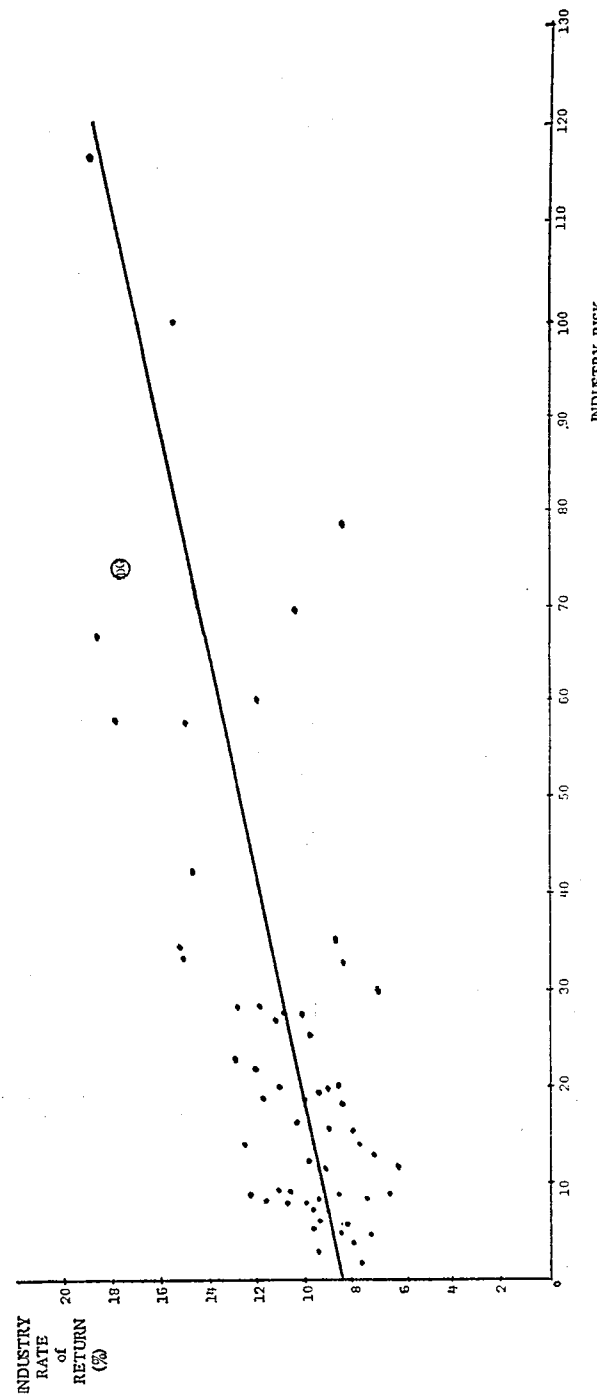

FIGURE 1 MODEL I: INDUSTRY RISK/RETURN PATTERN MEASURED AT BOOK VALUE

NOTE: (PO) REPRESENTS POSITION OF PHARMACEUTICAL INDUSTRY

19

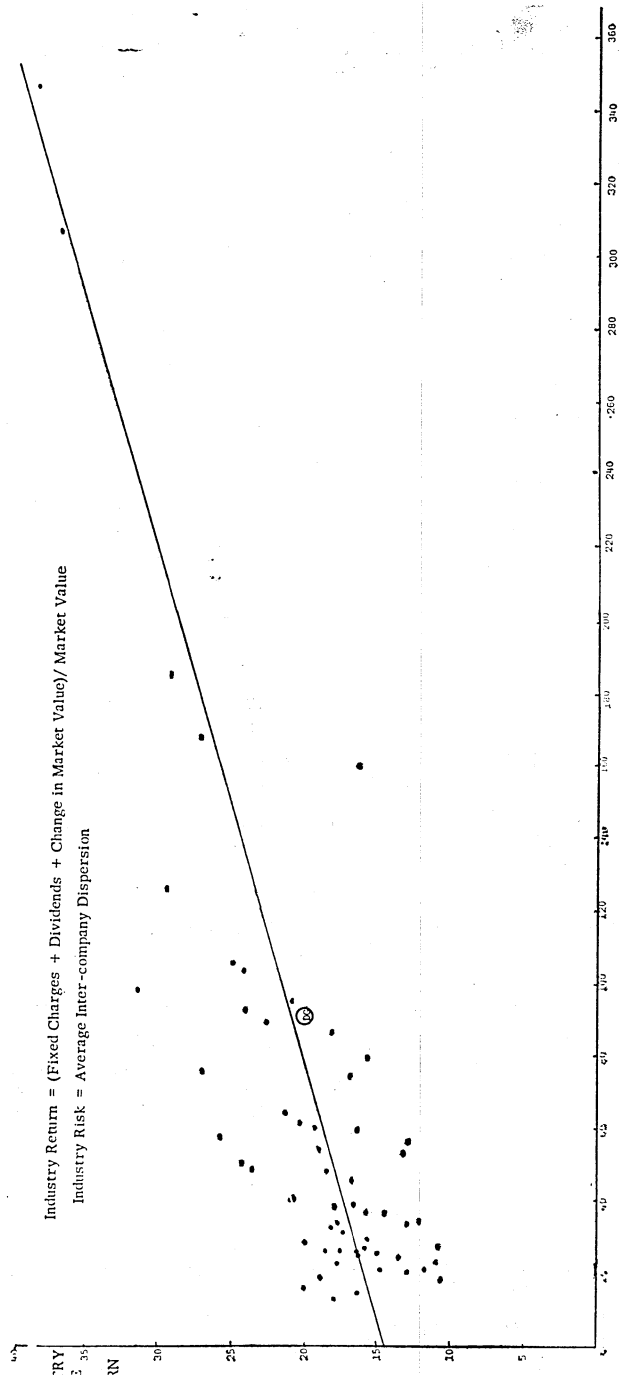

FIGURE 2 MODEL II: INDUSTRY RISK/RETURN PATTERN MEASURED AT MARKET VALUE

NOTE: (DG) REPRESENTS POSITION OF PHARMACEUTICAL INDUSTRY

Exact quantification of relationship, as well as assessment of its statistical significance requires the full regression analysis presented in Appendix E. From this analysis we have drawn the regression line fitted to the points. The equation is:

$$(I_B)\ \text{Industry Return}=8.6+0.038\ (\text{Industry Risk})$$

The b_2 (=0.038) coefficient is highly significant (F=50) at 57 degrees of freedom. The correlation coefficient (R) is .68 while R^2 equals .46.

Figure 2 portrays the same relationship, with Return and Risk measured at market value.

A glance at the graph or the equation (1_M) reveals much the same story:

$$(I_M)\ \text{Industry Return}=14.4+.007\ (\text{Industry Risk})$$

In this equation b_2 is again highly significant having an F test value of 82 with 57 degrees of freedom. The correlation coefficient equals .77 (out of a possible 1.00) while R^2 reached 0.59—most impressive for a basically cross-sectional analysis.

Now that the hypothesized relationship between risk and return has been statistically validated, we may turn to questions concerning individual industries and their relation to the normal risk/return pattern. Given that an industry has a higher than average rate of return, it is both meaningful and possible to ask whether its risk is proportionately higher than average risk. For example, in Figure 1 the pharmaceutical industry has one of the highest book rates of return as well as one of the highest risks. Using the regression statistics we may test whether its particular risk/return point could reasonably be generated by the economic mechanism described by the regression line. Using a two standard error test—i.e., greater than 95% confidence limits—we can conclude that the point does belong to the normal pattern.[10]

In an attemept to examine other dimensions of risk we expanded our original model to include temporal variances as well as the spacial variance first used to measure risk. The yearly variance of the industry's rate of return about its temporal average was added first:

$$(I')\ \text{Industry Return}=a+b_2\ (\text{Industry Risk})+b_3\ (\text{Industry Temporal Variance})$$

In both equations I'_B and I'_M there is some imphrovement in R^2 from 0.46 to 0.51 and from .59 to .61, respectively. This improvement was at the cost of a reduction in degrees of freedom as well as the value of the F statistic. Including an average of the individual companies' temporal variance added little or no independent or partial explanatory power.

Although we are primarily concerned with explaining industry rates of return, some time was devoted to analyses of individual company returns. The basic model used was:

$$(II)\ \text{Company Return}=a+b_2\ (\text{Company Risk})+b_3\ (\text{Industry Risk})$$

Company risk is the standard temporal variance used by most researchers. While it yields the expected results (b_2 positive and significant) for market rates of return, Model II yields a significantly negative value of b_2 for book rate of return. We attribute this negative coefficient to the high degree of auto-correlation found book value statistics. (In Section III we rejected the temporal variance as a measure of risk on theoretical grounds related to auto-correlation.)

In summary, we have seen that our hypothesized measure of industry risk has been statistically validated for both book and market measures of industry

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[10] Mathematically this finding is derived from the limits of prediction formula (cf. Miller & Freunds, *Probability and Statistics for Engineers*, p. 235):

$$(a+b_2x_0)\pm t_{\alpha/2}S_e\left[1+\frac{1}{n}+\frac{n(x_0-\bar{x})^2}{S_{xx}}\right]^{1/2}$$

where $t_{\alpha/2}=2$. Setting x_0 to 74 we get a y range of 19.4 to 10.2. The observed y value of 17.6 falls well within this range.

rates of return. Further, we have found the expected upward sloping risk/return relationship and have been able to test the concurrence of particular industries' results with the general pattern formed by American industry. The impressive magnitudes of both our t and F statistics as well as degrees of freedom, permit us to assert our results with a very high level of statistical confidence; higher in fact, than is usual in cross-sectional analysis.

APPENDIX A

MATHEMATICAL DERIVATION OF RISK/RETURN MEASURES

Notes

1. Part I of this appendix defines in a general framework the mathematical and statistical quantities used in this study. The notation is more general than that used in Part II which defines the exact quantities used in this analysis.
2. For simplicity the letter "C" is used to represent any return quantity we are measuring. For example, C may stand for Net Income/Total Asset.

PART I—GENERAL MODEL

DEFINITIONS AND CALCULATIONS OF RATES OF RETURNS AND VARIANCES FOR COMPANIES AND INDUSTRIES

Each company, i, is uniquely assigned to an industry, j. (i=1, . . ., n; j=1, . . ., N). The value of any variable for a given company in year t, may be written:

$$C_{ij}(t),\ (t=1,\ \ldots,\ T)$$

$C_{ij}(t)$ is read: the value of variable C for the i^{th} company in the j^{th} industry for year t.

The average value (mean) of variable C for company i is:

$$\overline{C}_{ij}=\frac{\sum_{t=1}^{T} C_{ij}(t)}{T}$$

The variance of C for company i is:

$$V(C_{ij})=\frac{T\sum_{t=1}^{T}[C_{ij}(t)]^2-\left[\sum_{t=1}^{T} C_{ij}(t)\right]^2}{T(T-1)}$$

For industry j the average (or 'industry') value of variable C in year t is:

$$C_{\cdot j}(t)=\frac{\sum_{i=1}^{n} W_{ij}(t)C_{ij}(t)}{\sum_{i=1}^{n} W_{ij}}$$

where the $W_{ij}(t)$'s are the weights assigned to each company. They may be equal or, if assets are used as weights, unequal.

(Note that a dot "." in place of a subscript means that we have summed over that subscript.)

The variance of $C_{\cdot j}(t)$ is given by:

$$V(C)_{\cdot j}=\frac{T\sum_{t=1}^{T}[C_{\cdot j}(t)]^2-\left[\sum_{t=1}^{T} C_{\cdot j}(t)\right]^2}{T(T-1)}$$

This statistic, $V(C_{.j})$, is the variance of the industry average over the years and must be carefully differentiated from $V[C_{.j}(t)]$. The variance of the companies about the industry average in any one year is given by:

$$V[C_{.j}(t)]=\frac{n\sum_{i=1}^{n}[C_{ij}(t)]^2-\left[\sum_{i=1}^{n}C_{ij}(t)\right]^2}{n(n-1)}$$

in the equal weight case, and by:

$$V[C_{.j}(t)]=\frac{\dfrac{\sum_{i=1}^{n}W_{ij}(t)[C_{ij}(t)]^2}{\sum_{i=1}^{n}W_{ij}(t)}-[C_{.j}(t)]^2}{\left\{1-\sum_{i=1}^{n}\left[\dfrac{W_{ij}(t)}{\sum_{i=1}^{n}W_{ij}(t)}\right]^2\right\}}$$

in the case of unequal weights.

The difference between $V(C_{.j})$ and $V[C_{.j}(t)]$ is quite significant for our analysis of interindustry riskiness. Year to year profitability for an entire industry may be quite stable. Yet in any one of those years, the individual companies whose profitabilities are averaged to yield the industry's figure, may be widely distributed about that mean. (That is, $V[C_{.j}(t)]$ may be very much larger than $V(C_{.j})$.) Using the year to year industry variance tends to hide the important company to company variance. The risk of a change in market share facing individual companies is not at all reflected in the time series variance of industry sales of the detergent or automotive industries. Our primary concern in this analysis is the risk as it appears to an individual company. Most scholars, on the other hand, have concentrated on the year to year industry variance.

The $V[C_{.j}(t)]$ calculations will yield a T-element vector, $V_{.j}$, each of whose elements is one year's value of $V[C_{.j}(t)]$. The question then arises how best to summarize this vector (for graphic presentation and interindustry comparisons). One method is to indicate the range of the elements. It would be preferable if some scalar could be used rather than two numbers. Should the elements of $V_{.j}$ prove to be serially uncorrelated, we could construct an estimate of the variance of the underlying process by taking a (weighted) average of the elements.

PART II—SPECIFIC NOTATION

DEFINITIONS AND CALCULATIONS OF RATES OF RETURNS AND VARIANCES FOR COMPANIES AND INDUSTRIES

The specific quantities used in our analyses are outlined below. It should be noted that all measures are derived from the single datum point C_{it}, which is defined in Part I, above, as $C_{ij}(t)$—the value in year t of any variable for company i (in industry j).

COMPANY

Company value in t:

$$C_{it}$$

Company's average value over time: [1]

$$\overline{C}_i=\frac{1}{T}\sum_{t=1}^{T}C_{it}$$

Company's temporal dispersion: [2]

$$V_t(C_{it})=\frac{1}{T}\sum_{t=1}^{T}(C_{it}-\overline{C}_{it})^2$$

[1] In Section V this statistic is called Company Return.
[2] In Section V this statistic is called Company Risk.

Company's temporal standard deviation:

$$\underset{t}{S}(C_{it})=\sqrt{[\underset{t}{V}(C_{it})]}$$

Company's temporal coefficient of variation:

$$\underset{t}{S}/\overline{C}_i$$

TYPICAL COMPANY (T.C.)

T.C. value in year t:

$$C_{*t}=\frac{1}{N}\sum_{i=1}^{N}C_{it}$$

Industry spacial dispersion about C_{*t} in t:

$$\underset{i}{V2}(C_{it})=\frac{1}{N}\sum_{i=1}^{N}(C_{it}-C_{*t})^2$$

Industry spacial standard deviation about C_{*t} in t:

$$\underset{i}{S2}(C_{it})=\sqrt{[\underset{i}{V2}(C_{it})]}$$

T.C. average value:

$$\overline{C}_*=\frac{1}{T}\sum_{t=1}^{T}C_{*t}$$

Average industry spacial dispersion about C_{*t}:

$$\underset{i}{\overline{V2}}(C_{it})=\frac{1}{T}\sum_{t=1}^{T}\underset{i}{V2}(C_{it})$$

Average industry spacial standard deviation about C_{*t}:

$$\underset{i}{\overline{S2}}(C_{it})=\frac{1}{T}\sum_{t=1}^{T}\underset{i}{S2}(C_{it})$$

Industry's spacial coefficient of variation (about $\overline{C}_*$):

$$\underset{i}{\overline{S2}}/\overline{C}_*$$

T.C. average value:

$$\overline{C}_*=\frac{1}{T}\sum_{t=1}^{T}C_{*t}$$

T.C. temporal dispersion:

$$\underset{t}{V^*}(C_{it})=\frac{1}{N}\sum_{i=1}^{N}\underset{t}{V}(C_{it})$$

T.C. temporal standard deviation:

$$\underset{t}{S^*}(C_{it})=\frac{1}{N}\sum_{i=1}^{N}\underset{t}{S}(C_{it})$$

T.C. temporal coefficient of variation:

$$\underset{t}{S^*}/\overline{C}_*$$

INDUSTRY

Industry value in year t:

$$C_{.t}=\sum_{i=1}^{N} w_{it}C_{it}$$

Industry spacial dispersion about $C_{.t}$ in t:

$$\underset{i}{V1}(C_{it})=\frac{1}{N}\sum_{i=1}^{N}(C_{it}-C_{.t})^2$$

Industry spacial standard deviation about $C_{.t}$ in t:

$$\underset{i}{S1}(C_{it})=\sqrt{\underset{i}{V1}(C_{it})}$$

Average industry value: [3]

$$\overline{C}_{.}=\frac{1}{T}\sum_{t=1}^{N}C_{.t}$$

Average industry spacial dispersion: [4]

$$\underset{i}{\overline{V1}}(C_{it})=\frac{1}{T}\sum_{t=1}^{T}\underset{i}{V1}(C_{it})$$

Average industry spacial standard deviation:

$$\underset{i}{\overline{S1}}(C_{it})=\frac{1}{T}\sum_{t=1}^{T}\underset{i}{S1}(C_{it})$$

Industry's spacial coefficient of variation:

$$\underset{i}{\overline{S1}}/\overline{C}_{.}$$

Industry's temporal dispersion about C: [5]

$$\underset{t}{V}(C_{.t})=\frac{1}{T}\sum_{t=1}^{T}(C_{.t}-\overline{C}_{.})^2$$

Industry's temporal standard deviation:

$$\underset{t}{S}(C_{.t})=\sqrt{\underset{t}{V}(C_{.t})}$$

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[3] In Section V this statistic is called Industry Return.
[4] In Section V this statistic is called Industry Risk.
[5] In Section V this statistic is called Industry Temporal Variance.

APPENDIX B

DEFINITIONS OF FINANCIAL RETURNS

The basic data source of our study was the Annual Industrial Compustat Tape issued by Standard Statistics, Inc., a Division of Standard & Poor's Corp. For each of the companies on the tape some or all of the quantities listed in Table B–1 are given. Their definitions are those currently used in financial analysis and may be found in any of Standard & Poor's source books. The rates of return used in our study have been constructed from the S & P variables and are defined in Table B–2 in terms of the S & P number used in Table B–1.

The base period for calculating the various quantities defined in Appendix A was 1950–1965. However, when a needed datum was not available in any particular year, that measure and all derived measures were adjusted to permit maximum use of all available information.

TABLE B-1.—LIST OF VARIABLES APPEARING ON COMPUSTAT ANNUAL INDUSTRIAL TAPE

S. & P. No.	Balance sheet variables
1	Cash and equivalent.
2	Accounts receivable.
3	Inventories.
4	Current assets.
5	Current liabilities.
6	Total assets.
7	Gross plant.
8	Net plant.
9	Long-term debt.
10	Preferred stock.
11	Common equity (book value).
	Income statement variables
12	Net sales.
13	Operating income.
14	Depreciation and amortization.
15	Fixed charges.
16	Income taxes.
17	Nonrecurring expenses.
18	Net income.
19	Preferred dividends.
20	Available for common.
21	Common dividends.
	Market value and miscellaneous variables
22	Stock price, high, $1 per share.
23	Stock price, low, $1 per share.
24	Stock price, close, $1 per share.
25	Shares outstanding.
26	Dividends per share.
27	Adjustment factor (for changes in number of shares outstanding).
28	Shares traded.
29	Employees.
30	Capital expenditures.

TABLE B–2.—*Definitions of variables used in study in terms of S. & P. numbers.*

Symbol	Accounting definition	S. & P. code definition †
B	$\frac{\text{Net income}+\text{Fixed charges}}{\text{Total assets}-\text{Current liabilities}}$	$\frac{18+15}{6-5††}$
B′	$\frac{\text{Net income}}{\text{Common equity}}$	$\frac{18}{11}$
B″	$\frac{\text{Net income}}{\text{Total assets}}$	$\frac{18}{6}$
M	$\frac{\text{Fixed charges}+\text{Dividends}+\Delta\text{Market value}\ †††}{\text{Market value}\ †††}$	$\frac{15+19+20+\Delta MV†††}{(25*24)+9+14}$

† See table B–1.
†† 6−5=9+10+11 because Total assets=Current liabilities=Total capitalization.
††† $MV_t=(25_t*24_t)+9_t+10_t$.
$\Delta MV=\text{ffi}V_t-MV_{t-1}$.

APPENDIX C.—INDUSTRIES USED IN THE ANALYSES

SIC No.	Industry	Total number of companies
0800	Forest products	7
1000	Metals, miscellaneous	12
1031	Lead and zinc	5
1042	Gold mining	5
1211	Coal, bituminous	7
1311	Oil, crude producers	9
1810	Motion pictures	8
	Food products	43
2000	Packaged foods	9
2010	Meat packers	7
2020	Dairy products	7
2030	Canned foods	7
2046	Corn refiners	2
2070	Confectionery	5
2082	Beverages, brewers	17
2085	Beverages, distillers	11
2086	Beverages, soft drinks	7
	Tobacco	10
2111	Cigarette manufacturers	6
2121	Cigar manufacturers	4
2200	Textile products	15
2300	Textile apparel manufacturers	11
2510	Home furnishings	9
2600	Paper	17
2650	Containers, paper	10
2700	Publishing	17
2731	Publishing books	9
2800	Chemicals	43
2830	Drugs	29
2844	Cosmetics	12
2850	Paint	5
	Oil	25
2912	Integrated domestic	18
2913	Integrated international	7
2950	Building materials, roofing and wallboard	10
3000	Tire and rubber goods	11
3141	Shoes	8
3221	Containers, metal and glass	7
3241	Building materials, cement	10
3291	Abrasive products	7
3310	Steel	22
3331	Copper	6
3334	Aluminum	5
3400	Machinery, metal fabricating	13
3430	Building materials, heating, air conditioning, plumbing	14
3449	Miscellaneous metal work	7
	Machinery	62
3511	Steam generating	4
3522	Agricultural	6
3531	Construction and meterials handling	7
3533	Oil well	6
3540	Machine tools	8
3550	Specialty	16
3560	Industrial	10
3569	General industrial	5
3570	Office and business equipment	14
3581	Vending machines	6
	Electrical products	30
3600	Electrical and electronic leaders	6
3610	Electrical equipment	14
3622	Electrical industrial controls	3
3630	Electrical household appliances	7
3651	Radio-RV manufacturers	7
	Electronic products	31
3670	Electronics	27
2679	Electronic components	4
3611	Automobile	5
3713	Auto trucks	5
3714	Auto parts and acceesories	17
3721	Aerospace	17
3740	Railroad equipment	11
3871	Watches	5
4210	Trucking	10
4400	Shipping	5
4511	Air transport	13
4830	Radio, TV broadcasters	7
5311	Retail, department stores	16
5331	Retail, variety stores	10
5411	Retail, food chains	21
5600	Retail, apparel chains	6
5812	Eating places	6
	Financial	14
6140	Finance	9
6145	Finance, small loans	5

APPENDIX D

REGRESSION ANALYSES

Section V described two regression models:
(I) Industry Return=a+b_2 (Industry Risk)+b_3 (Industry Temporal Variance)

(II) Company Return=a+b_2 (Company Risk)+b_3 (Industry Risk).

As indicated the description was quite abbreviated and did not detail the full models nor all the relevant statistic. In order to accomplish this, we shall use the notation introduced in Part II of Appendix A.

Before turning to the specific models studied, let us consider a general four variable step-wise regression model:

$$x_1=a+b_2x_2+b_3x_3+b_4x_4$$

In this model x_1 is the "dependent variable," while variables x_2, x_3, and x_4 are the "independent variables." Regressing x_1 on x_2 alone would yield the a and b_2 coefficients of the reduced model $x_1=a+b_2x_2$; regressing x_1 on both x_2 and x_3 would yield a, $b_{2.3}$, and $b_{3.2}$ of the model $x_1=a+b_2x_2+b_3x_3$. (The a's might, of course, be different.) In the following discussion and tables b_2 refers to the coefficient of variable 2 in a two-variable regression, b_3 refers to the coefficient of variable 3 in a two-variable regression (i.e., $x_1=a+b_3x_3$), $b_{2.3}$ the coefficient of variable 2 in a three-variable regression involving x_3 (i.e., $x_1=a+b_2x_2+b_3x_3$) etc.

Reformulating and expanding the models present in Section V we have:

$$\text{(I)}\qquad \overline{C}_{\cdot}=a+b_2[\overline{V}_{i}(C_{it})]+b_3[V_{t}(C_{\cdot t})]+b_4[V^{*}_{t}(C_{it})]$$

and

$$\text{(II)}\qquad \overline{C}_{i}=a+b_2[V_{t}(C_{it})]+b_3[\overline{V}_{i}(C_{it})]+b_4[V_{t}(C_{\cdot t})].$$

As will be recalled from Appendix A, $\overline{C}_{\cdot}$ measures the (15 year) average return for an industry, while $\overline{C}_{i}$ measures the (15 year) average return for a company.

Model I was fitted with 59 observations (one per industry), while Model II was fitted with 766 observations (one per company). Each model was fitted for each of the four basic rates of return—B, B′, B″, and M (see Appendix B for definitions).

Tables D–1 and D–2 summarize almost all of the statistics for the various regression steps. In simple regressions (y=a+bx) the F statistic serves as a test of significance of both b and R^2; in multiple regressions each coefficient has it own F test reported a does the R^2.

TABLE D-1.—*Regression model I* [a]

$$\overline{C}_{\cdot}=a+b_2[\underset{i}{\overline{V1}}(C_{it})]+b_3[\underset{t}{V}(C_{\cdot t})]+b_4[\underset{t}{V^*}(C_{it})]$$

Regression statistic	Definition of rate of return [b]			
	M	*B*	*B'*	*B''*
a	14.4	8.6	12.2	5.6
b_2	0.00724	0.08314	0.00215	0.1300
F	82.36	49.8	12.5	25.6
R^2	0.59	0.46	0.18	0.31
a	14.6	9.9	11.5	6.5
b_3	0.00760	0.126	0.04463	0.213
F	67.0	16.7	6.8	8.3
R^2	0.54	0.23	0.10	0.13
a	16.1	10.7	12.4	6.4
b_4	0.00153	0.00053	0.00001	0.07432
F	35.6	0.7	0.5	7.8
R^2	0.38	0.01	0.01	0.12
a	14.2	8.5	11.7	5.5
$b_{2.3}$	0.00502	0.071	0.00177	0.11496
F	9.7	32.8	7.1	17.5
$b_{3.2}$	0.00280	0.062	0.05197	0.10766
R^2	0.61	0.51	0.21	0.34
F	43.5	29.43	7.3	14.4
S_e	3.7632	2.1313	3.1105	1.7869
Mc	19.0	10.8	12.5	7.2
a	14.1	8.5		5.5
$b_{2.34}$	0.00311	0.07149		0.12393
F	2.3	32.8		15.9
$b_{3.24}$	0.00356	0.06065		0.13769
F	3.8	5.0		2.7
$b_{4.23}$	0.00047	0.0004	[c]	−0.92165
F	2.1	0.8		0.4
R^2	0.62	0.52		0.34
F	20.4	29.4		9.6
S_e	3.7236	2.1342		1.7966
Mc	19.0	10.8		7.2

[a] 59 observations.
[b] See appendix B.
[c] Decrease in significance if variable 4 allowed to enter regression.

TABLE D-2.—*Regression model II* [a]

$$\overline{C}_{i}=a+b_2[\underset{t}{V}(C_{it})]+b_3[\underset{i}{\overline{V1}}(C_{it})]+b_4[\underset{t}{V}(C_{\cdot t})]$$

Regression statistic	Definition of rate of return [b]			
	M	*B*	*B'*	*B''*
a	19.3	11.2	13.5	7.5
b_2	0.00131	−0.00084	−0.00057	−0.01611
F	647.1	479.6	630.5	6.9
R^2	0.46	0.38	0.45	0.0009
a	16.9	8.8	12.4	5.4
b_3	0.00851	0.04124	0.00090	0.15534
F	61.8	68.9	0.3	86.0
R^2	0.07	0.08	0.0004	0.09
a	17.7	10.7	13.1	7.0
b_4	0.00841	0.06523	−0.07799	0.11425
F	41.6	5.1	0.9	5.2
R^2	0.0516	0.007	0.0012	0.0067
a	16.7	8.9	13.1	5.5
$b_{2.3}$	0.00126	−0.00084	−0.00058	−0.02786
F	596.6	551.7	650.8	22.3
$b_{3.2}$	0.00083	0.69116	0.00421	0.17098
F	32.7	117.7	12.0	102.9
R^2	0.48	0.46	0.46	0.1244
F	353.3	334.9	325.6	55.3
S_e	11.4	5.1	15.5	3.5
Mc_i	21.8	11.0	12.5	7.3

[a] 76 observations.
[b] See app. B.

APPENDIX E

SAMPLE OF DATA GENERATED FROM COMPUSTAT ANNUAL INDUSTRIAL TAPE [1]

2830	1500	ABBOTT LABORATORIES
2830	26000	AMERICAN HOME PRODUCTS CORP.
2830	26100	AMERICAN HOSPITAL SUPPLY CORP
2830	69400	BAXTER LABORATORIES
2830	72860	BECTON DICKINSON CO
2830	91000	BRISTOL-MYERS COMPANY
2830	128251	CARTER WALLACE INC.
2830	202400	CUTTER LABORATORIES
2830	313600	GILLETTE CO.
2830	397700	JOHNSON/JOHNSON
2830	406300	KENDALL CO
2830	428700	LILLY ELI CO
2830	464400	MCKESSON & ROBBINS, INC. (MD.)
2830	465700	MEAD JOHNSON/CO
2830	471000	MERCK & COMPANY
2830	479000	MILES LABORATORIES INC
2830	543200	NORWICH PHARMACAL CO.
2830	565800	PARKE, DAVIS & CO.
2830	579000	PFIZER UCHASCD & COCT INCC
2830	591800	PLOUGH INC
2830	619550	RICHARDSON-MERRELL INC.
2830	629150	RORER WM H
2830	643300	SCHERING CORP.
2830	648000	SEARLE G D CO
2830	665500	SMITH KLINE/FRENCH LABORATORIES INC
2830	693600	STERLING DRUG INC.
2830	704920	SYNTEX CORP
2830	755550	UPJOHN CO
2830	768700	WARNER-LAMBERT PHARMACEUTICAL CO.

ABBOTT LABORATORIES—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	−8.287	19.575	19.256	14.021
1951	42.327	15.076	17.476	10.894
1952	−17.432	12.806	14.606	9.445
1953	1.814	13.063	15.051	9.777
1954	11.131	12.026	13.852	8.951
1955	77777.000	77777.000	15.169	9.837
1956	77777.000	77777.000	16.105	10.585
1957	77777.000	77777.000	17.434	11.133
1958	77777.000	77777.000	16.188	10.707
1959	77777.000	77777.000	14.936	10.196
1960	77777.000	77777.000	13.446	9.151
1961	77777.000	77777.000	11.477	8.226
1962	77777.000	77777.000	13.118	9.070
1963	77777.000	77777.000	14.356	9.871
1964	77777.000	77777.000	14.887	10.778
1965	77777.000	77777.000	15.159	11.024
No. years	5	5	16	16
C(I)*	5.910	14.509	15.157	10.229
V/T	529.167	9.285	3.516	1.745
S/T	23.004	8.047	1.875	1.321
(S/T)/(I)B	3.892	.210	.124	.129
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

[1] Any designation of 77777.000 indicates no data available.

AMERICAN HOME PRODUCTS CORP.—DRUGS

Year	Inc ret MV	Ern+int B capit	Earnings com ecty	Earnings assets
1950	2.724	16.215	18.825	11.540
1951	29.147	15.327	17.523	10.312
1952	1.784	14.953	16.751	10.051
1953	32.014	15.847	17.780	10.668
1954	47.394	18.894	21.019	12.431
1955	32.292	23.284	25.678	14.127
1956	50.383	31.548	34.288	18.437
1957	28.165	34.065	36.463	20.241
1958	62.147	33.260	35.401	20.672
1959	36.476	32.771	34.438	20.322
1960	8.268	31.015	32.300	18.995
1961	33.525	30.138	31.144	18.260
1962	−31.314	30.241	31.064	17.687
1963	18.087	30.663	31.281	17.512
1964	10.165	32.176	31.646	17.734
1965	77777.000	28.147	60.699	16.327
No. years	15	16	16	16
C(I)*	24.084	26.159	29.769	15.957
V/T	542.962	54.092	117.830	14.602
S/T	23.302	7.355	10.855	3.821
(S/T)/C(I)B	0.968	0.281	0.365	0.239
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

AMERICAN HOSPITAL SUPPLY CORP.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	earnings assets
1950	77777.000	23.408	28.932	12.137
1951	77777.000	15.011	16.315	9.730
1952	−1.959	12.601	13.216	8.344
1953	1.844	10.411	11.915	7.317
1954	13.938	10.446	12.537	7.460
1955	12.945	11.374	13.212	7.419
1956	27.847	14.035	16.259	9.150
1957	30.834	12.977	15.951	9.065
1958	64.399	14.067	16.006	9.575
1959	112.585	14.955	16.485	8.384
1960	57.900	12.183	12.778	8.239
1961	46.332	13.553	14.216	8.789
1962	−15.126	11.354	11.636	8.116
1963	−8.251	11.013	10.997	7.424
1964	49.087	12.350	12.150	8.277
1965	77777.000	13.399	13.280	9.104
No. years	13	16	16	16
C(I)*	30.183	13.321	14.743	8.658
V/T	1273.365	9.400	17.762	1.453
S/T	35.684	3.066	4.214	1.205
(S/T)/C(I)B	1.182	0.230	0.286	0.139
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

BAXTER LABORATORIES—DRUGS

Year	Inv ret MV	Ern + int B capit	Earnings com eqty	Earnings assets
1950	77777.000	21.671	24.486	14.500
1951	77777.000	13.165	17.086	9.333
1952	11.800	13.494	17.228	8.687
1953	−19.095	10.576	12.440	7.444
1954	−13.315	8.245	8.986	5.955
1955	4.119	8.816	9.920	6.404
1956	0.062	9.217	10.036	6.596
1957	106.255	10.156	13.380	6.584
1958	86.391	14.481	15.188	8.176
1959	74.008	13.481	18.119	8.889
1960	52.297	12.538	18.162	8.664
1961	27.329	13.910	18.678	8.456
1962	−16.496	11.420	18.228	7.161
1963	30.591	9.147	16.324	6.247
1964	7.684	9.641	15.563	5.649
1965	77777.000	10.752	17.601	6.699
No. years	13	16	16	16
C(I)*	27.049	11.919	15.717	7.840
V/T	1680.548	10.821	15.951	4.505
S/T	40.994	3.289	3.994	2.122
(S/T)/C(I)B	1.516	0.276	0.254	0.271
C(.)	20.523	14.524	18.942	12.049
C(*)B	25.860	17.988	19.701	12.259

BECTON DICKINSON CO.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	77777.000	77777.000
1951	77777.000	77777.000	77777.000	77777.000
1952	77777.000	77777.000	77777.000	77777.000
1953	77777.000	77777.000	77777.000	77777.000
1954	77777.000	77777.000	77777.000	77777.000
1955	77777.000	77777.000	77777.000	77777.000
1956	77777.000	77777.000	77777.000	77777.000
1957	77777.000	77777.000	77777.000	77777.000
1958	77777.000	77777.000	77777.000	77777.000
1959	77777.000	77777.000	77777.000	77777.000
1960	77777.000	77777.000	77777.000	77777.000
1961	77777.000	8.417	9.303	5.791
1962	77777.000	10.166	11.291	7.487
1963	77777.000	9.862	11.753	7.275
1964	13.133	10.043	12.214	7.231
1965	77777.000	11.464	13.738	8.193
No. years	1	5	5	5
C(I)*	13.133	9.990	11.660	7.195
V/T	99999.000	1.175	2.581	0.765
S/T	31.406	1.084	1.606	0.874
(S/T)/C(I)B	2.391	0.108	0.138	0.122
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

BRISTOL-MYERS CO.—DRUGS

Year	Inv Ret MV	Frn + Int B capit	Earnings com eqty	Earnings assets
1950	9.620	12.076	19.552	9.544
1951	13.406	18.548	21.048	9.962
1952	1.571	5.835	8.577	4.536
1953	−13.244	5.861	8.225	4.512
1954	49.903	7.753	11.029	5.921
1955	−2.693	10.168	14.701	7.842
1956	25.541	11.796	16.395	8.987
1957	20.657	12.613	16.933	9.027
1958	43.011	12.852	16.652	9.692
1959	70.893	15.466	19.882	9.684
1960	57.612	17.684	21.985	10.901
1961	41.119	19.770	23.837	11.571
1962	−1,587	22.434	26.204	12.800
1963	34.178	23.694	26.466	13.984
1964	19.471	24.881	26.834	15.902
1965	77777.000	28.376	28.266	17.240
No. Years	15	16	16	16
C(I)*	24.630	15.300	19.162	10.132
V/T	597.298	47.383	41.025	13.175
S/T	24.440	6.884	6.405	3.630
(S/T)/C(I)B	0.992	0.450	0.334	0.358
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

CARTER WALLACE, INC.—DRUGS

	Inv Ret MV	Ern+Int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	77777.000	77777.000
1951	77777.000	77777.000	77777.000	77777.000
1952	77777.000	77777.000	77777.000	77777.000
1953	77777.000	77777.000	77777.000	77777.000
1954	77777.000	77777.000	77777.000	77777.000
1955	77777.000	77777.000	77777.000	77777.000
1956	77777.000	47.462	47.462	24.560
1957	77777.000	42.090	42.090	25.525
1958	77777.000	38.798	38.798	24.371
1959	94.745	36.225	36.225	23.904
1960	−35.191	25.216	25.216	18.675
1961	29,960	27.387	27.387	17.666
1962	−15.761	24.180	24.180	15.338
1963	33.916	26.625	26.625	18.202
1964	−21,922	22.953	22.953	16.389
1965	77777.000	18.952	18.952	14.079
No. years	6	10	10	10
C(I)*	14.291	30.989	30.989	19.871
V/T	2353.276	89.352	89.352	18.418
S/T	48.511	9.453	9.453	4.292
(S/T)/C(I)B	3.394	0.305	0.305	0.216
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

CUTTER LABORATORIES—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	9.901	19.592	7.353
1951	77777.000	9.250	14.318	6.456
1952	−27.443	2.927	3.228	1.467
1953	3.036	10.589	15.491	6.988
1954	44.236	11.748	16.194	7.816
1955	32.930	−6.023	−16.880	−6.170
1956	−20.236	4.135	5.551	1.900
1957	−0.375	7.773	13.723	4.732
1958	108.441	8.300	10.906	5.441
1959	25.197	8.637	10.770	6.012
1960	−28.235	5.400	5.725	3.121
1961	10.363	6.918	7.403	3.804
1962	37.497	8.532	10.464	5.377
1963	36.850	9.480	11.462	6.261
1964	15.766	10.073	12.125	6.693
1965	77777.000	10.258	11.846	6.766
No. years	13	16	16	16
C(I)*	18.310	7,369	9.495	4.626
V/T	1347.201	18.480	67.592	11.876
S/T	36.704	4.299	8.221	3.446
(S/T)/C(I)B	2.005	0.583	0.866	0.745
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

GILLETTE CO.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	53.511	53.244	60.592	25.428
1951	37.328	44.613	50.932	20.442
1952	13.544	34.395	39.199	18.183
1953	55.298	38.089	43.228	18.599
1954	78.912	46.199	46.199	24.181
1955	18.876	49.193	49.193	23.021
1956	10.954	46.573	46.573	24.507
1957	−12.560	35.879	35.879	20.819
1958	40.896	36.178	35.178	21.339
1959	41.977	35.962	35.962	21.844
1960	44.084	39.617	39.617	23.494
1961	90.383	40.341	40.341	23.795
1962	−40.131	40.206	40.206	23.789
1963	3.255	34.174	34.174	20.428
1964	1.022	29.020	29.896	18.520
1965	77777.000	31.043	31.088	19.391
No. years	15	16	16	16
C(I)*	29.156	39.608	41.141	21.736
V/T	1198.335	46.801	64.814	5.546
S/T	34.617	6.768	8.051	2.355
(S/T)/C(I)B	1.187	0.171	0.196	0.108
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

JOHNSON & JOHNSON—DRUGS

Year	Inv ret MV	Ern+Int B Capit	Earnings cum eqty	Earnings assets
1950	44.237	16.005	18.223	12.285
1951	−4.917	9.237	10.329	7.207
1952	−10.550	8.820	9.688	6.941
1953	6.836	9.268	9.874	7.419
1954	24.113	9.533	9.809	7.562
1955	1.477	10.915	10.915	8.517
1956	−2.412	11.339	11.339	8.913
1957	16.365	10.601	10.601	8.569
1958	56.294	9.425	9.425	7.736
1959	31.073	10.333	10.333	8.545
1960	25.437	9.755	9.755	8.045
1961	31.586	9.473	9.473	7.837
1962	−23.102	9.619	9.619	8.077
1963	41.147	10.137	10.137	8.528
1964	9.855	11.609	11.609	9.699
1965	77,777.000	77,777.000	12.972	10.180
No. years	15	15	16	16
C(I)*	16.496	10.405	10.881	8.504
V/T	501.272	3.061	4.720	1.755
S/T	22.389	1.750	2.173	1.325
(S/T)/C(I)B	1.357	0.168	0.200	0.156
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

KENDALL CO.—DRUGS

Year	Inv reft Mv	Ern+Int B capit	Earnings Com eqty	Earnings assets
1950	44.000	16.340	20.035	12.469
1951	5.406	13.406	15.862	9.924
1952	−2.372	10.874	12.718	8.770
1953	21.160	11.820	13.619	9.580
1954	15.731	9.203	10.432	7.705
1955	13.793	7.164	8.972	5.910
1956	3.365	7.805	9.287	6.180
1957	2.880	6.873	8.707	5.493
1958	48.138	6.742	7.979	5.170
1959	12.158	8.420	10.097	6.594
1960	−0.998	8.105	9.508	6.320
1961	78.396	7.203	8.866	5.560
1962	−27.532	7.663	8.995	5.658
1963	32.705	7.939	9.298	6.062
1964	18.330	9.170	10.724	7.171
1965	77777.000	9.993	11.617	7.699
No. years	15	16	16	16
C (I)*	17.677	9.295	11.045	7.267
V/T	640.229	7.074	10.118	4.065
S/T	25.304	2.660	3.181	2.016
(S/T)/C (I) B	1.431	0.286	0.288	0.277
C (.)	20.523	17.524	18.942	12.049
C (*) B	25.860	17.998	19.701	12.259

LILLY, ELI CO.—DRUGS

Year	Inv rft MV	Ern+int B capit	Earnings Com eqty	Earnings assets
1950	77777.000	77777.000	21.154	16.381
1951	77777.000	77777.000	15.444	11.716
1952	77777.000	77777.000	10.523	6.921
1953	77777.000	77777.000	10.662	6.981
1954	−11.120	8.955	9.470	6.915
1955	26.982	13.334	12.601	10.225
1956	77777.000	77777.000	19.982	15.363
1957	77777.000	77777.000	19.146	14.919
1958	77777.000	77777.000	13.407	10.953
1959	77777.000	77777.000	13.036	10.912
1960	77777.000	77777.000	10.274	8.832
1961	77777.000	77777.000	12.459	10.420
1962	77777.000	77777.000	13.582	11.314
1963	77777.000	77777.000	13.363	10.819
1964	77777.000	77777.000	15.576	12.440
1965	77777.000	77777.000	18.642	14.339
No. years	2	2	16	16
C(I)*	7.931	11.145	14.333	11.216
V/T	725.897	9.588	13.442	8.774
S/T	26.942	3.096	3.666	2.962
(S/T)/C(I)B	3.397	0.278	0.256	0.264
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

McKESSON & ROBBINS, INC. (MD.)—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	8.841	9.724	11.613	6.632
1951	24.254	9.875	11.670	5.851
1952	−2.524	7.815	8.548	4.275
1953	21.711	7.140	8.790	4.416
1954	11.597	7.301	8.689	4.205
1955	9.197	8.358	9.921	4.827
1956	14.574	9.366	11.094	5.304
1957	15.691	8.599	9.925	5.041
1958	19.462	8.774	10.122	5.167
1959	33.348	9.309	10.506	5.476
1960	−2.732	8.990	8.270	4.287
1961	25.451	6.493	7.302	3.819
1962	−6.193	7.135	7.938	4.088
1963	17.559	7,308	8.130	4.194
1964	−13.077	7.617	8.502	4.340
1965	77777.000	77777.000	9.380	4.830
No. years	15	15	16	16
C(I)*	11.811	8.120	9.400	4.797
V/T	170.945	1.205	1.804	0.564
S/T	13.075	1.097	1.343	0.751
(S/T)/C(I)B	1.107	0.135	0.143	0.157
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

MEAD JOHNSON/CO.—DRUGS

Year	Inf rft MV	Ern + int B capit	Earnings com eqty	Earnings assets
1950	1.036	11.001	15.078	8.819
1951	15.135	10.481	13.996	8.088
1952	−1.530	0.972	12.976	7.734
1953	10.152	10.587	13.490	8.059
1954	50.022	12.199	15.326	9.375
1955	18.275	18.836	17.006	10.757
1956	25.346	15.743	18.688	11.837
1957	45.425	16.830	19.364	13.021
1958	26.374	14.068	15.635	10.829
1959	16.749	14.896	16.178	11.628
1960	109.140	28.636	30.201	17.976
1961	−1.696	17.926	18.646	13.120
1962	−48.750	8.287	8.345	6.360
1963	11.134	7.750	7.960	6.184
1964	−13.729	6.971	7.937	5.055
1965	77777.000	0.407	10.486	6.622
No. years	15	16	16	16
C(I)*	17.539	18.037	15.082	9.716
V/T	1203.068	28.090	30.289	11.100
S/T	34.685	6.300	5.504	3.332
(S/T)/C(I)R	1.978	0.407	0.365	0.343
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

MERCK & CO.—DRUGS

Year	Inv ret MV	Ern + int B capit	Earnings com Eqty	Earnings assets
1950	50.133	16.944	23.175	13.040
1951	62.814	13.448	22.411	9.371
1952	−15.763	8.771	14.331	7.351
1953	14.475	8.883	14.470	7.688
1954	18.365	9.569	15.346	8.125
1955	17.846	12.232	19.334	9.977
1956	10.415	14.580	19.905	12.036
1957	35.751	16.532	20.422	12.631
1958	86.484	17.108	18.550	13.791
1959	7.018	14.123	18.451	14.060
1960	7.846	14.885	15.961	12.393
1961	6.943	13.844	14.769	11.208
1962	−10.873	14.523	15.338	11.585
1963	43.172	16.838	17.608	13.270
1964	38.572	10.914	20.694	14.833
1965	77777.000	24.213	24.973	17.802
No. years	15	16	16	16
C(I)*	24.880	14.900	18.484	11.823
V/T	770.181	16.186	10.998	7.927
S/T	27.752	4.023	3.316	2.816
(S/T)/C(I)B	1.115	0.270	0.179	0.238
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

MILES LABORATORIES, INC.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com Eqty	Earnings assets
1950	77777.000	25.004	30.514	16.071
1951	77777.000	15.764	19.857	9.779
1952	77777.000	14.669	17.977	9.085
1953	77777.000	14.912	17.943	8.903
1954	77777.000	16.355	20.772	10.864
1955	77777.000	16.776	19.726	11.346
1956	−6.088	15.557	18.384	11.136
1957	48.704	21.156	23.951	13.310
1958	108.157	15.679	22.454	11.173
1959	39.976	21.217	29.390	9.821
1960	3.532	18.949	18.595	8.194
1961	67.310	15.761	20.480	9.226
1962	−34.425	14.642	17.396	8.509
1963	17.223	16.773	19.408	9.233
1964	14.786	17.400	20.070	9.706
1965	77777.000	17.473	19.749	9.267
No. years	9	16	16	16
C(I)*	28.797	17.130	21.042	10.352
V/T	1810.635	9.887	14.935	4.032
S/T	42.552	3.144	3.865	2.008
(S/T)/C(I)B	1.478	0.184	0.184	0.194
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

NORWICH PHARMACAL CO.—DRUGS

Year	Inv ret MV	Ern + Int B Capit	Earnings Com eqty	Earnings Assets
1950	39.948	16.157	21.240	12.710
1951	33.347	12.031	15.556	9.280
1952	5.272	13.946	16.052	10.455
1953	5.409	14.096	15.949	10.282
1954	68.443	17.087	19.986	12.750
1955	52.997	20.058	22.781	14.503
1956	14.874	21.193	23.601	15.530
1957	27.742	22.320	24.155	16.555
1958	49.696	23.087	23.768	17.683
1959	57.576	24.133	24.634	18.659
1960	23.136	24.685	24.602	19.010
1961	26.411	23.244	23.208	18.281
1962	−24.163	22.067	22.034	17.441
1963	−16.912	26.206	26.130	15.744
1964	20.114	25.890	25.721	17.341
1965	77777.000	27.248	27.093	18.718
No. years	15	16	16	16
C(I)*	25.593	20.840	22.282	15.309
V/T	694.003	22.856	13.322	10.708
S/T	26.344	4.781	3.650	3.272
(S/T)/C(I)B	1.029	0.229	0.164	0.214
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

PARKE, DAVIS & CO.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	13.183	27.812	27.734	19.648
1951	43.995	25.679	25.679	16.310
1952	−19.423	20.035	20.035	14.176
1953	−25.138	11.423	11.231	8.624
1954	24.797	12.278	12.082	9.459
1955	12.898	15.419	15.270	11.521
1956	20.176	17.277	17.151	12.670
1957	33.847	24.050	23.887	16.343
1958	98.488	21.726	21.602	14.939
1959	21.921	22.312	22.063	15.154
1960	−11.213	20.480	20.274	13.977
1961	−3.650	14.548	14.343	10.338
1962	−29.250	12.239	11.921	9.042
1963	29.891	13.679	13.237	9.758
1964	3.125	15.693	15.150	10.764
1965	77777.000	18.485	17.888	12.081
No. of years	15	16	16	16
C(I)*	14.243	18.321	18.097	12.800
V/T	1034.834	25.697	26.479	9.968
S/T	32.169	5.069	5.146	3.157
(S/T)/C(I)B	2.259	0.277	0.284	0.247
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

PFIZER UCHASCD & COCT INCC—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	54.182	21.660	24.250	15.879
1951	76.930	14.969	19.699	10.532
1952	−15.672	12.264	15.835	9.359
1953	4.150	15.927	20.315	11.401
1954	19.615	15.722	19.592	11.931
1955	14.904	14.557	17.761	10.594
1956	17.843	16.009	17.056	11.646
1957	16.656	19.412	19.017	12.756
1958	94.956	16.864	18.166	11.323
1959	2.735	14.581	16.686	10.294
1960	−3.309	14.426	15.793	9.932
1961	75.671	15.360	16.239	10.195
1962	1.109	14.964	15.345	10.221
1963	8.403	16.127	16.059	9.600
1964	5.439	19.311	16.872	9.596
1965	77777.000	17.993	18.306	10.891
Number years	15	16	16	16
C(I)*	24.907	16.072	17.937	11.009
V/T	1134.011	4.773	5.223	2.556
S/T	33.675	2.185	2.285	1.599
(S/T)/(I)B	1.352	0.136	0.127	0.145
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

PLOUCH, INC.—DRUGS

Year	Inv ret MV	Ern+Int B capit	Earnings com eqty	Earnings assets
1950	23.011	9.631	14.360	6.792
1951	9.108	7.859	9.711	4.513
1952	8.817	8.236	10.105	5.490
1953	−0.852	8.348	10.236	4.758
1954	48.668	8.983	11.765	5.120
1955	35.933	9.692	12.610	5.840
1956	40.858	12.001	15.129	7.895
1957	33.196	17.456	21.483	11.609
1958	75.018	18.044	21.743	12.105
1959	63.112	17.749	20.480	12.146
1960	31.748	17.135	18.891	11.887
1961	24.406	15.841	17.268	11.541
1962	−25.344	15.827	17.054	11.424
1963	4.589	16.404	17.413	11.571
1964	77777.000	77777.000	17.976	12.159
1965	77777.000	77777.000	19.491	13.393
No. years	14	14	16	16
C(I)*	26.590	13.086	15.982	9.265
V/T	700.077	17.130	16.846	10.891
S/T	26.459	4.139	4.104	3.300
(S/T)/C(I)B	0.995	0.316	0.257	0.356
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

RICHARDSON-MERRELL, INC.—DRUGS

Year	Inv ret MV	Ern+Int B capit	Earnings com eqty	Earnings assets
1950	15.397	20.063	20.063	14.383
1951	5.068	15.791	15.791	10.469
1952	4.889	12.685	12.685	8.210
1953	34.176	15.006	15.006	9.805
1954	75.899	17.517	17.517	12.211
1955	13.535	16.119	16.119	11.436
1956	−15.451	15.259	15.259	10.526
1957	41.891	15.443	15.443	10.958
1958	86.505	17.631	17.631	12.494
1959	129.132	17.940	17.940	11.592
1960	18.637	21.807	21.807	12.570
1961	21.701	22.108	22.108	13.602
1962	−37.390	19.668	19.668	12.435
1963	−17.509	19.379	19.379	12.357
1964	21.595	19.900	19.900	11.726
1965	77,777.000	19.924	19.924	12.069
No. years	15	16	16	16
C(I)*	26.538	17.890	17.890	11.678
V/T	1,855.378	7.166	7.166	2.191
S/T	43.074	2.677	2.677	1.480
(S/T)/C(I)B	1.623	0.150	0.150	0.127
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

RORER, WM H.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	77777.000	77777.000
1951	77777.000	77777.000	77777.000	77777.000
1952	77777.000	77777.000	77777.000	77777.000
1953	77777.000	77777.000	77777.000	77777.000
1954	77777.000	77777.000	77777.000	77777.000
1955	77777.000	77777.000	77777.000	77777.000
1956	77777.000	77777.000	77777.000	77777.000
1957	77777.000	36.212	38.174	23.182
1958	77777.000	39.664	40.627	22.432
1959	104.969	44.616	45.470	27.292
1960	88.077	42.854	43.396	27.727
1961	77777.000	77777.000	38.610	25.000
1962	77777.000	77777.000	41.090	28.730
1963	77777.000	77777.000	38.763	27.987
1964	77777.000	77777.000	41.534	30.309
1965	77777.000	77777.000	40.026	27.631
No. years	2	4	9	9
C(I)*	96.523	40.836	40.854	26.699
V/T	142.660	13.706	5.702	6.820
S/T	11.944	3.702	2.388	2.611
(S/T)/C(I)B	0.124	0.091	0.058	0.098
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

SCHERING CORP.—DRUGS

Year	Inv ret MV	Ern + int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	77777.000	77777.000
1951	77777.000	11.860	11.860	9.648
1952	77777.000	16.206	13.206	10.562
1953	−12.844	11.835	11.835	9.581
1954	116.484	10.987	10.987	8.619
1955	127.979	30.159	39.159	23.156
1956	−2.765	36.984	36.984	23.341
1957	68.312	30.999	37.413	21.895
1958	60.792	21.777	25.580	16.916
1959	36.018	18.478	21.298	14.770
1960	−22.717	14.421	16.466	11.736
1961	11.594	13.885	15.712	10.962
1962	−31.437	14.008	15.826	10.813
1963	19.089	14.403	16.274	10.659
1964	20.514	17.075	17.075	11.832
1965	77777.000	19.037	19.037	12.572
No. years	12	15	15	15
C(I)*	32.585	19.028	20.581	13.804
V/T	2678.357	84.151	94.177	25.971
S/T	51.753	9.173	9.704	5.096
(S/T)/C(I)B	1.588	0.478	0.472	0.369
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

SEARLE, G. D. CO.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	36.923	36.923	25.963
1951	101.483	28.736	28.736	17.467
1952	3.800	24.972	24.972	16.325
1953	7.847	24.560	24.560	15.802
1954	46.583	30.125	30.125	21.471
1955	19.108	27.914	27.914	20.399
1956	−2.638	26.967	26.967	20.309
1957	13.540	25.658	25.658	20.116
1958	41.675	23.909	23.909	18.940
1959	13.010	23.389	23.389	18.814
1960	24.035	22.290	22.290	18.019
1961	94.675	26.324	26.324	20.772
1962	−28.545	31.340	31.340	23.373
1963	107.339	34.705	34.705	25.952
1964	7.705	37.623	37.623	28.789
1965	77777.000	32.952	32.952	26.636
No. years	14	16	16	16
C(I)*	32.115	23.649	28.649	21.197
V/T	1731.042	23.476	23.476	15.184
S/T	41.606	4.845	4.845	3.897
(S/T)/C(I)B	1.296	0.169	0.169	0.184
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

SMITH KLINE/FRENCH LABORATORIES, INC.—DRUGS

Year	Inv rft MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	29.201	19.676
1951	77777.000	77777.000	22.308	15.242
1952	77777.000	77777.000	21.673	13.917
1953	77777.000	77777.000	22.122	14.232
1954	131.545	34.580	34.580	22.238
1955	41.783	42.882	42.882	26.756
1956	20.001	40.324	40.324	25.763
1957	16.725	37.580	37.580	25.122
1958	62.747	38.086	33.086	23.567
1959	77.260	35.493	35.493	25.971
1960	−19.101	31.109	31.109	22.988
1961	56.498	31.963	31.963	22.672
1962	−9.172	31.978	31.978	22.565
1963	1.744	31.595	31.595	22.211
1964	14.697	31.621	31.621	22.745
1965	77777.000	35.779	35.779	23.269
No. years	11	12	16	16
C(I)*	35.884	34.833	32.081	21.808
V/T	1933.155	14.362	37.342	16.329
S/T	43.968	3.790	6.111	4.041
(S/T)/C(I)B	1.225	0.109	0.190	0.185
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

STERLING DRUG, INC.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	2.793	17.764	24.916	11.414
1951	13,592	18.152	20.144	9.052
1952	−3.794	18.287	17.572	8.468
1953	9.311	16.954	18.677	8.824
1954	24.666	18.063	19.614	9.662
1955	34.179	18.002	22.798	11.445
1956	−2.656	17.619	22.062	11.581
1957	18.362	19.378	24.006	11.989
1958	59.419	21.349	26.815	12.835
1959	10.870	21.601	26.610	13.327
1960	34.161	21.004	25.422	13.096
1961	27.499	20.660	24.359	13.322
1962	−11.405	20.085	23.221	13.407
1963	10.823	19.484	22.069	13.193
1964	12.154	20.700	23.037	14.050
1965	77777.000	21.467	23.261	14.489
No. years	15	16	16	16
C(I)*	15.998	18.535	22.786	11.885
V/T	324.443	7.932	7.262	3.770
S/T	18.012	2.816	2.695	1.942
(S/T)/C(I)B	1.126	0.152	0.118	0.163
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

SYNTEX CORP.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	77777.000	77777.000
1951	77777.000	77777.000	77777.000	77777.000
1952	77777.000	77777.000	77777.000	77777.000
1953	77777.000	77777.000	77777.000	77777.000
1954	77777.000	77777.000	77777.000	77777.000
1955	77777.000	77777.000	77777.000	77777.000
1956	77777.000	77777.000	77777.000	77777.000
1957	77777.000	77777.000	77777.000	77777.000
1958	77777.000	77777.000	77777.000	77777.000
1959	77777.000	−9.654	−11.983	−8.333
1960	33.650	5.260	5.741	4.384
1961	22.705	5.221	5.558	4.175
1962	0.162	8.775	8.749	7.179
1963	977.826	27.414	27.342	23.774
1964	−45.293	36.720	36.720	31.296
1965	77777.000	36.835	35.835	26.175
No. years	5	7	7	7
C (I)*	197.810	15.653	15.423	12.664
V/T	91049.650	316.677	333.156	210.789
S/T	437.092	17.767	18.253	14.519
(S/T)/C (I) B	2.210	1.135	1.183	1.146
C (.)	20.523	17.524	18.942	12.049
C (*) B	25.860	17.998	19.701	12.259

UPJOHN CO.—DRUGS

Year	Inv Ret MV	Ern+Int B Capit	Earnings Com eqty	Earnings assets
1950	77777.000	77777.000	19.543	77777.000
1951	77777.000	77777.000	14.651	77777.000
1952	77777.000	77777.000	12.894	77777.000
1953	77777.000	77777.000	13.053	77777.000
1954	77777.000	77777.000	12.727	77777.000
1955	77777.000	77777.000	16.000	77777.000
1956	77777.000	77777.000	16.816	77777.000
1957	77777.000	17.217	17.217	14.206
1958	77777.000	18.003	18.003	14.692
1959	77777.000	18.496	18.496	14.659
1960	29.973	16.469	16.469	13.308
1961	3.965	15.384	15.384	12.489
1962	−38.081	14.769	14.769	11.934
1963	64.126	15.347	15.347	12.231
1964	0.135	16.346	16.346	12.835
1965	77777.000	18.686	18.686	14.640
No. years	5	9	16	9
C(I)*	12.023	16.746	16.025	13.444
V/T	1438.402	2.073	4.378	1.262
S/T	37.926	1.440	2.092	1.124
(S/T)/C(I)B	3.154	0.086	0.131	0.084
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

WARNER-LAMBERT PHARMACEUTICAL CO.—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950	77777.000	77777.000	77777.000	77777.000
1951	77777.000	77777.000	77777.000	77777.000
1952	77777.000	77777.000	77777.000	77777.000
1953	77777.000	77777.000	77777.000	77777.000
1954	77777.000	77777.000	77777.000	77777.000
1955	77777.000	77777.000	77777.000	77777.000
1956	77777.000	18.576	22.833	12.786
1957	52.188	21.320	25.046	14.100
1958	42.477	19.186	22.223	13.602
1959	27.868	19.745	21.538	14.159
1960	17.736	19.966	19.778	13.710
1961	32.637	18.192	18.856	12.858
1962	31.982	18.175	23.838	13.443
1963	11.756	19.236	24.161	13.823
1964	21.985	21.227	26.735	14.407
1965	77777.000	22.407	27.767	14.626
No. years	8	10	10	10
C(I)*	29.829	19.704	23.277	13.751
V/T	172.953	2.129	8.052	0.371
S/T	13.151	1.459	2.838	0.609
(S/T)/C(I)B	0.441	0.074	0.122	0.044
C(.)	20.523	17.524	18.942	12.049
C(*)B	25.860	17.998	19.701	12.259

INDUSTRY—DRUGS

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1950:				
C(.T)	18.893	18.916	22.284	13.803
V1/T	551.618	85.798	79.611	23.641
C(*T)	23.622	20.106	23.881	13.940
V2/T	473.379	107.232	96.810	27.278
N	15	20	23	22
1951:				
C(.T)	35.458	15.617	18.452	10.665
V1/T	741.027	58.611	61.428	13.836
C(*T)	31.776	15.728	18.683	10.503
V2/T	828.836	68.145	68.610	13.838
N	16	21	24	23
1952:				
C(.T)	−8.444	12.868	14.851	8.930
V1/T	112.594	40.499	41.629	13.423
C(*T)	−3.526	18.170	15.191	9.076
V2/T	128.237	45.505	47.790	14.569
N	19	21	24	23
1953:				
C(.T)	9.533	12.735	14.946	9.001
V1/T	441.489	45.571	50.934	12.032
C(*T)	7.903	13.458	15.665	9.203
V2/T	359.389	47.639	51.671	11.580
N	20	21	24	23
1954:				
C(.T)	31.750	13.936	16.159	10.103
V1/T	1108.568	81.708	83.759	27.888
C(*T)	40.800	15.251	17.026	10.475
V2/T	1342.096	91.226	80.414	28.626
N	22	23	24	23
1955:				
C(.T)	22.658	16.701	18.805	11.567
V1/T	335.189	115.589	109.187	32.451
C(*T)	25.684	17.420	18.448	11.291
V2/T	740.475	159.766	166.863	49.478
N	21	22	24	23
1956:				
C(.T)	14.351	19.022	20.845	13.202
V1/T	306.950	119.093	96.674	33.034
C(*T)	10.952	20.059	21.367	13.101
V2/T	313.540	151.703	123.520	41.498
N	21	23	26	25
1957:				
C(.T)	22.599	19.776	21.485	13.731
V1/T	360.760	85.838	77.235	27.962
C(*T)	30.011	20.887	22.707	14.035
V2/T	632.353	103.109	90.100	36.273
N	22	25	27	27
1958:				
C(.T)	64.417	19.083	19.897	13.172
V1/T	514.013	71.270	69.057	25.982
C(*T)	64.635	20.122	21.298	13.567
V2/T	646.942	87.638	79.800	30.948
N	22	25	27	27
1959:				
C(.T)	33.901	19.320	19.985	13.219
V1/T	904.126	73.069	70.952	28.212
C(*T)	47.528	19.526	20.604	13.028
V2/T	1288.330	123.029	121.951	52.112
N	24	26	28	28
1960:				
C(.T)	12.144	18.475	18.848	12.561
V1/T	682.990	75.630	74.541	27.500
C(*T)	20.914	19.111	19.780	12.844
V2/T	1179.114	95.191	89.443	37.509
N	26	26	28	28
1961:				
C(.T)	35.330	17.676	18.136	12.093
V1/T	887.972	76.516	74.306	27.267
C(*T)	35.245	17.456	18.818	12.198
V2/T	764.455	74.061	82.011	34.401
N	25	26	29	29
1962:				
C(.T)	−21.196	17.363	18.116	12.064
V1/T	322.463	76.691	76.567	27.220
C(*T)	−17.413	17.088	18.774	12.222
V2/T	422.913	75.447	86.549	37.409
N	25	26	29	29
1963:				
C(.T)	26.572	17.979	18.609	12.224
V1/T	5775.285	67.872	66.169	25.259
C(*T)	60.509	18.284	19.718	12.909
V2/T	37200.690	78.927	76.657	39.688
N	25	26	29	29

INDUSTRY—DRUGS—Continued

Year	Inv ret MV	Ern+int B capit	Earnings com eqty	Earnings assets
1964:				
C(.T)	9.883	19.018	19.700	12.846
V1/T	325.914	65.321	61.070	27.618
C(*T)	9.253	19.317	20.679	13.733
V2/T	354.226	81.148	81.981	51.068
N	25	25	29	29
1965:				
C(.T)	77777.000	21.897	21.955	13.607
V1/T	99999.000	48.326	113.479	23.631
C(*T)	77777.000	21.013	22.569	14.026
V2/T	99999.000	68.468	120.969	38.191
N	0	23	29	29
C(.)B	20.523	17.524	18.942	12.049
V1B/T	891.397	74.213	75.412	24.810
S1B/T	26.075	8.529	8.619	4.935
Spacial Cf. var	1.271	0.487	0.455	0.410
C(*)B	25.860	17.998	19.701	12.259
V2B/T	3111.665	90.827	91.571	34.029
S2B/T	36.207	9.394	9.457	5.720
Spacial cf. var	1.400	0.522	0.480	0.467
T	15	16	16	16
C(*)B	25.860	17.998	19.701	12.259
V*/N	7865.479	31.104	37.562	14.728
S*/N	45.612	4.488	4.983	2.928
Temporal cf. var	1.764	0.249	0.253	0.239
N	28	29	29	29
V(C.T)/T	376.262	6.201	4.692	2.386
S(C.T)/T	19.397	2.490	2.166	1.545
V(C*T)/T	474.877	5.894	5.616	2.608
S(C*T)/T	21.792	2.428	2.370	1.615

APPENDIX F

INDUSTRY RESULTS RANKED ACCORDING TO VARIANCE

TABLE F-1.—INDUSTRY VARIANCE AND RETURN BASED ON BOOK VALUE

Industry	Variance (risk)	Mean (return)	Industry	Variance (risk)	Mean (return)
1. Radio-TV broadcasters	116.859	18.929	32. Home furnishing	15.485	8.007
2. Publishing books	99.085	15.477	33. Food products	15.476	9.199
3. Gold mining	78.783	8.797	34. Air transport	14.330	7.878
4. Drugs	74.213	17.524	35. Office and business equipment	14.170	12.453
5. Publishing	69.936	10.552	36. Auto trucks	13.321	9.242
6. Cosmetics	67.284	18.726	37. Beverages (distillers)	13.320	7.209
7. Aerospace	59.901	12.231	38. Textile apparel manufacturers	12.497	9.849
8. Automobile	58.127	17.989	39. Shipping	11.812	6.224
9. Radio-TV manufacturers	57.631	15.042	40. Tobacco	9.259	10.764
10. Confectionery	41.800	14.699	41. Building materials (roof)	9.219	11.137
11. Building materials (heat)	34.965	8.754	42. Retail variety stores	8.948	6.625
12. Beverages (soft drinks)	34.338	15.214	43. Vending machines	8.769	12.177
13. Lead and zinc	33.259	15.275	44. Building materials (cement)	8.708	11.666
14. Miscellaneous metal work	32.866	8.532	45. Blast furnaces	8.682	8.591
15. Watches	29.705	7.114	46. Textile products	8.477	7.519
16. Auto parts accessories	28.321	12.949	47. Paper	8.157	9.443
17. Oil (crude producers)	28.217	11.950	48. Abrasive products	8.061	10.082
18. Electrical products	27.486	10.959	49. Retails food chains	7.804	10.819
19. Machinery	27.426	10.121	50. Oil	7.494	10.634
20. Metals, miscellaneous	26.777	11.348	51. Forest products	7.255	9.689
21. Beverages (brewers)	25.412	9.831	52. Paint	6.018	9.531
22. Electronic products	22.822	12.949	53. Coal (bituminous)	5.331	8.304
23. Chemicals	21.306	12.144	54. Tire and rubber	5.080	9.673
24. Shoes	20.535	8.698	55. Steel	5.014	8.534
25. Trucking	19.873	11.107	56. Railroad equipment	4.521	7.410
26. Machinery (metal fabrication)	19.580	9.019	57. Containers (metal and glass)	3.709	8.091
27. Copper	19.528	9.493	58. Financial	2.899	9.546
28. Eating places	18.637	11.852	59. Aluminum	1.579	7.778
29. Retail department stores	18.599	10.002			
30. Retail apparel chains	18.312	8.547			
31. Container (paper)	16.111	10.396			

TABLE F-2.—INDUSTRY VARIANCE AND RETURN BASED ON MARKET VALUE

Industry	Variance (risk)	Mean (return)	Industry	Variance (risk)	Mean (return)
1. Vending machines	3,470.231	37.810	30. Air transport	396.196	20.663
2. Radio-TV broadcasters	3,065.328	37.070	31. Abrasive products	383.552	16.420
3. Radio-TV manufacturers	1,846.492	29.358	32. Aluminum	381.385	17.837
4. Electronic products	1,678.849	27.576	33. Oil, crude products	371.760	15.741
5. Watches	1,603.163	16.438	34. Containers, metal, glass	368.422	14.362
6. Trucking	1,254.363	29.667	35. Beverage, distillers	349.911	12.086
7. Aerospace	1,035.241	24.275	36. Shipping	343.822	13.113
8. Cosmetics	978.049	31.524	37. Auto parts and accessories	334.167	17.766
9. Blast furnaces	942.631	20.841	38. Electrical products	318.502	17.872
10. Eating places	926.807	24.183	39. Building materials, cement	316.581	17.390
11. Miscellaneous metal work	905.513	13.839	40. Home furnishing	294.983	15.766
12. Drugs	891.397	20.523	41. Paper	277.359	19.839
13. Forest products	889.586	22.780	42. Chemicals	271.955	15.763
14. Machinery, metal fabrication	863.014	18.121	43. Retail, variety stores	271.311	10.998
15. Building material, heat	799.024	15.708	44. Railroad equipment	269.984	16.745
16. Office and business equipment	754.982	27.104	45. Retail department stores	264.626	17.549
17. Publishing	741.272	16.902	46. Retail, food chains	263.056	18.562
18. Coal-bituminous	645.716	21.184	47. Retail, apparel chains	261.813	16.566
19. Textile apparel, man	613.654	20.259	48. Food products	258.851	15.029
20. Building materials, roof	598.336	18.835	49. Paint	247.688	13.504
21. Machinery	596.420	19.343	50. Steel	230.489	17.895
22. Publishing, books	573.698	25.885	51. Beverages, soft drinks	228.762	10.791
23. Gold mining	554.829	12.783	52. Shoes	216.719	12.841
24. Metals, miscellanous	540.377	18.900	53. Lead and zinc	212.193	14.578
25. Beverages, brewers	533.354	13.173	54. Confectionery	210.379	11.982
26. Auto trucks	504.340	24.440	55. Tobacco	195.247	11.863
27. Containers, paper	479.836	18.677	56. Oil	180.911	18.835
28. Automobile	476.015	23.836	57. Financial	156.716	20.007
29. Textile products	451.491	16.460	58. Copper	148.405	16.340
			59. Tire and rubber	131.975	18.022

(The prepared statement of Mr. Gordon R. Conrad and accompanying study, "Trends in Market Shares for Ethical Pharmaceutical Products," follow:)

STATEMENT OF GORDON R. CONRAD, SENIOR STAFF ASSOCIATE, ARTHUR D. LITTLE, INC.

Mr. Chairman and members of the subcommittee, my name is Gordon R. Conrad and I am a Senior Staff Associate with the Industrial Economics Section of Arthur D. Little, Inc., Cambridge, Massachusetts. I have been in charge of a number of economic and marketing research studies conducted at Arthur D. Little, Inc. under the sponsorship of the Pharamaceutical Manufacturers Association. I would like to introduce into the hearing record, the attached study, "Trends in Market Share for Ethical Pharmaceutical Products," Report to Pharmaceutical Manufacturers Association, May, 1967.

Using market research data collected by the National Prescription Audit of R. A. Gosselin & Co., Inc., Dedham, Massachusetts, we examine in this report the changes in market position of major pharmaceuticals used in the United States during the ten-year period 1956 to 1965.

Arthur D. Little, Inc.'s analysis of the results of this survey indicates that a significant degree of interproduct competition (within specific therapeutic classifications of pharmaceuticals) has been in evidence during the past ten years. This competition, we believe, points to the nature of some of the uncertainties and risks that individual products face in attempting to serve the needs of the public and the medical profession. It suggests that products can and do in fact gain and then lose position in a therapeutic class, sometimes within the short time span of only a few years. It further suggests that there are significant instances of products which, having held a major and dominant position in a particular therapeutic class for a number of years, suddenly lose this position due to the introduction of new and superior agents in the same general competitive field of therapeutic activity.

We consider that these results illustrate one aspect of the potentially high risks facing pharmaceutical manufacturers, that of the genuine uncertainties as to the length of time any one product can be expected to contribute to a company's profit.

[Report to Pharmaceutical Manufacturers Association]

TRENDS IN MARKET SHARES FOR ETHICAL PHARMACEUTICAL PRODUCTS

I. SUMMARY

A. PURPOSE AND SCOPE

The purpose of this study is to examine the competition between ethical pharmaceutical products in selected therapeutic classes over the ten year period, 1956 through 1965. Competitive products have been evaluated on the basis of relative market shares of leading products within a defined product grouping or class. Over the ten year period, we were able to identify new introductions, growth, decline and obsolescence. The products are grouped into therapeutic classifications agreed upon by the pharmaceutical manufacturers and several market research companies whose pharmaceutical audits serve the industry. Although the therapeutic classes are not mutually exclusive, they provide a framework for classifying products to measure their market performance.

Since individual product sales are confidential in nature, the leading products in each class shown in this report are designated by code number. The report does not explain the reasons for competitive changes over the time period since this would require revealing product names and company strategy.

Seventeen classes are analysed, generally representing the largest sales volume of the ten year period. These seventeen classes account for approximately 58% of the 1965 dollar sales volume out of a total of 137 product classes. They include:

Non-narcotic analgesics.
Non-steroidal antiarthritics.
Broad and medium spectrum antibiotics.
Penicillin.
Antihistamines.
Antiobesity—Amphetamines.
Ataraxics.
Rauwolfia—Diuretic Combinations.
Coronary Vasodilators.
Diabetic—Other than Insulin.
Corticoid hormones.
Corticoids with Anti-infectives.
Oral muscle relaxants.
Psychostimulants.
Sedatives—Barbiturate.
Sulfonamides.

B. CONCLUSIONS

Over the last ten years, the total ethical prescription market has grown about 75% from over 554 million prescriptions written and filled in 1956 to 967 million in 1965. The sales volume in manufacturers dollars increased from $765 million to $1.61 billion or 110%. As a result of the advances in research and product development in major therapeutic areas, the market growth is due largely to the increased use of new chemotherapeutic agents and combinations of agents, i.e. antibiotics, ataraxies, cardiovascular products, diuretics, rauwolfia-diuretic combinations, hormones, etc. These new products have been introduced to cure or alleviate conditions more effectively than older products or other therapeutic methods have in the past. Many new products gained rapid acceptance by the medical profession, seeking additional agents to meet the needs of their practice. Some new products were accepted initially but lost market share to newer products or equally effective older ones.

With this growth has come increasing and more dynamic competition. In eight of the major classes studied, the leading products of 1956 have declined dramatically or dropped from the market completely. In the other nine classes the leading product in 1956 also declined in market share although more slowly as demonstrated in the non-steroidal, antiarthritics, antihistamines, ataraxics, coronary vasodilators, and sulfonamides. Often products introduced during the

ten year period (i.e. in the non-narcotic analgesics, diuretics and psychostimulant classes) rapidly achieved significant market shares and then were displaced just as rapidly by still newer discoveries. Products offering new types of action such as analgesics, antibiotics, diuretics and corticoids soon met intense competition from products based on modifications by these newer approaches. New dosages and forms have offered major competitive advantages as seen in the coronary vasodilator and sulfonamides. Two classes, diabetic—other and rauwolfia-diuretic combinations, did not exist in 1956 and grew significantly to approximately 3% of all prescriptions written by 1965.

One of the most outstanding factors leading to the constantly changing competitive atmosphere has been the development of effective products with fewer and less severe side effects. Non-narcotic analgesics, non-steroidal antiarthritics, ataraxics and diuretics are examples of product classes experiencing such changes. Life saving products such as some of the antibiotics require weighing the benefits of their use against possible serious side effects. Modifications of these products are often developed in an attempt to reduce or eliminate these side reactions. Highly potent analogs have been introduced to reduce the total amount of medication needed by the patient.

Another factor affecting the competitive environment is the introduction of combination products in which the ingredients provide synergistic effects beneficial to many patients. Combination forms insure proper dosage as fixed in the product and also provide convenience to patients who otherwise might have to take several different medications at different times during the day and night. Some obvious economies are in manufacturing, packaging and distribution resulting in direct price benefits to the patient. Less time is required by the pharmacist also to prepare a prescription for a combination than for the several individual components. Similarly new products are introduced in unique forms such as sustained release capsules, repeat action tablets and long acting suspensions for the convenience of patients.

In some instances of extreme significance to the competitive situation, new products provide a completely new mode of action as seen among the diuretics and several of the ataraxics. Because of these new developments, new medical approaches have evolved and treatment has been made easier or more effective. Tranquilizers in mental health and sulfonylureas in diabetes have been important in the latest medical techniques developed in these areas.

It is clear that where the products offer different modes of action or are specific for certain kinds of conditions there is intense competition and frequent change in market positions. The broad and medium spectrum antibiotics, muscle relaxants and psychostimulants illustrate these characteristics.

However, where new products do not offer any marked advantages, the established products retain their leadership as in the case of non-steroidal antiarthritics, antihistamines, coronary vasodilators and sulfonamides. In some instances, products that hold promise to be an improvement gain rapid acceptance initially, only to lose market share if they do not demonstrate superiority.

To illustrate the magnitude of changes that have occurred it should be pointed out that:

During the ten year period 118 out of the 213 leading products studied or 55% were introduced after 1956.

Fourteen or 6.6% achieved the leading market share in ten product classes at some time during the ten years. Eight of these were in the first position in 1965.

The leading position changed 32 times in 12 product classes while the second position changed 59 times in 15 product classes.

Five products maintained first place in their respective classes for the entire ten year period.

Sixteen products introduced during the ten years in nine classes grew rapidly gaining a 20% market share in two years. Conversely, eleven products declined in eight classes and lost more than 20% of the market in two years.

These major product shifts demonstrate the risk involved in introducing new products and the importance of providing continuing promotional support in the market. New products often are abruptly replaced by modifications, combination products or other still newer products. The strong positon of a product can be violently upset by one or two new products or slowly reversed by a steady flow of many new product entries over several years.

II. Methodology

The ten year data in the seventeen product classes has been provided by the National Prescription Audit (NPA) of the R. A. Gosselin and Company, Inc., Dedham, Massachusetts. The NPA includes prescriptions written by physicians and filled in a panel of retail pharmacies for products classified by their therapeutic activity. The new and refill prescription activity provides a measurement of product movement to the consumer (patient) and does not necessarily reflect the manufacturers' factory sales for the same time period.

Data for the ten year period is given on numbers of prescriptions written and filled and in dollars at the manufacturers' level reflected by these prescriptions. Market shares were computed for numbers of prescriptions and dollar volumes as a percent of the category totals. The leading products shown anonymously in the tables account for approximately three-fourths of the total prescriptions written and dollar volume in each class. The products leading each class in 1956 and 1965 have been included for complete trend data during the ten year period or less if they were introduced after 1956. Other products gaining a first or second market position during the intermediate years have been included, also. The tables for each product class show the calculated market shares for the leading products providing a clear picture of relative changes in market position and size of the market shares over the ten years. Trends, shifts in market position, and the effects of new product introductions can be easily analysed.

The dollar figures are based on the number of new prescriptions written plus a calculated refill rate. Manufacturers' prices are calculated by taking the prescription price and making adjustments for the normal retail and wholesale profit margins. (Example: Calculation for a $3.00 prescription to the patient $3.00 \times .60 \times .833 = 1.4994$ or $1.50 manufacturer's selling price.)

Brand product prices are verified in The Red Book or Blue Book at the net or wholesale list price level. Products specified by the generic name might be filled by a popular brand or one of a number of generic or less popular brands at a wide price range. Therefore, the calculated manufacturers' selling price does not always coincide with the manufacturer's actual prices since quantity discounts or deals to the trade are not usually reflected nor does each pharmacy follow an identical pricing policy. However, the relative positions of the products based primarily on numbers of prescriptions and also dollar volume permit a valid comparative analysis of market shares and long term competitive trends of the products discussed in this study.

The trends expressed in market shares in most cases are the same for dollar volume and numbers of prescriptions. Differences in market share between prescriptions and dollar volume for a product reflect:

1. Its price relative to others in the class;
2. Its potency and the size of the prescription; and
3. The length of time the product is taken

The last point may also reflect the incidence of side effects which might severely limit the continuing use of any of the products. A product with fewer side effects presumably could be given in larger doses and for longer periods of time but actually resulting in fewer prescriptions written.

III. Analgesics—Non-Narcotic

Non-narcotic analgesic is a general classification for pain relievers, not included in the morphine class. They are used in a wide variety of medical conditions. The total category has increased approximately 400% in total number of prescriptions written and over 700% in dollar volume between 1956 and 1965. Non-narcotic analgesics represented 1.64% of all prescriptions written in 1956 and accounted for 4.75% in 1965. The increase in importance of this class among all products is due to the development of synthetic types of analgesics which have reduced the danger of habit or drug dependency developing in conjunction with treatment. Although 16 products represented three-fourths of the total class in 1965, there were 182 products being marketed which were audited (See Tables 1A &1B). Over 50% of the 1965 market is represented by drugs introduced since 1956.

TABLE 1-A.—ANALGESIC, NONNARCOTIC

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	15.6	11.3	4.9	3.6	3.3	2.5	3.2	2.3	3.1	2.5
2	13.2	10.9	5.8	3.7	3.5	2.9	2.2	2.0	1.5	1.9
3	10.9	12.1	8.7	8.7	7.7	7.2	10.4	8.7	8.5	11.1
4	7.5	4.6	6.1	2.9	2.9	2.3	2.0	1.9	1.7	1.4
5	6.7	4.7	.1	.1	.1	.1	.1	.1		
6	5.9	5.3	2.7	1.3	2.2	1.9	2.7	1.6	1.2	1.2
7	5.0	3.1	2.8	1.0	.9	.7	1.0	.6	1.3	1.1
8	4.9	4.0	3.1	1.2	1.3	1.0	1.1	.8	1.4	1.1
9	4.3	2.4	2.4	1.3	1.1	.8	.4	.6	.4	.4
10		11.3	37.4	30.5	26.4	14.0	9.8	9.6	6.4	4.8
11		2.9	9.8	8.6	8.7	8.8	10.6	13.1	12.0	10.9
12		.4	6.3	6.6	6.5	4.1	3.4	3.4	2.5	2.0
13				1.2	6.9	4.5	3.0	3.3	2.0	2.2
14					1.9	4.1	4.8	6.7	6.3	5.7
15					1.7	15.6	24.8	25.6	29.8	28.1
16									1.8	3.7
Cumulative market share of above products	74.0	72.9	90.0	70.7	75.1	71.4	79.6	80.3	79.9	78.1
All others	26.0	27.1	10.0	29.3	24.9	28.6	20.4	19.7	20.1	21.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 1-B.—ANALGESIC, NONNARCOTIC

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	19.3	15.5	6.0	4.0	3.3	2.4	2.9	2.0	2.7	2.2
2	10.5	8.7	4.5	2.7	2.6	2.0	1.5	1.2	1.0	1.2
3	9.0	10.7	7.3	7.9	6.5	5.8	8.0	6.5	6.1	8.5
4	8.3	5.6	5.6	3.0	2.6	1.9	1.7	1.5	1.3	1.1
5	6.7	5.0	.1	.1	.1	.1	.1	.1		
6	12.8	10.8	5.1	2.3	3.4	2.7	4.1	2.5	1.7	1.6
7	3.9	2.4	2.1	.8	.7	.5	.6	.3	.8	.7
8	4.1	3.0	2.4	.9	.9	.7	.7	.5	.9	.7
9	3.2	1.9	1.7	.8	.7	.5	.3	.4	.2	.2
10		12.6	39.3	30.2	26.0	13.6	8.7	8.2	5.3	4.0
11		3.6	11.7	10.5	10.6	9.7	12.0	13.8	12.7	11.1
12		.5	7.7	8.1	7.9	4.1	3.3	3.0	2.3	2.0
13				1.5	7.9	4.7	3.1	3.4	1.9	2.1
14					3.0	6.3	7.2	9.7	9.0	8.1
15					2.1	18.7	27.8	29.3	32.3	30.0
16									2.5	5.0
Cumulative market share of above products	77.9	80.4	93.6	72.7	78.3	73.7	82.0	82.4	80.7	78.5
All others	22.1	19.6	6.4	27.3	21.7	26.3	18.0	17.6	19.3	21.5
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

IV. Antiarthritics—Non-Steroidal

Although the non-steroidal antiarthritic class implies use only in arthritis, several of the products are also used in a broader range of indications including gout. This class has been dominated essentially by one product, which has slowly lost market share over the ten year period.

The non-steroidal antiarthritics have grown approximately 131% in total number of prescriptions written and 188% in dollar volume over the ten year period. They represented 1.05% of the total prescriptions written in 1956 and 1.40% in 1965. In 1965, ten products accounted for 85% of the class although 48 products were indentified in the audit (see Tables 2A & 2B). Over 44% of the market represents products introduced since 1956.

TABLE 2-A.—ANTIARTHRITICS, NONSTEROIDAL

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	47.5	43.8	36.4	41.9	43.3	35.9	30.8	33.9	28.9	22.9
2	15.0	13.6	14.0	11.2	8.2	7.9	8.5	6.4	3.9	4.
3	8.3	7.2	8.2	7.4	6.5	4.7	4.4	5.7	4.5	4.2
4	6.8	5.3	3.4	1.7	.7	.8	.9	.9	1.6	1.2
5	1.6	3.4	3.6	3.5	4.5	5.7	7.0	5.9	9.0	8.4
6		3.8	8.5	5.2	4.3	3.2	5.9	1.4	1.2	.8
7			6.1	11.5	15.6	13.9	12.6	15.5	15.7	13.5
8					.1	.5	1.8	5.5	4.0	3.1
9						9.2	14.5	14.1	11.4	10.0
10										1619
Cumulative market share of above products	79.2	77.1	80.2	82.4	83.2	81.8	86.4	89.3	80.2	85.7
All others	20.8	20.8	19.8	17.6	16.8	18.2	13.6	10.7	19.8	14.6
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 2-B.—ANTIARTHRITICS, NONSTEROIDAL

[Percent share of market based on dollar volume, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	52.5	46.2	36.3	41.7	41.8	34.3	28.7	32.0	25.7	19.3
2	13.0	11.7	10.9	8.9	6.4	6.0	6.6	4.8	2.9	3.0
3	7.2	6.4	7.2	6.1	5.4	4.0	3.7	4.9	4.0	3.6
4	5.3	4.2	2.8	1.3	.6	.7	.7	.7	1.4	1.4
5	3.1	6.3	6.6	6.5	8.0	9.0	11.6	10.2	14.4	13.3
6		5.4	12.2	6.8	5.9	4.3	7.9	2.0	1.3	.9
7			5.8	11.5	16.0	14.0	12.1	15.2	14.4	11.9
8					.1	.6	2.8	8.6	6.3	5.3
9						10.3	15.4	14.9	11.8	9.9
10										19.7
Cumulative market share of above products	81.1	80.2	81.8	82.8	84.2	83.2	89.5	93.3	82.2	88.8
All others	18.9	19.8	18.2	17.2	15.8	16.8	10.5	6.7	17.8	11.2
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

V. Antibiotics—Broad and Medium Spectrum

Broad and medium spectrum antibiotics represent the largest product class both in number of prescriptions written and dollar volume and are characterized by a large number of highly competitive products. The broad range of infections treated by antibiotics and their prophylactic use against reinfection contribute to the size and growth of this class. It has increased between 85% and 90% both in prescription and dollar volume over the last ten years, representing 7.3% of the total number of prescriptions written in 1956 and 7.8% in 1965. Seven major products used in 1956 accounted for nearly 70% of the class. By 1965, these same products accounted for only 35% of the prescriptions written. The introduction of other products (new agents or modifications of existing products) in the intervening ten years were responsible for the decline. Over 40% of the 1965 market was from products introduced since 1956. Thirteen products represented over 76% of the class in 1965 while 84 were identified in the audit (see Tables 3A & 3B).

TABLE 3-A.—ANTIBIOTICS, BROAD AND MEDIUM SPECTRUM

Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1955	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	33.7	23.6	10.9	6.8	5.7	5.1	4.5	4.1	3.7	3.7
2	9.7	10.6	12.9	14.7	14.5	10.0	5.6	4.9	4.9	4.0
3	9.3	5.4	4.5	3.6	5.2	7.4	8.3	8.1	7.8	7.9
4	7.4	5.1	6.3	3.0	1.1	.8	.9	.7	.5	.4
5	6.1	2.7	1.2	.6	.5	.3	.3	.2	.2	.3
6	1.8	1.5	1.9	2.1	1.4	1.6	3.3	4.8	7.6	7.2
7	1.6	5.5	5.0	5.0	4.3	4.9	5.8	5.2	5.1	5.5
8	.3	.2	.1	.1	.2	.3	.6	.8	2.7	5.9
9		14.9	22.7	22.3	14.7	11.6	10.5	9.0	9.4	8.8
10		.1	2.0	3.7	4.1	5.3	5.1	5.0	5.2	4.0
11			.8	7.5	9.6	10.0	8.7	6.9	7.7	7.1
12				3.3	16.6	17.5	17.6	15.8	15.4	15.3
13					1.4	5.1	7.6	7.5	7.1	6.5
Cumulative market share of above products	69.9	69.6	68.3	72.7	79.3	79.9	78.8	73.0	77.3	76.6
All others	30.1	30.4	13.7	27.3	20.7	20.1	21.2	27.0	22.7	23.4
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 3-B—ANTIBIOTICS, BROAD AND MEDIUM SPECTRUM

[Percent share of market based on dollar volume 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	32.8	21.3	9.4	5.5	4.7	4.0	3.8	3.5	2.9	2.9
2	10.9	11.4	13.4	15.2	15.4	11.2	6.8	6.1	6.4	5.4
3	8.8	4.7	3.8	3.0	4.8	7.3	8.0	7.7	7.4	7.3
4	7.5	4.8	5.9	2.5	.8	.6	.6	.5	.3	.3
5	6.1	2.6	1.2	.6	.5	.4	.3	.3	.2	.2
6	2.1	1.7	2.1	2.2	1.5	1.6	3.5	5.0	7.8	7.4
7	1.7	5.5	5.0	4.8	4.1	4.5	5.3	4.7	4.7	5.1
8	.3	.2	.1	.1	.3	.4	.8	1.0	2.6	5.0
9		15.9	22.5	21.9	14.3	11.5	10.1	8.8	8.9	8.0
10		.2	2.9	5.1	5.4	6.7	6.8	6.7	6.8	5.4
11			1.0	8.2	9.3	9.6	8.2	6.4	7.3	6.7
12				3.4	16.2	16.8	16.6	14.7	14.5	15.2
13					1.5	5.6	8.4	8.1	7.5	7.2
Cumulative market share of above products	70.2	68.3	67.3	72.5	78.8	80.2	79.2	73.5	77.3	76.1
All others	29.8	31.7	32.7	27.5	21.2	19.8	20.8	26.5	22.7	23.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

VI. Antiobiotics—Penicillins

Penicillin is synonymous with the dramatic growth in the drug industry and frequently is regarded as *the* antibiotic. Penicillins represent a growth of approximately 92% in the number of prescriptions written and an increase of 108% in dollar volume during the ten years. In 1965, they accounted for 3.15% of all prescriptions—slightly higher than their 2.86% share in 1956. Much of the growth can be attributed to the development of new synthetic penicillins, although some of the old established products have continued to be prescribed more frequently than a decade earlier. In 1965, eleven products accounted for almost 84% of the class while 89 products were reported in the audit (see Tables 4A & 4B). Forty-three percent of the market was represented by new products introduced since 1956.

TABLE 4-A.—ANTIBIOTICS, PENICILLINS

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	19.9	20.8	12.3	5.0	1.5	2.2	1.3	1.2	1.1	0.8
2	17.1	16.1	16.3	12.5	21.8	24.5	30.1	27.5	24.2	21.2
3	14.8	11.6	11.1	8.6	6.3	5.7	5.2	3.6	2.7	1.8
4	13.2	9.9	10.4	9.2	13.5	12.1	12.0	13.9	15.0	14.9
5	8.9	13.7	10.8	7.9	2.9	3.9	4.2	4.0	2.6	1.9
6		3.0	15.3	19.3	18.9	19.5	20.1	21.0	23.2	20.8
7			1.0	3.5	2.8	2.7	2.6	2.5	4.0	5.0
8			.9	5.0	3.7	5.5	4.7	5.1	4.4	4.6
9				.9	8.1	6.3	4.1	4.3	4.0	2.1
10									2.8	6.3
11										4.7
Cumulative market share of above products	73.9	75.1	78.1	81.9	79.7	82.4	84.3	83.1	84.0	83.8
All others	26.1	24.9	21.9	18.1	20.3	17.6	15.7	16.9	16.0	16.2
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 4-B.—ANTIBIOTICS, PENICILLINS

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	24.4	24.9	14.1	5.5	3.0	2.1	1.3	1.2	1.0	0.7
2	13.7	12.4	12.7	18.2	18.9	21.2	26.2	25.1	22.2	19.3
3	16.9	12.4	12.6	8.6	6.5	6.8	5.2	4.3	3.1	2.4
4	9.0	6.7	6.9	6.2	8.9	8.4	8.7	9.8	9.6	9.2
5	10.8	15.7	12.7	8.5	6.4	4.1	4.6	3.9	2.7	1.9
6		4.2	18.9	23.1	21.4	21.4	21.4	22.4	24.7	20.9
7			1.3	4.2	3.3	3.2	3.0	4.0	4.6	5.4
8			1.0	5.9	4.3	6.0	5.0	5.4	4.4	4.4
9				1.1	10.4	8.6	5.4	5.3	4.5	2.2
10									5.2	10.3
11										5.1
Cumulative market share of above products	74.8	76.3	80.2	81.3	83.1	81.8	80.9	81.4	82.0	81.8
All others	25.2	23.7	19.8	18.7	16.9	18.2	19.1	18.6	18.0	18.2
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

VII. Antihistamines

Antihistamines represent one of the more slowly growing therapeutic categories of the drug industry. Their performance depends on the severity of the hay fever and cold seasons. Both the effectiveness and the side effects of the various products vary from patient to patient. Trial of several different products may be necessary to find the one product most effective with the fewest side effects for the particular patient and disorder being treated. Dollar volume over the 1956–1965 period increased 53.5% while the number of prescriptions increased 19.2%. In 1956 this category represented 4.25% of prescriptions written while in 1965 it represented only 2.92%. Only six products accounted for over 86% of the class although 62 products were audited in 1965 (see Table 5A & 5B).

Considered a breakthrough in the late 1940's, antihistamines reached a point beyond which no significant new products have emerged. The leading antihistamine products in 1956 continue to be the leading products ten years later. They are often switched in patients when drowsiness, the most common side effect, occurs. The leading six products which accounted for nearly 92% of the number of prescriptions written in 1956 accounted for 78.3% in 1965. The top seven products accounted for 86.2% of all antihistamine prescriptions written in 1965.

TABLE 5-A.—ANTIHISTAMINES

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	25.2	24.8	21.5	18.2	20.3	20.7	20.5	19.5	22.8	24.5
2	24.4	28.4	27.7	19.8	23.0	23.1	23.8	20.6	24.0	23.0
3	17.0	16.0	16.0	12.0	10.1	8.9	9.9	8.4	7.5	6.5
4	10.3	10.5	11.0	10.7	9.7	9.5	9.5	10.5	11.0	12.3
5	9.1	12.8	10.0	7.9	7.9	6.3	5.4	5.9	5.9	5.6
6	4.8	6.5	6.6	7.0	6.3	5.9	5.6	5.0	6.6	6.4
7		.3	5.6	6.3	6.1	6.5	9.0	6.2	7.9	7.9
Cumulative market share of above products	91.8	99.3	98.4	81.9	83.4	80.9	83.7	76.1	85.7	86.2
All others	8.2	.7	1.6	18.1	16.6	19.1	16.3	23.9	14.3	13.8
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 5-B.—ANTIHISTAMINES

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	20.6	19.7	16.6	14.0	15.2	15.9	15.6	14.8	17.4	18.2
2	25.7	29.7	29.1	20.2	23.4	23.7	24.1	20.9	24.6	24.0
3	16.7	16.9	16.5	11.2	10.0	8.7	9.4	8.4	7.4	6.4
4	16.3	15.3	14.8	13.6	12.3	12.3	12.0	13.7	13.8	15.1
5	7.7	10.4	7.9	6.2	6.5	5.5	4.9	5.4	5.4	5.3
6	4.8	7.0	7.4	7.7	7.0	6.5	6.1	5.2	7.0	6.7
7		.4	6.2	7.0	6.9	6.8	9.6	6.4	8.0	8.1
Cumulative market share of above products	91.8	99.4	98.5	79.9	81.3	79.4	81.7	74.8	83.6	83.8
All others	8.2	.6	1.5	20.1	18.7	20.5	18.3	25.2	16.4	16.2
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

VIII. ANTIOBESITY—AMPHETAMINES

Among the products used to control weight gain and when necessary, encourage weight loss are the amphetamines. Included in this product class are combinations with sedatives to modify the exhilaration often produced by amphetamines, or tranquilizers to provide relief of tension-anxiety symptoms. The number of prescriptions written have increased approximately 36% during the ten year period while the dollar volume has increased approximately 64%. This increase has been due principally to the introduction of new products through 1960. The total class represented 3.4% of all prescriptions written in 1956 declining to 2.6% in 1965.

Although the eleven products shown in Tables 6A & 6B represent over 80% of the market for amphetamine products the importance of this class is reflected by the number of products which are competing in the antiobesity market. In 1965 over 80 products were being sold by brand or generic name in the amphetamine class.

TABLE 6-A.—ANTIOBESITY—AMPHETAMINES

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	35.5	35.2	31.6	25.0	25.7	20.9	17.9	13.0	11.7	12.5
2	31.1	29.6	33.9	32.9	27.6	27.5	25.1	25.8	25.3	21.0
3	3.6	3.1	2.2	5.3	6.8	6.3	7.5	7.8	8.4	7.4
4	2.4	2.8	3.2	2.7	2.3	1.7	1.6	1.7	2.1	2.1
5	1.7	1.0	.7	.4	.6	2.8	2.6	2.7	3.7	5.0
6	1.4	3.0	5.3	8.4	8.1	9.8	10.0	7.4	6.7	5.4
7			.5	2.2	1.9	1.4	1.2	1.6	3.2	3.1
8				.2	6.5	7.3	10.1	13.5	13.8	15.0
9					.5	1.5	2.4	2.1	2.8	4.5
10						2.9	3.0	1.5	2.8	2.2
11						.7	1.8	2.5	3.7	3.9
Cumulative market share of above products	75.7	74.7	77.4	77.1	80.0	82.8	83.2	79.6	84.2	82.1
All others	24.3	25.3	22.6	22.9	20.0	17.2	16.8	20.4	15.8	17.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 6-B.—ANTIOBESITY-AMPHETAMINES

[Percent share of market based on dollar volume, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	40.5	38.7	33.4	25.9	24.9	20.2	17.1	12.3	11.0	11.5
2	31.8	30.1	35.3	34.9	27.6	27.6	24.6	25.0	25.1	20.3
3	2.1	1.8	1.2	3.7	5.4	4.7	5.3	6.0	6.7	5.8
4	1.8	2.2	2.6	2.3	1.9	1.5	1.2	1.2	1.6	1.4
5	1.0	.8	.5	.3	.6	2.7	2.4	2.7	3.9	5.3
6	1.6	3.5	6.3	9.7	9.2	11.1	11.4	7.9	7.0	6.0
7			.5	2.1	1.7	1.3	1.1	1.3	2.6	2.6
8				.2	8.0	9.1	13.0	17.0	17.2	18.5
9					.8	2.0	3.0	2.5	3.3	5.3
10						2.9	3.1	1.4	2.8	2.1
11						1.0	2.4	3.2	4.7	4.9
Cumulative market share of above products	78.8	77.1	79.8	79.1	70.1	84.1	84.6	80.5	86.0	83.7
All others	21.2	22.9	20.2	20.9	29.9	15.9	15.4	19.5	14.0	16.3
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

IX. Ataraxics

The term ataraxic is generally used to designate products which are employed as calming or tranquilizing agents. However, these products may be used to treat a number of different disorders so that they vary considerably in strength and action. Our discussion is restricted to those products used to treat patients residing at home rather than those who are hospitalized in mental institutions.

This classification of drugs represents one of the more important areas of the drug industry and is one which has grown significantly over the past decade in both numbers of prescriptions (93%) as well as in dollar volume (100%). One half of the tranquilizers on the market in 1965 did not exist in 1956. In 1965 these products accounted for 7.4% of prescriptions dispensed as compared to 6.6% in 1956. Twelve products represented almost 87% of the class in 1965 of the 56 which were audited (see Tables 7A & 7B). New products introduced since 1956 account for over 50% of the market.

TABLE 7-A.—ATARAXICS

[Percent share of market based on numbers of prescriptions written 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	43.0	39.5	32.9	32.9	27.4	23.7	21.1	17.5	13.6	13.5
2	21.5	15.9	12.3	10.2	8.8	8.4	9.7	7.4	6.8	7.4
3	18.4	14.0	11.8	11.8	12.7	10.4	8.7	7.6	7.3	6.7
4	4.5	5.6	5.2	4.6	3.4	3.6	2.2	2.0	2.0	1.9
5	3.1	4.9	5.4	4.4	2.9	2.5	1.9	3.1	2.3	1.6
6	.6	10.3	17.8	16.7	14.4	12.6	9.3	8.5	7.3	6.3
7		3.6	2.9	1.5	.6	.5	.2	.1	.1	.1
8		2.5	3.3	4.5	2.3	1.2	1.2	.7	.7	.7
9			.5	1.6	1.1	1.4	1.4	1.3	1.7	1.9
10				3.1	7.7	6.6	7.5	7.9	7.3	5.4
11					11.4	26.0	29.4	31.4	32.1	29.7
12								.2	8.0	12.9
Cumulative market share of above products	91.1	96.3	92.1	91.3	92.7	96.9	92.6	87.6	88.3	86.7
All other	8.9	3.7	7.9	8.7	7.3	3.1	7.4	12.4	11.7	13.3
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 7-B.—ATARAXICS

[Percent share of market based on dollar volume 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	46.3	42.4	32.9	32.9	27.0	23.1	19.8	16.6	12.2	12.3
2	18.8	13.5	11.4	9.9	8.8	8.2	9.7	7.6	7.1	7.8
3	19.7	15.2	12.0	11.9	12.5	10.4	8.7	7.5	7.0	6.4
4	4.2	4.8	4.9	4.2	2.9	3.1	1.9	1.7	1.7	1.6
5	3.1	4.8	5.6	4.4	3.0	2.8	2.1	3.4	2.7	1.8
6	.5	10.5	17.9	16.2	12.9	10.8	7.5	6.8	5.4	4.7
7		3.8	2.6	1.5	.6	.4	.2	.1	.1	.1
8		2.7	4.3	4.8	2.4	1.1	1.3	.8	.7	.7
9			.6	2.0	1.3	1.8	1.7	1.6	2.0	2.1
10				3.1	8.3	7.0	8.1	8.9	8.5	6.1
11					12.1	27.4	30.7	32.6	32.8	30.1
12								.2	8.0	12.9
Cumulative market share of above products	92.6	97.7	92.2	90.9	91.8	96.1	91.7	87.8	88.2	86.6
All others	7.4	2.3	7.8	9.1	8.2	3.9	8.3	12.2	11.8	13.4
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

X. Rauwolfia—Diuretic Combinations

Rauwolfia—diuretic combinations provide the anti-hypertensive action of rauwolfia plus the diuretic action (increasing the secretion of urine) of the thiazide products. The latter is considered important in the management of hypertension also, producing a complementary anti-hypertensive action. The reduction of body fluid apparently is related to lessening some causal effects of hypertension. Although rauwolfia products have been used since the early 1950's and mercurial diuretics even longer, it was not until after the introduction of thiazide diuretics that the rauwolfia—diuretic combination gained acceptance in medical practice. The importance of this class can be seen by the rapid rate of growth over the past seven years and the many new product entries into the market (see Tables 8A & 8B). The first five rauwolfia—diuretic combinations introduced in 1959 accounted for 0.67% of all prescriptions written and by 1965 this category represented 1.71% of all prescriptions written. As a class, the prescriptions increased by 344% from 1956 to 1965. The dollar volume increased by 334% during the same period.

Strong interest in new combinations indicates that there is a medical need for additional compounds to try on individual patients who were unresponsive to an earlier product or whose prognosis might be improved by a newer product. The demand for these products clearly indicates that a need exists and virtually

a new market has been created for products combining complementary therapeutic effects. Although the fixed dosages of manufactured products of this kind limit the versatility often needed to treat individuals, they are appropriate to treat large numbers of patients. One obvious reason for the acceptance of these combinations is the greater assurance that the patient will take one tablet or capsule containing several medical ingredients than he would if several tablets or capsules had to be taken separately. If the dose of any ingredient is critical, each can be prescribed separately and patients can be controlled on an individual basis.

TABLE 8-A.—RAUWOLFIA-DIURETIC COMBINATION

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1				54.2	36.0	28.9	28.5	29.1	22.9	18.3
2				20.4	19.7	11.1	8.5	7.5	4.6	2.6
3				14.1	23.4	25.6	18.0	20.5	15.7	18.6
4				5.2	10.6	6.6	5.7	2.6	3.4	1.5
5				.2	3.4	2.0	1.4	1.3	1.0	.7
6					3.7	9.8	10.3	8.1	9.4	7.5
7					1.7	4.6	9.3	8.6	12.9	17.6
8					1.3	8.7	8.3	6.9	10.2	8.2
9						1.3	3.2	5.8	5.8	3.5
10						.7	2.3	2.6	3.8	6.5
11						.4	1.4	1.0	2.0	1.6
12									1.5	2.6
13									.7	3.5
Cumulative markets share of above products				100.0	99.8	99.7	96.7	93.9	93.9	92.6
All others					.2	.3	3.3	6.1	6.1	7.4
Category total				100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 8-B.—RAUWOLFIA-DIURETIC COMBINATION

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1				50.5	34.1	27.9	28.2	27.2	22.8	19.1
2				22.8	22.1	11.3	9.0	8.2	5.7	3.2
3				13.6	23.6	26.5	18.2	21.2	15.7	19.5
4				6.3	8.8	5.9	5.2	2.5	3.2	1.3
5				.1	3.3	1.7	1.4	1.2	.9	.8
6					4.4	10.8	11.4	8.9	10.5	8.9
7					1.7	4.2	8.1	7.9	10.7	14.9
8					1.5	9.2	7.8	6.8	11.6	9.1
9						1.5	3.4	6.5	6.0	3.5
10						.7	2.2	2.6	3.8	6.6
11						.5	1.6	1.3	2.2	1.6
12									1.4	2.4
13									.6	2.8
Cumulative market share of above products				100.0	99.6	99.9	96.6	94.3	95.0	93.8
All others					.4	.1	3.4	5.7	5.0	6.2
Category total				100.0	100.0	100.0	100.0	100.0	100.0	100.0

XI. Coronary Vasodilators

This therapeutic category contains the drugs which are used primarily to bring symptomatic relief of angina pectoris and essential hypertension.

The prescriptions written for these drugs during 1956-1965 increased at a slower rate than that of the overall drug industry. The number of prescriptions increased 72% while the equivalent dollar volume of these products increased 158%. These products accounted for 1.74% of the prescriptions written both in 1956 and 1965. Thirteen out of 68 products represented over 90% of the class in 1965 (see Tables 9A & 9B).

Although this product class is the subject of active research efforts, may of the new products introduced have not made a significant impact. Patients responding to one kind of treatment are usually not switched when new products are introduced. Of seven products introduced between 1956 and 1965, only two have made any impact on the market.

TABLE 9-A.—CORONARY VASODILATORS

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	29.5	39.4	41.8	37.3	35.2	36.8	25.6	23.8	20.9	22.4
2	19.6	19.4	19.1	17.7	22.5	27.5	20.4	22.1	18.6	19.1
3	7.7	6.6	10.3	8.4	8.6	10.3	8.2	4.9	5.7	6.3
4	4.6	4.5	1.9	1.4	2.5	.9	.4	.4	1.0	.7
5	2.1	2.5	3.3	6.6	5.6	5.0	4.7	6.0	4.6	3.9
6	.5	2.5	2.6	2.3	1.8	1.3	1.6	2.3	1.3	1.3
7			1.0	2.1	3.0	2.5	1.7	2.1	1.6	1.2
8			.4	.6	.8	.7	2.1	2.1	4.2	2.6
9					.5	1.1	1.2	1.9	6.7	9.0
10							10.1	12.8	16.9	12.5
11							5.2	3.3	6.4	8.7
12							5.0	6.8	4.5	5.1
13								.5	2.1	3.5
Cumulative market share of above products	64.0	74.9	80.4	76.4	80.5	86.1	81.3	84.2	86.3	91.1
All others	36.0	25.1	19.6	23.6	19.5	13.9	18.7	15.8	13.7	8.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 9-B.—CORONARY VASODILATORS

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	32.7	45.0	52.9	45.7	44.3	46.1	28.1	26.4	21.8	22.1
2	6.2	5.8	6.0	5.2	7.2	8.9	6.5	7.0	5.4	5.3
3	7.8	8.6	9.4	9.0	10.8	14.3	9.7	5.1	6.0	6.2
4	7.0	7.1	3.0	2.3	3.5	1.3	.6	.4	.8	.6
5	.6	.8	1.1	2.2	1.7	1.5	1.3	1.6	1.3	1.0
6	.8	3.5	3.9	3.8	2.6	1.8	2.2	2.9	1.6	1.9
7			1.8	3.4	4.5	4.1	2.6	2.6	2.2	1.6
8			.3	.5	.6	.6	1.8	1.8	3.7	2.2
9					.5	1.2	1.3	2.2	7.8	13.5
10							18.1	20.8	25.4	17.9
11							5.2	3.3	6.4	8.7
12							5.0	6.8	4.5	5.1
13								.8	2.9	4.7
Cumulative market share of above products	55.1	70.8	78.4	72.1	75.7	79.8	82.4	81.7	83.4	90.8
All others	44.9	29.2	21.6	27.9	24.3	20.2	17.6	18.3	16.6	9.2
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XII. Diabetic Therapy—Other

Diabetic products other than insulin fall into two chemical classes-sulfonylureas and biguanide. Each of the products shown in Tables 10A & 10B is a different chemical compound except one sustained release form. None of these products existed in 1956 and only one was available in 1957. They can lower the blood sugar level when given orally in the treatment of selected patients with diabetes without the need for insulin injections.

The product class has grown over 1400% in total numbers of prescriptions written since 1957. By 1965 these products represented 1.26% of all prescriptions written and 2.3% of the total dollar market. In 1965, the total product class was represented by 8 products with the five shown accounting for over 99% of the market.

Although the products in this class have achieved a significant prescription volume, they are not a replacement for insulin injections (estimated annual sales of $22 million) where the patient's insulin requirement is high. Their principle advantage is that where they are indicated they can be given orally replacing the daily injection required to administer insulin.

TABLE 10-A.—DIABETIC THERAPY, OTHER

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	100.0	99.0	82.2	84.0	81.7	77.0	77.3	75.0	70.2	
2		1.0	14.5	8.7	12.0	15.3	16.6	12.8	13.2	
3			3.3	7.3	5.9	5.0	3.5	3.8	3.4	
4					.4	2.7	2.6	5.3	8.1	
5								3.1	4.8	
Cumulative market share of above products	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.7	
All others									.3	
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	

TABLE 10-B.—DIABETIC THERAPY, OTHER

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	100.0	99.1	85.1	85.7	84.9	81.3	79.1	77.6	72.8	
2		.9	12.9	9.2	10.3	12.4	16.7	11.9	12.8	
3			2.0	5.1	4.3	3.3	2.2	3.0	2.5	
4					.5	3.0	2.0	5.1	7.6	
5								2.3	3.9	
Cumulative market share of above products	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.6	
All others								.1	.4	
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	

XIII. Diuretics

Diruetic agents are used to treat edema which may be associated with a number of different disorders. The drugs may be used as adjuncts in the management of congestive heart failure, to control the severity of cardiac decompensation or to treat patients with edema associated with kidney and liver disease, pregnancy, obesity, etc. The diuretic class had one of the most dramatic increases over the ten year span increasing 490% in the number of prescriptions written and 560% in dollar volume. Of the total industry volume, diuretics accounted for 1.12% of the prescriptions written in 1956 but increased to 3.68% of those written in 1965. Eleven products accounted for 80% of the class of 43 products audited in 1965 (see Tables 11A & 11B).

In reviewing the 1965 data it appears that diuretics that did not exist in 1956 are responsible for nearly all of the prescriptions written. The market is fairly well fractionated with about a dozen compounds actively competing for significant positions.

TABLE 11-A.—DIURETICS

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	960	1961	1962	1963	1964	1965
1	52.6	53.5	17.0	7.8	6.6	5.6	4.7	5.1	5.0	3.7
2	13.3	12.9	3.3	1.4	.9	.4	.2	.2	.4	.3
3	6.3	2.4	.2	.1						
4	5.6	3.1	.6	.3	.1	.1	.1		.1	
5		.8	72.1	61.8	42.3	33.3	32.7	23.7	23.1	25.9
6				14.3	20.6	19.6	17.3	18.8	14.4	20.0
7				7.8	11.3	7.8	6.9	4.5	3.3	4.9
8					5.4	5.0	5.4	6.3	7.1	4.1
9					1.0	3.0	4.9	5.7	6.6	5.9
10					.2	2.2	3.2	5.7	8.7	3.3
11					.1	3.5	4.1	5.0	5.1	4.7
12						.4	6.1	4.9	4.4	4.9
13									.2	2.6
Cumulative market share of above products	77.8	72.7	93.2	93.5	88.5	80.9	85.6	79.9	78.4	80.3
All others	22.2	27.3	6.8	6.5	11.5	19.1	14.4	20.1	21.6	19.7
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 11-B.—DIURETICS

[Percent share of market based on dollar volume, 1956–65]

Product	1965	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	49.6	48.7	14.0	7.7	7.3	6.4	5.8	6.9	6.7	5.4
2	18.4	15.6	3.9	1.7	1.4	.5	.2	.3	.4	.4
3	8.2	3.1	.3	.1						
4	2.4	1.2	.2	.1			.1			
5		1.1	74.5	64.1	41.5	32.8	30.5	22.1	21.5	24.2
6				13.4	19.4	18.9	17.1	18.0	13.9	19.3
7				7.2	10.5	7.6	6.2	4.3	3.1	4.7
8					5.2	4.7	5.6	6.6	6.8	4.4
9					.9	3.0	4.8	5.4	5.9	5.6
10					.3	2.3	3.3	6.4	9.2	3.6
11					.1	3.2	4.0	4.4	5.1	4.5
12						.4	5.9	4.7	4.3	4.7
13									.2	2.7
Cumulative market share of above products	78.6	69.7	92.9	94.3	89.6	79.8	83.5	79.1	77.1	79.5
All others	21.4	30.3	7.1	5.7	10.4	20.2	16.5	20.9	22.9	20.5
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XIV. Hormones, Corticoids

The term corticoid is short form of the name corticosteroid. The desired action of corticoids is to favorably influence a large number of clinical conditions by the suppression of inflammatory or immulogical processes. Unfortunately the anti-inflammatory action of the corticosteroids is inseparable from their metabolic effect which limits their usefulness for prolonged administration because of rather serious side effects. Because of these side effects a great number of derivatives have been prepared and are used extensively in treating patients with various types of disorders—both acute and chronic conditions (collagen diseases, bronchial asthma, hay fever, allergies, dermatoses and certain inflammatory eye diseases).

The number of prescriptions written for hormones increased 88% over the ten year time span although the equivalent dollar value has declined 0.7% due in part to the significant price reductions made available through the development of newer more potent synthetic agents. These products were responsible for 2.3% of all prescriptions written in 1956 and about the same in 1965. Of the 125 products audited in 1965, 18 accounted for 77% of the class (see Tables 12A & 12B).

Six products accounted for 73.8% of the corticoid market in 1956 but only 5.4% of the prescriptions written in 1965. Over 60% of the 1965 market is due to new products introduced since 1956.

TABLE 12-A.—HORMONES, CORTICOIDS

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	37.5	31.8	19.8	10.0	8.7	5.9	5.3	2.7	3.0	1.8
2	13.6	8.0	6.7	4.9	2.6	2.0	1.3	1.0	.9	.8
3	6.5	5.8	4.5	3.1	3.7	1.5	1.2	.8	.4	.5
4	6.5	5.2	2.1	.6	.4	.2	.4	.8	.7	.6
5	5.6	5.6	1.6	.5	.1	.1	.2	.2	.5	.5
6	4.1	5.4	6.8	6.0	4.4	2.0	1.9	2.0	1.4	1.2
7	.3	.4	.8	1.2	3.9	5.5	7.6	8.3	10.2	11.5
8		.7	13.2	10.8	14.0	11.4	5.5	6.2	5.0	5.0
9			17.6	17.3	14.2	13.2	10.6	11.5	8.8	8.9
10			.7	4.8	4.4	5.3	4.4	4.7	6.4	7.0
11			5.4	3.6	3.4	2.4	1.6	2.3	3.3	2.7
12			2.0	16.2	16.2	14.7	11.5	11.3	9.2	10.5
13				2.3	1.9	1.1	.4	.4	.2	.2
14						3.4	5.9	6.9	6.3	5.3
15						1.7	3.7	2.2	1.3	.8
16						1.4	6.8	6.3	6.5	6.6
17						.5	4.1	8.1	9.3	10.8
18							.7	1.7	2.0	2.0
Cumulative market share of above products	74.1	62.9	81.2	81.3	76.9	73.3	73.1	77.4	75.4	76.7
All others	25.9	37.1	18.8	18.7	23.1	26.7	26.9	22.6	24.6	23.3
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 12-B.—HORMONES, CORTICOIDS

[Percent share of market based on dollar volume, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	40.0	41.9	24.1	13.6	11.8	9.2	7.9	4.2	4.4	2.7
2	6.9	4.9	4.2	3.3	2.1	1.7	1.2	.9	.7	.8
3	3.4	3.6	2.7	2.0	2.0	1.1	.9	.7	.4	.5
4	5.5	5.9	2.1	.6	.3	.2	.3	.7	.4	.4
5	5.0	6.3	1.4	.6	.2	.1	.3	.2	.3	.4
6	2.0	3.4	4.7	4.5	3.5	2.4	1.6	1.8	1.3	1.2
7	.3	.7	.7	1.6	3.3	4.6	6.2	6.2	6.7	7.4
8		.9	16.0	12.5	16.3	13.3	6.7	8.3	6.9	7.1
9			20.2	18.7	16.7	15.0	12.4	13.9	11.1	11.0
10			.4	3.0	3.1	3.8	3.2	3.7	5.9	6.9
11			6.0	4.2	4.0	2.9	1.8	3.2	4.9	3.9
12			2.2	19.5	17.0	15.6	12.1	12.3	10.9	11.9
13				2.6	2.2	1.5	.5	.5	.2	.3
14						4.0	7.3	9.2	7.9	6.8
15						2.0	4.3	2.9	1.8	1.2
16						.9	4.6	4.9	5.4	6.0
17						.5	3.2	7.5	9.0	10.6
18							.7	1.6	1.8	2.0
Cumulative market share of above products	63.1	67.6	84.7	86.7	82.5	78.8	75.2	82.7	80.0	81.1
All others	36.9	32.4	15.3	13.3	17.5	21.2	24.8	17.3	20.0	18.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XV. Corticoids With Anti-Infectives

Corticoids with anti-infectives describes a group of products which represent the combination of the anti-inflammatory corticosteroids with various anti-infectives in topical preparations with a maximum local effect. Because of the broad range of competitive corticosteroids and anti-infective agents, there are numerous possible combinations obtaining different effects (see Tables 13A & 13B). Consequently, the many companies which have marketed preparations make this category one of the most highly competitive in the entire field. Over the last ten years the category has grown approximately 78% in numbers of prescriptions written and 87% in dollar volume. The category has maintained its relative position representing 1.51% of all prescriptions written in 1956 and 1.55% of all prescriptions written in 1965. The dollar volume for this category declined from 1.63% of total in 1956 to 1.45% of total in 1965.

It appears from the large number of products being offered in this class plus the interest in a variety of combinations of corticosteroids and anti-infectives that there is a need for a broad range of products to treat infections and inflammation from many different causes. Twenty-five products account for over 80% of the class and 76 products make up the other 20%. Many of these combination products are available in specialized forms for treatment of conditions located in the eyes, ears, and nose as well as for general topical use anywhere on the body surface.

TABLE 13-A.—CORTICOIDS WITH ANTI-INFECTIVES

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	41.1	29.7	23.8	16.4	14.9	12.7	10.0	8.1	7.3	.7
2	18.2	14.7	12.0	7.4	5.7	4.9	3.3	2.3	2.0	2.0
3	8.8	4.2	3.3	1.9	1.7	1.7	.6	.6	.7	.5
4	4.6	3.8	3.1	3.0	3.4	3.9	2.4	1.9	2.9	2.5
5	2.8	4.3	2.7	3.4	3.3	2.9	2.5	2.5	2.2	1.7
6	2.8	3.7	4.4	6.2	6.2	8.4	7.9	8.2	7.8	8.7
7	2.6	1.9	1.3	.8	.7	.4	.3	.2	.3	.3
8	2.3	2.5	2.3	2.1	1.6	1.1	1.1	.9	.6	.4
9	1.2	1.3	2.3	2.7	1.4	1.0	1.1	.5	.5	.5
10	.8	9.5	12.6	12.1	11.7	10.1	9.6	11.0	10.0	9.5
11	.4	.4	2.1	2.0	1.8	1.5	1.4	1.3	1.1	1.4
12	.2	6.1	14.2	14.3	9.2	6.7	5.4	4.2	3.5	2.6
13		1.0	1.9	2.2	3.1	3.3	3.0	2.4	2.4	2.5
14		.1	.8	2.4	2.1	1.8	1.3	1.5	1.9	1.8
15			.1	2.2	1.9	1.9	1.0	1.3	1.3	1.2
16				3.5	2.2	1.4	.5	.5	.3	.1
17				1.9	5.3	6.9	8.2	8.3	9.3	11.3
18				1.8	7.8	10.7	13.4	11.1	13.2	11.5
19					1.4	1.4	.5	.4	.2	.1
20					.8	1.2	1.8	1.6	1.6	2.4
21						1.4	7.1	6.8	6.4	5.4
22						.2	.9	1.7	1.7	2.1
23							1.1	1.5	2.9	2.5
24							.8	1.8	2.7	3.2
25							.3	.8	1.1	1.2
Cumulative market share of above products	85.8	83.2	86.9	86.3	86.2	85.5	85.5	81.4	83.9	82.3
All others	14.2	16.8	13.1	13.7	13.8	14.5	14.5	18.6	16.1	17.7
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 13-B.—CORTICOIDS WITH ANTI-INFECTIVES

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	41.7	29.0	23.0	16.0	14.6	12.0	9.4	7.5	6.9	6.1
2	14.2	12.7	11.2	6.3	4.7	4.0	2.8	1.9	1.6	1.6
3	6.1	2.9	2.3	1.3	1.1	1.2	.4	.4	.5	.4
4	4.6	3.8	3.1	3.0	3.4	3.9	2.4	1.9	2.9	2.5
5	3.4	4.7	4.3	4.3	4.0	3.6	2.9	2.9	2.6	1.8
6	2.5	3.8	4.2	6.2	6.2	7.9	7.0	7.1	6.6	7.3
7	2.6	2.1	1.3	.8	.7	.4	.2	.2	.3	.2
8	2.4	2.7	2.4	2.3	1.8	1.3	1.3	1.0	.6	.5
9	1.4	1.5	2.9	3.6	1.7	1.1	1.3	.6	.6	.6
10	.7	10.8	14.8	14.1	13.9	12.5	11.3	12.6	11.3	10.8
11	.3	.4	1.6	1.6	1.5	1.2	1.2	1.0	.9	1.0
12	.2	6.7	13.0	13.6	8.2	5.7	4.4	3.5	2.9	2.1
13		1.3	2.1	2.7	3.6	3.7	3.1	2.6	2.5	2.5
14		.1	.8	2.4	2.1	1.8	1.3	1.5	1.9	1.8
15			.1	2.1	2.1	2.2	1.1	1.6	1.5	1.4
16				2.4	1.5	.9	.4	.4	.2	.1
17				1.8	5.6	7.0	8.6	8.8	9.7	12.1
18				1.6	7.5	10.0	12.4	10.1	12.2	10.4
19					1.1	1.1	.3	.2	.1	.1
20					1.0	1.5	2.1	1.9	1.9	2.8
21						1.5	7.2	7.1	6.7	5.6
22						.2	1.1	2.1	2.1	2.5
23							1.1	1.4	3.0	2.3
24							.9	1.9	3.0	3.5
25							.5	1.1	1.5	1.4
Cumulative market share of above products	81.7	83.9	88.1	87.0	87.1	85.8	85.2	81.3	84.2	82.0
All others	18.3	16.1	11.9	13.0	12.9	14.2	14.8	18.7	15.8	18.0
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XVI. Oral Muscle Relaxants

Drugs in this group act on the central nervous system and are useful in promoting relaxation of skeletal muscle spasm. They have been recommended as an aid in the management of almost every musculo-skeletal and neuromuscular condition in which painful muscle spasm occurs. Thus these agents can be used in connection with the treatment of a number of different medical conditions.

Over the past decade the number of prescriptions for these products has increased 350%, while the equivalent dollar value has increased 405%. In 1956 these products accounted for 0.56% of the total number of the prescriptions written. In 1965 they were responsible for 1.26% indicating wider acceptance of the use of these products in various conditions.

The top five products in 1956 were responsible for nearly 76% of all prescriptions written. By 1965, one-third of the 47 products in the class accounted for over 82% of the prescriptions (see Tables 14A & 14B). The newer products introduced the combined effect of muscle relaxants and analgesics or sedatives, or both. The effectiveness of muscle relaxants alone was not enough in many cases for satisfactory treatment. If muscle spasm caused pain, then pain relief was also indicated. If muscle spasm could be reduced by a sedative, working in the central nervous system, then a sedative was indicated. From these experiences, the new, convenient forms evolved, increasing competition further.

TABLE 14-A.—ORAL MUSCLE RELAXANTS

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	28.4	33.8	11.1	5.8	4.9	2.1	.1			
2	16.0	14.1	5.8	1.6	1.0	.9	.8	.8	.6	.6
3	15.6	12.1	6.7	2.3	2.0	1.4	2.3	1.4	1.1	1.3
4	10.9	15.2	10.4	10.0	9.8	4.9	8.2	14.4	14.4	15.6
5	4.7	2.7	2.3	1.5	2.8	2.9	2.4	2.4	5.6	7.0
6		4.3	28.3	17.4	17.6	10.9	10.0	5.9	6.1	5.4
7			9.4	5.2	1.7	1.7	.4	.3	.4	.2
8			.4	22.1	12.8	9.2	6.4	3.9	3.5	3.3
9				10.1	15.4	14.5	12.5	13.2	10.8	8.5
10				.1	4.0	5.2	7.7	7.4	8.6	7.2
11				.1	9.7	5.4	4.2	2.7	3.3	3.4
12					6.4	9.7	10.4	8.7	8.1	8.9
13					.2	4.8	8.6	10.1	9.4	9.2
14						1.3	4.2	3.2	4.9	5.4
15							1.0	8.8	4.1	2.9
16							.6	1.0	2.2	3.6
Cumulative market share of above products	75.6	82.2	74.4	76.2	88.3	74.9	79.8	84.2	83.1	82.5
All others	24.4	17.8	25.6	23.8	12.7	25.1	20.2	15.8	16.9	17.5
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 14-B.—ORAL MUSCLE RELAXANTS

[Percent share of market based on dollar volume, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	37.0	39.2	10.6	5.5	4.8	2.0	0.1			
2	13.0	10.9	4.0	1.1	.6	.7	.7	0.7	0.5	0.5
3	14.4	10.0	4.9	1.7	1.3	1.0	1.6	.8	.6	.8
4	9.1	11.9	9.4	6.0	6.8	4.4	5.3	9.5	9.1	10.5
5	4.8	2.6	1.6	1.1	2.1	2.1	1.8	1.6	4.3	5.2
6		5.6	32.9	19.3	18.4	11.4	10.5	6.0	6.6	6.0
7			10.5	5.6	1.8	1.8	.4	.3	.3	.2
8			.5	21.8	13.0	9.1	6.4	3.9	3.5	3.7
9				10.6	15.8	14.8	12.5	13.3	11.6	9.1
10				.1	4.5	5.5	8.7	8.6	10.4	8.6
11				.1	9.6	5.5	4.0	2.6	3.7	3.6
12					6.3	9.8	10.3	8.1	8.3	9.2
13					.3	4.6	8.7	10.4	10.0	9.8
14						1.6	4.9	3.8	6.5	6.9
15							1.0	8.6	4.1	3.0
16							.7	1.3	3.2	5.7
Cumulative market share of above products	78.3	80.2	74.4	72.9	85.3	74.3	77.6	79.5	82.7	82.8
All others	21.7	19.8	25.6	27.1	14.7	25.7	22.3	20.5	17.3	17.2
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XVII. PSYCHOSTIMULANTS

Drugs in this therapeutic category are used to treat depressed patients with widely varying causes. Thus the compounds can offer different types and different mechanisms of action. This category has shown dramatic growth although the base was small in 1956 (0.38% of total prescriptions written in 1956 to 1.3% in 1965). The number of prescriptions written has increased 510% over the period 1956–1965, while the dollar volume of these products has increased tenfold.

The three principal products in 1956 accounted for 70% of the prescriptions written. Two of these were withdrawn from the market in 1962. By 1965, twelve products represented over 87% of prescriptions in a class of 36 products (see Tables 15A & 15B). New products in this field have been viewed with guarded optimism since the effects of psychostimulants might mask underlying problems. As a result, each new product is tried in different kinds of patients to find where it is most effective. The product class, therefore, has a history of product introduction, initial acceptance and a decline to some lower level of use.

TABLE 15-A.—PSYCHOSTIMULANTS

[Percent share of market based on numbers of prescriptions written, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	39.2	42.8	23.6	20.1	13.6	11.0	12.5	12.5	16.0	15.9
2	19.6	10.2	1.7	1.6	.4	.1				
3	11.3	7.2	2.4	2.3	1.7	.8	.4	.3	.7	1.2
4	.4	11.9	27.4	8.5	2.4	.6				
5			30.1	39.9	21.2	19.0	12.8	19.7	18.3	12.5
6				8.2	17.9	18.8	16.3	15.4	23.6	15.2
7				7.0	12.7	5.3	2.0	3.2	5.0	1.8
8				6.5	13.7	12.5	8.7	5.6	3.8	2.2
9				4.8	10.9	6.3	3.6	2.8	2.4	1.7
10						10.6	16.4	20.5	22.2	29.5
11						6.9	12.8	21.6	4.9	3.1
12										7.3
Cumulative market share of above products	70.5	72.1	71.7	80.1	91.0	89.4	83.0	96.8	93.7	87.7
All others	29.5	27.9	28.3	19.9	9.0	10.6	17.0	3.2	6.3	12.3
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 15-B.—PSYCHOSTIMULANTS

[Percent share of market based on dollar volume, 1956–65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	32.5	36.0	18.2	11.5	7.8	6.0	7.3	7.7	9.9	10.3
2	25.6	14.3	2.1	1.1	.3	.1				
3	9.4	4.1	1.7	.8	.5	.3	.2	.1	.3	.5
4	.4	15.5	17.2	6.7	1.9	.6				
5			30.1	39.9	21.2	1.9	12.8	19.7	18.3	12.5
6				13.0	22.9	23.6	20.8	19.1	28.1	18.2
7				8.8	13.7	5.8	2.1	3.2	5.5	2.1
8				6.1	11.5	10.9	8.0	5.4	3.3	2.0
9				6.4	12.4	7.1	4.5	3.3	2.8	1.8
10						10.8	17.0	21.3	21.6	30.2
11						5.9	11.8	19.8	4.5	2.7
12										6.8
Cumulative market share of above products	67.9	69.3	69.3	94.3	92.2	90.1	84.5	98.6	94.3	87.1
All others	32.1	30.1	30.7	5.7	7.8	9.9	15.5	1.4	5.7	12.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XVIII. SEDATIVES—BARBITURATE

The barbiturates comprise an important and valuable class of central nervous system depressants. It has been reported that they are used more to produce sleep than for any other purpose. [1] Proper selection and rational use of the barbiturates depend on an intimate knowledge of their pharmacology and toxicology as well as an acquaintance with the important variations in action and toxicity produced by certain individual products. Barbiturates are differentiated by their duration of action ranging from longer duration barbital and phenobarbital to shorter duration secobarbital, pentobarbital and hexobarbital. Combinations of barbiturates are often used to provide a more balanced effect by combining those with differing rates of action and dissipation.

The total category has increased approximately 7% in total number of prescriptions written and 22% in dollar volume between 1956 and 1965. Barbiturates represented 7% of all prescriptions written in 1956 but only 4.3% in 1965.

The lack of significant increases in demand for barbiturates may be related to the development of non-narcotic analgesics, tranquilizers and barbiturate-analgesic combinations. The importance of this class, however, is seen by the large number of products competing. Although the five products in Tables 16A & 16B account for almost three-fourths of the product class, there were 78 products on the market in 1965.

[1] *The Pharmacological Basis of Therapeutics*—Second Edition Goodman and Gilman.

TABLE 16-A.—SEDATIVES—BARBITURATE

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	24.1	24.5	26.4	21.5	22.0	22.2	22.9	19.7	21.5	20.9
2	15.1	15.2	13.4	13.8	15.6	16.5	15.5	17.3	16.8	14.9
3	13.2	12.8	15.2	14.7	19.3	17.7	17.4	15.1	14.2	15.4
4	10.7	12.0	11.8	14.2	14.5	13.7	10.2	12.5	14.2	13.2
5	5.8	5.5	7.3	8.6	9.4	9.6	6.8	7.8	8.0	9.7
Cumulative market share of above products	68.9	70.0	74.1	72.8	80.8	79.7	72.8	72.4	74.7	74.1
All others	31.1	30.0	25.9	27.2	19.2	20.3	27.2	27.6	25.3	25.9
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 16-B.—SEDATIVES, BARBITURATE

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	16.7	18.1	20.1	15.9	15.7	16.9	17.3	15.1	16.5	16.2
2	14.7	15.5	14.1	13.7	15.8	16.4	15.0	16.8	16.4	14.1
3	13.2	13.1	15.6	14.7	19.5	18.0	17.5	15.3	14.1	15.4
4	10.6	12.9	13.4	16.9	16.8	16.3	12.6	15.4	17.3	16.1
5	5.8	6.3	7.8	9.0	10.1	10.1	7.1	8.0	8.2	9.8
Cumulative market share of above products	61.0	65.9	71.0	70.2	77.9	77.7	69.5	70.6	72.5	71.6
All others	39.0	34.1	29.0	29.8	22.1	22.3	30.5	29.4	27.5	28.4
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

XIX. SULFONAMIDES

Products in this group are used to treat a broad range of infections. Some products are specific for either systemic or urinary tract infections while others treat both types. Over the ten year time span the number of prescriptions for sulfonamides has increased 25% while the dollar volume has increased 72%. Sulfonamides represented 2.85% of prescriptions written in 1965 as compared to 4.0% in 1956.

The principal products used in 1956 continue to be major products in 1965. However, approximately 76% of prescriptions written are for 14 out of 173 products audited in 1965 (see Tables 17A and 17B).

TABLE 17-A.—SULFONAMIDES

[Percent share of market based on numbers of prescriptions written, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	38.0	32.8	30.6	27.7	28.0	29.4	26.5	26.3	25.6	26.5
2	8.4	6.1	5.0	4.4	4.2	3.6	2.4	2.5	1.8	2.1
3	3.8	3.6	2.7	2.0	2.7	2.2	1.5	1.5	1.1	1.0
4	3.6	5.4	5.9	5.8	6.5	7.7	8.8	8.8	9.0	9.3
5	3.5	2.8	2.1	1.4	1.5	1.3	1.1	1.1	1.2	1.3
6	3.0	3.1	3.0	2.3	1.9	2.0	1.9	1.8	1.0	1.5
7	.6	3.0	3.0	1.6	1.2	1.2	1.3	.9	1.0	.6
8	.2	3.6	3.5	1.4	1.2	.6	.5	.6	.6	.4
9		6.5	9.7	8.7	7.1	5.5	3.5	3.1	2.7	2.2
10			2.8	3.5	3.6	3.4	2.0	2.2	1.8	1.1
11			1.8	15.1	16.0	16.7	15.0	13.4	13.7	12.4
12			.9	1.7	3.2	3.2	3.2	3.5	3.6	4.9
13					1.1	1.6	2.4	2.3	1.6	1.8
14						.3	8.9	8.8	10.2	10.8
Cumulative market share of above products	61.1	66.9	71.1	75.6	78.2	78.7	79.0	75.8	74.9	75.9
All others	38.9	33.1	28.9	24.4	21.8	21.3	21.0	24.2	25.1	24.1
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

TABLE 17-B.—SULFONAMIDES

[Percent share of market based on dollar volume, 1956-65]

Product	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965
1	39.5	32.8	30.3	27.6	27.9	28.6	25.1	24.1	24.1	24.7
2	7.9	5.3	4.4	3.7	3.6	3.0	2.0	2.0	1.4	1.6
3	5.0	4.4	3.5	2.7	3.3	2.6	1.7	1.5	1.3	1.2
4	4.8	6.7	7.3	7.3	7.9	9.0	10.3	10.0	9.8	10.2
5	2.8	2.0	1.6	1.0	1.2	1.1	.8	.7	.8	1.0
6	2.8	2.6	2.6	1.9	1.6	1.7	1.6	1.4	.8	1.2
7	.9	4.1	4.1	2.2	1.6	1.6	1.6	1.1	1.3	.7
8	.2	5.0	4.4	1.7	1.3	.7	.5	.7	.6	.4
9		7.7	9.9	8.8	7.0	5.4	3.3	2.9	2.4	2.0
10			2.7	3.2	3.2	2.9	1.6	1.8	1.5	.9
11			1.8	14.7	16.6	17.6	15.5	13.9	14.2	12.8
12			1.0	1.7	3.4	3.3	3.2	3.7	3.7	5.0
13					1.3	1.9	2.7	2.5	1.7	1.9
14						.4	9.8	9.9	11.2	11.9
Cumulative market share of above products	63.9	70.6	73.6	76.5	79.9	79.8	79.7	76.2	74.8	75.5
All others	36.1	29.4	26.3	23.5	20.1	20.2	20.3	23.8	25.2	24.5
Category total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

(Whereupon, at 5:30 p.m. the hearing adjourned, subject to call of the Chair.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

THURSDAY, JANUARY 18, 1968

U.S. SENATE,
MONOPOLY SUBCOMMITTEE OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 318, Old Senate Office Building, Senator Gaylord P. Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson, Javits, and Scott.

Also present: Benjamin Gordon, staff economist; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. We will open the hearing of the Subcommittee on Monopoly of the Small Business Committee.

Our witness this morning is Dr. Willard F. Mueller, Chief Economist and Director of the Bureau of Economics of the Federal Trade Commission.

I have read your statement, Dr. Mueller, and I find it commendable and lucid compared to the economic presentation given last month by the economists sponsored by the Pharmaceutical Manufacturers Association, which, quite frankly, I did not understand very well.

Will you introduce your associates for the record, and, if, at anytime, one of them wants to make a comment, will he just identify himself so we can keep the record straight.

I appreciate very much your taking the time to come here this morning and the obvious extensive work you have put into your statement.

You may proceed to present it in any way you see fit.

I assume you have no objection to us interrupting you with questions from time to time.

Dr. MUELLER. Not at all, Mr. Chairman.

Senator NELSON. And do you have a biographical statement?

Dr. MUELLER. Yes; I have a sketch which I can give to the reporter or read into the record.

Senator NELSON. Read it into the record for us, please.

STATEMENT OF DR. WILLARD F. MUELLER, CHIEF ECONOMIST AND DIRECTOR, BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION, WASHINGTON, D.C.; ACCOMPANIED BY DR. RUSSELL C. PARKER, ASSISTANT DIRECTOR; AND WILLIAM H. KELLY, MEMBER, BUREAU OF ECONOMICS

Dr. MUELLER. First, I would like to introduce my two colleagues. To my immediate left is Dr. Russell C. Parker, assistant to the Direc-

81-280—68—pt. 5—17

tor of the Bureau of Economics, and next to him is Mr. William H. Kelly of our staff.

I am Chief Economist and Director of the Bureau of Economics of the Federal Trade Commission. Prior to my current appointment, I was Chief Economist to the Select Committee on Small Business of the House of Representatives. Previous to that assignment, I was professor at the University of Wisconsin, from 1957 to 1961. I was assistant professor at the University of California from 1954 to 1957. I also have taught on a part-time basis at American University; served as a visiting professor at Michigan State University, and I am currently a part-time staff member of the Department of Economics, University of Maryland.

It is a privilege and a pleasure to appear before this subcommittee.

My appearance today is in response to the request of your Chairman that I submit testimony on the subject of profits in the drug industry, as well as present an independent analysis of the study "Risk and Return in American Industry—an Econometric Analysis," presented to this committee on December 19, 1967.[1] The study was sponsored by the Pharmaceutical Manufacturers Association and prepared by Gordon R. Conrad and Irving H. Plotkin of Arthur D. Little, Inc., in consultation with Prof. Jesse W. Markham and Prof. P. J. Cootner. Hereafter we shall refer to the study as the Conrad-Plotkin study.

Before turning to the study, we shall first place in perspective the profits of drug manufacturers by comparing them with those earned by business enterprises in other American industries.

Figure 1 shows for 1966 the average rate of return on stockholders investments of leading firms in 22 important American manufacturing industries. Profit rates of leading drug manufacturers exceeded those of large firms in the 21 other industries. In fact, drug industry profits were twice as great as one-third of the remaining industries; were 44 percent or more above those of all but four other industries; and they exceeded even such traditionally high profit industries as motor vehicles and computing machines.

Nor was 1966 an exceptional year. Table 1 compares over the period 1950–66, the average profits of large drug companies and large companies in the 22 industries shown in figure 1. Several points are of special interest. First, in the early years, 1950–55, average drug company profits were about equal to or somewhat above the average of other large manufacturers. Second, beginning in 1956, however, average profit rates of drug companies were well above the average of other large companies. Finally, since 1956 drug companies have consistently ranked either first or second among all large manufacturing industries. This indicates that during the last decade large drug companies have occupied an especially advantaged position relative to large companies in other American industries. Table 2 summarizes profit data of all drug companies and all manufacturing companies for the period of 1956–67. Over the period covered it shows essentially the same picture as table 1. Since 1956 drug manufacturers have failed to occupy first place in only one year.

[1] The study, "Risk and Return in American Industry—an Econometric Analysis," by G. R. Conrad and I. H. Plotkin, begins at p. 1746, supra.

This pattern of persistently high profits indicates that large drug companies occupy a unique position in the American economy. And they appear to have become increasingly unique since the mid-1950's.

Before turning to an analysis of the Conrad-Plotkin-Markham-Cootner explanation of high profits in the drug industry, I shall briefly review what appears to be a virtual consensus of opinion among researchers in the field of industrial organization concerning the causes of high profits of drug manufacturers.

In this connection I would like to emphasize the crucial role which congressional hearings have played in developing the facts necessary for scholars to study the organization and performance of the drug industry. Prior to the Kefauver drug hearings on administered prices in 1959–61, not a single article concerning the American pharmaceutical industry had appeared in a professional economic journal.

Senator NELSON. Are you referring to any article of any kind or just articles in economic publications?

Dr. MUELLER. I am referring to articles on the structure and organization of the drug industry. This observation is based on the recent study that I cited in a footnote by Professor Walker of the University of Indiana, who surveyed the literature.[1]

Since the first such article appeared in 1962, there has been a growing volume of research literature on the subject, all of which has drawn heavily on the Kefauver and subsequent congressional hearings. The facts developed by this committee have made another enormous contribution to the fund of knowledge concerning the drug industry. I am confident that scholars will be sifting and winnowing the facts for years.

The preponderance of economic evidence argues that the persistently high profits of the drug industry are the result of the absence of effective price competition in the sale of many products. Price competition in drugs is ineffective for several reasons. Concentration in the production of many drugs is high because of the patent privilege. And even where there are relatively many sellers, as well as many potential sellers—for example, in the case of unpatented drugs sold under generic names—effective price competition often is muted by vast advertising, promotion, and other selling efforts which differentiates in the minds of consumers the products of the largest drug manufacturers selling under their own brand or trade names from those of other manufacturers. Hence, manufacturers selling chemically identical drugs under generic names frequently have difficulty in selling them at any price.

Senator NELSON. Are you referring to the retail market particularly in this instance?

Dr. MUELLER. That is correct; the sales of druggists in the prescription market.

Senator NELSON. We do find from the testimony, as I am sure you have noted, that generic companies or generic drugs are competing effectively in bids to nonprofit institutions and to the Federal Government, and you will also find testimony that brand name drugs drop substantially in their price when they bid in this competitive area.

[1] The complete prepared statement submitted by Dr. Mueller begins at p. 1824, infra.

Dr. MUELLER. That is correct.

The evidence shows that when the buyers are well informed such as, hopefully, the purchasers for hospitals and the U.S. Government, they usually purchase on a generic basis rather than a brand basis, or when they do buy on a brand basis they purchase the brand selling at the lowest price rather than simply the most popular one or well known one.

Senator NELSON. So, you are explaining, I take it, the difference between the price situation in the retail market, where you will find a brand name product sold to the pharmacist at the highest price charged in the country, and the price situation in the institutional market where the same company bidding its brand name product to the Government or some nonprofit institution will offer it at a substantially lower price; is that correct?

Dr. MUELLER. That is correct. I think every person who has studied the record of congressional hearings where this sort of evidence has been developed and has been explored and subjected to extensive comment by informed people outside and within the drug industry, as well as medical doctors, has come essentially to this conclusion: namely, that there are very substantial differences between prices for products purchased by hospitals and other large buyers and prices paid in drugstores for the identical product.

Senator NELSON. And I understand it to be your conclusion that in general that is because you will very frequently find competition in bids to the Government or bids to nonprofit institutions while there is much less, or in some cases not any, competition at the retail level and the price charged by the company to the retailer and the wholesaler is not a competitive one; is that correct?

Dr. MUELLER. And the key factor for generating the competition is the presence of an informed buyer in one case and an uninformed one in the other, and, as a result, this broadens the market. People who have a product to sell that is physically identical to that of other sellers have an opportunity to bid, and, consequently, you broaden the market, which means broadening the opportunity for competition to work.

Senator NELSON. You referred to an informed buyer versus an uninformed buyer. That factor is at work in purchases by nonprofit organizations or government. If the purchasing agent is informed and takes competitive bids and has the personnel to evaluate the quality of the drugs, you have an informed buyer and you have competition and a lower price. In the same institution, nonprofit or government, if the buyer is not informed the price is back up high again.

Now, you are not suggesting that the question of an informed buyer makes any difference in the retail price, are you?

In other words, is it not correct that the wholesaler or the retailer is charged a certain price, and although quantity buying accounts for some differential, an informed purchaser for a large drug chain is still being charged a high price, the same price as is paid by an uninformed purchaser for another drug chain; wouldn't that be correct?

Dr. MUELLER. That is correct. As I interpreted the evidence that had been developed on this point, the only opportunity of getting a lower price at this level from the ultimate consumer's standpoint, namely, the patient of a doctor, is if his doctor orders the drug on a generic basis.

And then, of course, we may be able to get the product at the retail level at a lower price than for the branded product.

But on your specific point as to whether the branded product sells at the same price or a higher price through drug stores in these comparative bids, I agree with your interpretation of the facts.

Mr. GORDON. I think there may be another point, and that is that the purchasing agent for the ordinary consumer is not the one who pays. In other words, the doctor does not pay for the medicine. He does the purchasing. He orders the drug, and the patient, the consumer, does not have much of a choice.

Dr. MUELLER. I have heard many people speak to that point, including doctors, who say that some doctors are more discriminating in this respect than others. And I think increasingly, with publicity concerning the alternatives available, consumers often ask their doctors: "What is this generic business all about?" So this, I suspect, makes the doctor a little bit more price conscious. And I think this is one of the benefits of publicity concerning the alternatives available to consumers. It is sort of a counter to the advertising which promotes brand names so decisively in the minds of consumers today.

Senator NELSON. Go ahead.

Dr. MUELLER. The resulting wide price spread between advertised and generic drugs often applies to unpatented as well as patented drugs. These factors shelter the leading concerns, or any concern with a highly differentiated drug product, from effective price competition.

This explanation of high drug profits is not novel. Nearly all researchers who have analyzed the drug industry in detail have come essentially to the same conclusion. Similarly, empirical studies which have cut across many industries have identified the elements of market structure that are primarily responsible for high noncompetitive profits. These elements are high seller concentration, high barriers to entry, and product differentiation.

Mr. GORDON. Dr. Mueller, for the record, will you please explain exactly what product differentiation is?

Dr. MUELLER. I had anticipated this question. I know that Senator Nelson was an undergraduate student in economics but now is primarily a lawyer—or, I should say, primarily a statesman.

Senator NELSON. You may make that statement here, but no place else.

Dr. MUELLER. I am thinking of back in Wisconsin.

There is a definition of product differentiation which appears in the Antitrust Law and Economic Review which, presumably, is written for lawyers. I am not sure if this is an improvement on one that I could make for students.

That is the way they define it—they say:

> Product differentiation refers to the distinguishing of substitute products from one another by advertising and the like. Whereas buyers of homogenous products regard the output of any particular seller as identical in all respects to that of all other producers of that product, the seller of a "differentiated" product enjoys a favored position over its rivals, in that the buyers consider it a superior product and are willing to pay a "premium" price for it rather than accept the substitutes offered by those rivals. Since new entrants must frequently accept a lower price than established firms are able to get for a product of equal quality and cost, this disadvantage is said to constitute a "barrier to entry," one that permits established firms to charge a supercompetitive price without attracting new entry.

And, as I said, I will later have some things to say about product differentiation created by advertising or promotion, which in effect creates a barrier to entry facing potential competitors. This is what this definition is supposed to explain.

Senator NELSON. When you say "product differentiation," are you referring to the same chemical compounds which are differentiated by advertising and other means?

In other words, you are talking about a drug, a basic compound, which a company differentiates from the same drug put out by another firm simply by the capsule it is in and the advertising. You are not talking about two different drugs?

Dr. MUELLER. No, sir, they are chemically identical.

Senator NELSON. So, you would have two drugs that have the same chemical composition but are differentiated in one way or another by trade name and advertising and that sort of thing?

Dr. MUELLER. That is correct. People have an impression that there is a difference. It is a psychological thing. You believe it is different, and, therefore, you behave differently, even though it is physically identical.

Senator NELSON. So, a drug such as prednisone, which is the generic name, manufactured by a number of companies. One of them gives it the brand name "Paracort," and one of them "Meticorten." They are the same chemical compound, but are differentiated products in the marketplace; is that what you are saying?

Dr. MUELLER. That is correct.

Senator NELSON. And they have the same purpose and the same objective in the treatment of the patient?

Dr. MUELLER. Yes. I am assuming that they are physically or chemically identical, and yet, because of this differentiation in the minds of the consumer you are able to have a unique demand for them which permits you to get a higher price for one than the other.

Senator NELSON. So, you are saying that the difference, when you use the word "differentiation," is in the minds of the consumers and not in the chemical composition of the product itself?

Dr. MUELLER. That is correct. That is the way I am using it here, as I think it applies most accurately in the drug industry. In some instances, of course, there may be some physical difference in products, and forms differentiate them further through advertising and the like.

Senator NELSON. In the method by which they are compounded or by the coating on the tablet, and that sort of thing?

Dr. MUELLER. I was thinking of products other than drugs.

In the case of soaps, they are very similar often, but they may be slightly different physically plus having blue in them, and so forth, which is similar to putting a different coating on the pill. But the basic idea is that they are essentially identical products in an economic sense because of the underlying physical and chemical characteristics, but that, because of this differentiation created by promotion, and so forth, the consumer thinks they are different.

Senator NELSON. Soap would be one of the items that you refer to as homogeneous products; is that it?

Dr. MUELLER. It is very much differentiated in the minds of consumers. You pay a tremendous difference in the price of Tide, say, and Safeway's detergent. And the only point I was making here, and I

probably introduced an element of confusion by doing so, is that in some cases there are slight physical differences as well as this psychological difference created in the mind of the consumer; whereas, in ethical drugs most frequently the products are physically and chemically identical.

Senator NELSON. Go ahead.

Dr. MUELLER. Perhaps the most pervasive factor blocking effective price competition in drugs is the presence of substantial product differentiation of branded drug items. A recent econometric study demonstrates that advertising and promotion-created barriers to entry are the single most important explanation for differences in profit rates in American industry. The drug industry was among the industries included in that study.

Professor Seymour Harris of Harvard University pretty well summarizes the conclusions of academic scholars concerning the organization and performance of the drug industry:

> Many are concerned that at industry which comes close to being a public utility achieves the highest profits in relation to sales and investment of any industry; is highly concentrated in its control of the market; reveals serious monopolistic trends; increases the cost to consumers by differentiating the product at a dizzy pace, with the differentiated product usually similar to or identical with existing products; and greatly inflates the cost through record expenditures on selling. The competition among companies to overwhelm the doctors by repetitious and often misleading advertising, and a failure to give as much publicity to the bad side effects as to the immediate beneficial effects, are unfortunate. Thus competition forces even highly moral firms to become less ethical in their behavior. In the drug industry the relation of labor to total costs is minimal; and like the soap and tobacco industries, using similar selling techniques, their relation of labor to value added is a minimum—selling expenditures and profits are the large items in gross receipts.
>
> The cost of drugs is too high. I say this, though I am aware that the research contributions of the industry are important and that the lives saved, the suffering averated, and the acceleration of recoveries are worth more than the $4 billion spent on drugs. But the cost could be substantially less.

Does this mean that risk plays no role in high drug profits? Not necessarily. Although these high profits can be explained by the structural characteristics of the industry—namely, high concentration, high entry barriers, and a high degree of product differentiation—it is conceivable that risk also played some part. Conrad, Plotkin, Markham and Cootner testified that they believed high drug prices and profits were due primarily to uniquely high risks assumed by large drug manufacturers, and that the Conrad-Plotkin study measured the magnitude of this risk. The relevant question, of course, is how much of total profits can be attributed to the risk factor. Let us therefore turn to the empirical evidence on this subject.

Mr. GROSSMAN. Dr. Mueller, before you do that, I wonder if I could take you back to Professor Harris' quote?

In the first line he says:

"Many are concerned that an industry which comes close to being a public utility," et cetera.

How do you feel about that?

Do you think the drug industry should be treated as a public utility?

Is it close to being so?

Should it be?

Dr. MUELLER. I think what he is referring to is that one characteristic of a public utility is that it is providing a service to the consumer

which is especially unique, is required for matters of safety and public welfare. And this, I think is the definition he is using.

Mr. GROSSMAN. When Mr. Squibb testified he said that this was a possible end result if the drug industry did not do something on its own, that we would eventually treat them like public utilities. Do you think the time to do this is now?

Dr. MUELLER. I personally am among those who are very reluctant to see more direct regulation of American business of the kind we have in the railroads and transportation, and so on. It presents a great many difficulties. And my personal inclination is to try to make competition work wherever it is at all possible, and I would hope that there are solutions to this problem short of the public utility approach.

Mr. GROSSMAN. Thank you.

Senator NELSON. Is it your opinion that if there were—whatever the word means—effective competition at the retail level, that this would basically resolve the problem that we are talking about here?

I realize that this involves a question of fact and all kinds of other things.

Dr. MUELLER. If we could achieve effective competition, I think it would resolve the problem. This gets into the question of how you achieve it and whether it can be achieved.

Mr. GROSSMAN. I wonder if you could explain what you mean by high seller concentration?

Dr. MUELLER. The fact that there are very few sellers of some drugs.

Mr. GROSSMAN. Thank you.

Senator NELSON. I believe you address yourself to that particular question a little later on, with some comparisons with the auto industry and so forth.

Dr. MUELLER. In terms of seller concentration?

Senator NELSON. Yes.

Dr. MUELLER. No, sir. I think earlier in my summary of what people have said of the industry I made some references to concentration.

Senator NELSON. I meant lack of competition, because one or two or three companies may be the only producers of a product.

Dr. MUELLER. That is correct.

I might ask, with your permission, that the fairly extensive footnotes and so on which I have in my prepared statement be incorporated in the record. I tried to cut down on my statement by putting a good deal of the underlying data in the footnotes and references.

Senator NELSON. The full statement, including the footnotes, will be included in the record, and at anytime the footnotes seem to be important to an understanding or appreciation of your basic text, you may read them or explain them extemporaneously or however you see fit.

Dr. MUELLER. Thank you.

One way of gaining insight into the question of "risk" is to look at what investment analysts tell investors about the drug industry. This may seem to be a rather homespun approach to the problem, but after all it is what investors believe about an industry that determines investment decisions.

A perusal of studies by investment analysts indicates that they generally advise investors that the drug industry is a rapid growth,

high profit industry where established firms hold a strong position relative to small companies and potential entrants. The industry is frequently described as "depression resistant" because, as one analyst put it, "Illness is no respector of business cycles, and Americans have shown that they will buy the medicine they need regardless of economic conditions." These characteristics are considered to make drug stocks good "defensive" investments. As a result, drug stocks sell at relatively high price-earnings ratios, indicating that investors are confident of a high future payout. A Standard & Poor's analysis of drugs summed up the factors affecting drug stocks as an investment as follows:

> Shares of drug equities have historically sold at relatively high price-earnings ratios, owing to the industry's recession-resistant characteristics, its above-average earnings growth rate, and its strong underlying position. Moreover, it is difficult to enter the drug field.

Investment analysts generally emphasize that the high earnings of drug companies make drug stocks a good buy. This is not to imply, of course, that investment analysts view the industry as completely riskless. The staff of Moody's Investors Service, after explaining a number of reasons why drug stocks were a good investment, stated:

> The drug industry cannot be risk-free. The postwar years have seen periods of slowdown, and individual companies have suffered temporary setbacks. The causes have been many. Competition has led to price-cutting in popular products, such as penicillin, where capacity has been overexpanded. Occasionally, a profitable new drug is found to have unsuspected and unfavorable side effects. This, however, is less of a problem than product obsolescence or the expiration of patents on major drugs that have been exclusive with one company. In recent years, government regulation has been tightened at the drugmaker's expense. Finally, the ebb and flow of respiratory diseases often causes sharp fluctuations in drug sales.

But after enumerating the above points, the Moody's analysts continued:

> The impact of such development has caused only temporary deviations in a growth curve that has pointed strongly upward.

Thus, while the drug industry faces uncertainties and problems, from an investor's standpoint these "risks" apparently are no greater than those found in many other industries. On the contrary, drugs are considered a sound growth investment.

Investment analysts frequently make mention of the fact that drug profits may be adversely affected by factors that will increase price competition and thereby erode high profits. The most frequent reference of this sort is the observation that anything threatening to increase the use of generic drugs as opposed to brand name drugs threatens high profits. An analysis by "Value Line" of the possible effects of medicare on drug profits is typical of investment analysts' views on the subject. After explaining that medicare very probably would increase drug sales, "Value Line" concluded that drug profits would not go up by a corresponding amount because:

> Hospitals and institutions usually, wherever possible, buy generic name drugs rather than brand names in order to reduce costs. *The most profitable business for the drug manufacturers is that which comes through drugstores, where drugs are prescribed on a brand name basis.* [Emphasis added.]

Senator NELSON. May I interrupt, just for clarification of a point? You state that the hospitals and institutions whenever possible buy generic drugs rather than brand names in order to reduce cost. Isn't it the actual situation that hospitals and the Government use the formulary system when they purchase drugs. They take bids on a generic basis, and then the contracts are made with companies that produce only generic drugs and companies that produce both brand names and generics. Brand name companies bid their brand, but here is where you find the example about the effect of competition on prices: They may very frequently win; they may very frequently underbid the generic company in the institutional field, that is, Government and hospitals, and therefore the trade name drug may very frequently be used. But here is where you see the contrast between the price that is charged by the brand named company in the competitive field versus the price they charged in the retail field. In the retail market they can hold their market price against a lower priced generic drug, but they can't hold it against a generic drug in a Government purchase unless they substantially reduce the price when they bid. Is that a correct statement?

Dr. MUELLER. That is correct. I think investment analysts view the end effect of this process.

This observation, of course, is concerned with how medicare might affect competition because of the increasing use of generic drugs; it is not explaining profits associated with risks.

In sum, there is no reason to conclude, on the basis of advice being given investors by investment analysts, that the drug industry is a uniquely risky industry. On the contrary, the generally glowing reports of investment analysts suggest that large drug companies should have little difficulty obtaining adequate capital should they choose to go into the market for it. Actually, however, their profits are so large that drug companies seldom need go to the capital market for equity capital. And there is no reason to expect that drug companies would have difficulty getting adequate capital even if they enjoyed profit rates comparable to most other American industries.

But perhaps this is a too prosaic approach to the problem. Let us, therefore, turn to the Conrad-Plotkin-Markham-Cootner "econometric" explanation of high profits in the drug industry.

My comments today concerning the Conrad-Plotkin analysis will be limited to an evaluation of the testimony presented to this committee last month. Arthur D. Little, Inc. has promised to provide us with the underlying data used in their analysis.

Mr. GROSSMAN. Dr. Mueller, before you go on: At what point do you think investors would not invest? How low do we have to go in market percentages before we lose the investors?

Dr. MUELLER. In the drug industry?

Mr. GROSSMAN. Yes.

Dr. MUELLER. I am not sure just where that level is. There are companies that have had fairly low earning experiences that have been able to obtain capital funds.

I think you will recall Dr. Whitney's statement that in the early 1950's drug companies were investing at a greater rate than other companies, by a 3-to-1 ratio, or something like that. Actually, at that

time drug profits on the average were very similar to the average of all American industry.

So, it is difficult to know precisely where this level is. I have little doubt in my own mind that it is considerably below the 21 percent level the large companies have earned in recent years, and there is not any persuasive evidence to argue that they would have difficulty getting capital if their profits were the same as most other American industries.

Mr. GROSSMAN. In the same line of questioning, what do you think is a fair return for the drug industry? We are talking in terms of social responsibilities.

What would you say would be a fair profit?

We have had a lot of discussion about the percentage return. Is there any specific percentage?

In other words, should we say: You can't go over 15 percent?

Isn't this all rather vague?

Dr. MUELLER. Yes, unless you are going to take a public utility approach which I find, personally, repugnant. Until we try other methods, I would not say that any particular percentage is appropriate. I would like to see the industry exposed more to the breezes of price competition and see what reasonable rate of return would be generated by competitive market forces, rather than to set arbitrarily some specific rate.

Senator NELSON. Is there any evidence that during the period you refer to, 1950–55, the drug industry was receiving profits fairly comparable to the average in all industries. Did the industry experience any difficulty in attracting investment capital if they needed it?

Dr. MUELLER. I just have not had an opportunity to look into that point. I think it would be interesting to see what the experience was. The observation I make, though, is that there are many examples of companies that were making profits by which this 21 percent standard would be very modest, in fact quite mediocre profits, or close to those earned by the rest of the American industry on the average. Yet they have been able to generate capital on their own or borrow it and grow effectively.

So, simply asserting that because someone is earning a high rate of return that this must somehow demonstrate that they must earn such a return in order to continue to grow is to just define the problem out of existence. And I am afraid that is what Professor Whitney might have been doing in his exchanges with you; at least that was my impression as I read the testimony last night.

Mr. GROSSMAN. Do you give any stock to his point about the railroads, how they prospered for 30 years?

Dr. MUELLER. I think he is factually correct, that they did profit for 30 years.

Mr. GROSSMAN. Then, I assume that there is a risk, and we will have to wait for 50 years before we can ever know?

Dr. MUELLER. I would not wait on the problems in the drug industry for 50 years to find out whether or not Professor Whitney's theory is correct.

With your permission, we will provide a brief supplemental memorandum to the committee should we have any additional observations after reviewing these data.

Senator NELSON. If we thought it would be of value, would you be prepared to submit the supplemental data to the committee at a subsequent date?

Dr. MUELLER. Certainly. I would be happy to.[1]

You will recall that Conrad and Plotkin attempted to test the hypothesis that the level of an industry's profit rate is positively correlated with the degree of risk faced by firms within the industry. In other words, the more risky an industry, the higher its average profits.

The concept of risk in investment decisionmaking theory refers to situations where it is impossible to predict with certainty the outcome of particular economic events. The presence of uncertainty is assumed to affect investors' decisions. A common assumption is that investors must be paid a "risk premium" if they have an aversion to assuming risks. "Risk aversion" has been an underlying assumption in a number of recent theoretical works, particularly in the areas of portfolio selection and monetary theory. However, the assumption of "risk aversion" is not a universal economic law. One need only view the crowds at the racetrack paying for the privilege of taking a gamble to infer that some persons regard risktaking as furnishing positive rather than negative satisfaction. These individuals may be viewed as "risk lovers." As a group, these risk lovers lose money at the racetrack. This is also the case with persons gambling in commodity futures markets.

In order to explain why individuals will both purchase insurance to guard against large losses and undertake gambles with remote possibilities of achieving high returns, Friedman and Savage have argued that some persons regard risk-taking as furnishing positive rather

This, in a nutshell, is what risk aversion theory is all about. But note two important points. First, the size of the risk premium is an empirical question. The theory tells us nothing about the amount of the premium, nor even whether it is positive or negative. Second, central to the hypothesis that is necessary to offer a positive premium to investors in order to attract adequate capital into a risky industry is the idea that risk may cause firms to incur losses, as well as to enjoy abnormally high profit rewards. Hence, risky industries would be characterized by the presence of both firms with abnormally high profits and firms with abnormally low profits. It would be inconsistent with risk theory if nearly all firms in an industry made very high profits and few or none ever suffered losses.

The Conrad-Plotkin measure of risk misses this point. Risk is quantified by Conrad and Plotkin by measuring the variance of individual companies' rates of return about the industry average in a given year and computing a simple average of these values for the 16-year period 1950–65. This measure assmues that the greater the variation in the profit rates of firms about the industry average, the riskier the industry. The chief conceptual shortcoming of this measure is that it does not necessarily tell us anything about the probability of incurring losses. In truth, using this measure an industry may be defined as risky even though all firms in it earn excessively high profits; on the other hand, this measure may define an industry as having very low risk even though all firms are making little or no profit. An example will illustrate this point. By the Conrad-Plotkin measure, the drug

[1] See supplemental statement beginning at p. 1843, infra.

industry is a high risk industry and the aluminum industry is a low risk industry. Conrad and Plotkin's estimates of the average rate of return, standard deviation, and variance for the two industries are as follows, and I show that in my statement in tabular form.

The drug companies in their sample experienced an average rate of return of 17.5 percent over the period 1950–65. The standard deviation in profits around this average was 8.6 percent. This means that the profit ratio of roughly two-thirds of the companies in the industry fell in the range, 8.9 percent to 26.1 percent.

On the other hand, the average rate of return of a group of aluminum companies was 7.8 percent, with a standard deviation of 1.3 percent. This means that two-thirds of the time aluminum company profits fell in the range, 6.5 percent to 9.1 percent.

Thus, according to Conrad and Plotkin, the drug industry is riskier than the aluminum industry because of the greater standard deviation in the profit rates of drug manufacturers.

Just what do these facts concerning the variation in profits tell an investor about the relative profit expectations in these two industries? They say, in effect, that there is a 2-to-1 chance that profit rates in the drug industry will fall in a range from 8.9 percent to 26.1 percent, whereas there is a 2-to-1 chance in the minimum industry that profit rates will fall in a range from 6.5 percent to 9.1 percent. Can anyone seriously argue that investors would prefer to place new capital in the aluminum industry rather than in the drug industry? The only risk that the aluminum investor is saved from is the high probability that aluminum companies will earn less than 9 percent—there is only 1 chance in 6 of getting more than 9 percent.

On the other hand, the risk the investor in the drug industry faces is that the chances are poor that drug companies will earn a rate of return as low as the average return in the aluminum industry. In fact, there is only 1 chance in 6 that they will earn a rate of return of below 9 percent, whereas there are 4 chances out of 6 that they will earn between 9 and 26 percent, and 1 chance in 6 that they will earn over 26 percent. In other words, five-sixths of the time the drug companies would be well above the aluminum companies' average return. Clearly, then, it is nonsense to infer from the Conrad-Plotkin variance measure of risk that the drug industry is riskier than the aluminum industry in terms of attracting new capital.

Losses, or even low profits, are practically unheard of among large drug companies. In this respect the drug industry is practically unique among important American industries. Figure 2 shows for 22 major industries the percent of the time the eight largest companies fell in various profit rate categories during the period 1954–66. Large drug companies not only earned a higher return than any other of the major manufacturing industries shown, but none of the drug companies ever experienced losses during the period, nor did any companies experience profit rates below 5 percent. Only two other industries enjoyed this distinction, petroleum refining and cigarettes. I might say parenthetically that I used this 5 percent figure because it represents the approximate rate that someone would receive when purchasing very secure bonds during this period. So, in effect, this is the upper level of very secure investments. And when you receive

below 5 percent, you are receiving less than you would earn in sort of an insured, risk-free investment.

Companies in most manufacturing industries had profit rates ranging between 5 percent and 15 percent. By considering this range to represent a sort of "norm," we can visualize the extent to which large drug manufacturers departed from it. Over the period 1954–66, the eight largest drug manufacturers were in this range about 25 percent of the time and none ever fell below it. On the other hand, 75 percent of the time the leading drug manufacturers earned profits exceeding 15 percent, and fully 17 percent of the time they had profit rates exceeding 25 percent.

No other industry matched drugs in the frequency with which companies had profit rates exceeding 15 percent. In only three other industries—motor vehicles, computing machines, and aircraft—did large firms have profit rates exceeding 15 percent more than 50 percent of the time. On the other hand, all but four of the remaining 18 industries had profit rates exceeding 15 percent less than one-fourth of the time. Finally, some companies in all but two of the 21 industries outside drugs earned below 5 percent at least part of the time. These contrasting patterns cast serious doubt on the proposition that large drug companies face a serious risk of incurring losses.

I might add parenthetically that if we take the 29 drug companies used in the Conrad-Plotkin study, their profit performance was not a great deal different than the eight used in that chart. The 29 companies earned below 5 percent only 0.4 percent of the time. If we had used as many companies, say 29 companies, in those other 21 industries, the red area shown on the right, these other industries—in other words, the below 5 percent area—would be considerably wider.

Figure 3 illustrates the profit experience of leading drug companies in each year during the 1954–66 period. Most importantly, it shows a pattern of persistently high profits. None of these large companies earned below 5 percent in any year, and in only 4 years did any company earn between 5 percent and 10 percent; 3 of these years were in the beginning of the period—1954, 1955, and 1956. Since then, in only 1962 did a company earn below 10 percent. And in the last 3 years only a small percentage earned below 15 percent.

This actual profit experience seems to fly in the face of the Conrad-Plotkin-Markham-Cootner inference that drug manufacturing is a uniquely risky business. The explanation, of course, is to be found in their definition of risk. Using a different definition of risk, Dr. Irving N. Fisher and Dr. George R. Hall of the Rand Corp. concluded that risk accounts for a very small portion of the high profits of drug companies. The findings are shown in table 3. They show that for the period 1959–64 drug companies earned an average return of 18.32 percent. Fisher and Hall attributed 1.68 percent of this to risk. They concluded that the "risk premiums" for drugs are "very low" and that the explanation for high profits "must be sought in factors other than risk." [1]

Mr. GORDON. Mr. Plotkin testified here last month. I quote from his testimony on page 2743 of the transcript:

[1] The report "Risk and Corporate Rates of Return," by Dr. I. N. Fisher and Dr. G. N. Hall, appears as Appendix II, p. 2120, infra.

Management, it is our contention, forms its risk expectations not solely on the past profit history, of its own company, but also on the diversity of histories that other companies undertaking similar ventures, to use the term again, other companies within its industry undertake.

Would you comment on that, please?

Dr. MUELLER. Well, I think that is essentially true, that they would look at the experience in their industry. And applying that to drugs, they would find that if they were going to go into the industry at the level of success of the leading concerns, that the profit experience is very good. On the other hand, they would look at the profit experience of the generic producer, say, who does not sell the differentiated product, does not have a monopolistic product due to a patient, say, and the profit experience would demonstrate a very poor prospect. So, one must understand what it is he is looking at. And they have in their measure tried to capture the risk factor by looking at the difference in the profit rates of the leading 29 companies. If they had taken the top eight companies, for example, the profit variance would be considerably less. In some other industries they have as few as five companies. So, it turns out, that their measure is very arbitrary.

It is true that Conrad and Plotkin have found a statistically significant relationship between their measure of risk and industry profits. It is statistically significant in the sense that the correlations that they came up with could not have been due simply to chance. And in this sense it is significant statistically. This does not imply that there is necessarily a causal relationship between the two variables they were measuring. In truth, they have misinterpreted the causal factors responsible for their statistical relationship.

Upon close analysis, the Conrad-Plotkin measure of risk turns out to be a better proxy of relative market power than of risk. Their measure assumes the existence of "homogeneous" industries; that is, "industries in which all the firms product similar products, compete in the same markets, and, in general, face the same elements of risk and uncertainty." In fact, however, when broad industry definitions are used, such as those in the Conrad and Plotkin study, the constituent firms within each "industry" are frequently highly differentiated from one another by a variety of factors. Hence, each firm in the industry may face different risks and other factors having a bearing on profits. This is particularly true in consumer, service, and other so-called differentiated product industries. Because of advertising and other factors, some firms in such industries have a pronounced and persistent advantage over others. As a result, the most advantaged firms earn persistently higher profits than the less advantaged firms. Such a difference between the profits of the most advantaged and least advantaged firms in an industry may provide a rough measure of the height of the entry barriers into the industry. Economic theory predicts and empirical analysis verifies that the higher an industry's entry barriers, the higher its profits. Hence, if intra-industry profit variance measures the height of entry barriers, we may expect a positive statistical association between industry variance and average industry profit rates. Thus, it is not surprising that Conrad and Plotkin find some statistical association between intra-industry profit variance and average industry profit rates. Unfortunately, they misinterpreted the significance of their own findings.

The effect of product-differentiation-created intra-industry profit variance on the Conrad-Plotkin analysis is obvious by inspection of specific industries with a high degree of product differentiation.

I should apologize, Senator, for this rather theoretical and, I am sure, obscure explanation of risk.

Senator SCOTT. That is all right. We do not understand it either.

Dr. MUELLER. But I think the following illustrations explain what I am getting at here.

Automobiles, for example, show up as a very "risky" industry in the Conrad-Plotkin study. This is the case because of the wide disparity in profits between the strongest, most entrenched firms and the weakest, marginal ones. For example, during the last 5 years automobile companies enjoyed average profits as follows: General Motors, 21 percent; Chrysler, 15 percent; Ford, 14 percent; American Motors, 6 percent. During most of the 1950's while Studebaker was in the industry it operated in the red. I think nearly all students of industrial organization will agree with Bain that the reason for the high average profit rates in the automobile industry is the high degree of market concentration and the very great barriers confronting potential entrants. Thus, the persistently high average profit rates of the automobile industry are primarily due to the structure of the industry, not its risk, as measured simply by the difference in the profit rates of the low and high companies.

Nor are automobiles the exception. On the contrary, of the industries included by Conrad and Plotkin, eight of the nine with average profit rates exceeding 14 percent were industries characterized by substantial differentiation advantage among even the largest firms, and in each case the most advantaged firms held a substantial and persistent profit advantage over the less advantaged firms.

The drug industry is an especially poor candidate for the explicit assumption of the Conrad-Plotkin model that industries must be homogeneous. There are great product differences among even the 29 drug companies they studied. They produce varying mixes of ethical and proprietary drugs, varying proportions of branded and generic drugs, and then enjoy varying degrees of differentiation for their branded drugs. All of these factors, as well as a number of others, result in persistently higher profits for some drug companies than others. American Home Products, for example, not only earned average profits well above all other drug companies, but over the entire period 1954–1966, it had profits higher than every other firm. On the other hand, over the same period, Rexall Drug had the lowest profits among the top eight companies in all but 2 years, when it was second lowest.

Although a number of factors affect the profit differential among drug companies, the degree of advertising-achieved-product differentiation plays a big role. Table 4 classifies the 29 drug companies used in the Conrad and Plotkin study by the volume of their advertising outlays. The five companies with advertising outlays in excess of $50 million in 1966 enjoyed an average rate of return of 29.2 percent during 1961–1965; those with advertising outlays between $10 million and $50 million had an average rate of return of 19.7 percent; and those spending less than $10 million earned 17.3 percent. Significantly, all of the top five advertisers earned in excess of the average return of those spending between $10 million and $50 million.

The preceding reveals that much of the profit variance which Conrad and Plotkin found among leading drug companies is the result of the product differentiation advantage held by some firms in the industry.

If we are correct in believing that differences in intraindustry profit variance actually measures differences in the degree of product differentiation rather than risk, then Conrad and Plotkins' correlation results may have been heavily influenced by the inclusion of highly differentiated industries. We now turn to an examination of this possibility.

To test the hypothesis that product differentiation caused profit variance is largely responsible for the statistical association uncovered by Conrad and Plotkin, we have analyzed separately their consumer goods and producer goods manufacturing industries. Product differentiation, of course, shows up primarily in consumer goods.

Figure 4 shows all the industries used by Conrad and Plotkin. They find a modest degree of correlation between intraindustry profit variance and profits using one measure of profits rates. Using a number of other measures they found less close relationships.

Figure 5A shows that the plotted observations of the consumer goods industries used in the Conrad-Plotkin analysis, and figure 5B shows the plotted observations of the producer goods industries. Among consumer goods industries, you will observe, there is a quite strong positive relationship, whereas among producer goods industries the relationship is very weak, and is not statistically significant.

In consumer goods, 76 percent of the variation among average industry profit rates is associated with the variance of intraindustry profit rates. Additionally, the slope of the regression line fitted to these observations is quite steep, which means industry profit rates rise sharply with high intraindustry profit variance.

On the other hand, when only producer goods industries are used in the analysis, the statistical relationship is extremely weak. Only 8 percent of the variation in industry profit rates is associated with variation in intraindustry profit variance. Moreover, the regression line is much less steeply inclined, indicating that average industry profit rates increase very slightly with increases in intraindustry profit variance.

These findings are extremely significant. They demonstrate that the statistical relationship found by Conrad and Plotkin was due almost entirely to the consumer goods industries in their sample. The fact that no significant statistical relationship remains when only producer goods industries are used to test their model is especially damaging to the Conrad-Plotkin analysis. A basic assumption of their method of measuring intraindustry risk is that the industries analyzed be homogeneous. Producer goods manufacturing industries are, of course, much more homogeneous than are consumer goods industries. Hence, according to their assumptions the "purest" relationship between "risk" and profits should have been uncovered in the analysis of producer goods industries. And, of course, there was none.

The close statistical relationship existing in consumer goods industries very probably results because intraindustry profit variance in consumer industries is a rough proxy for the height of entry barriers. Thus, Conrad and Plotkin unwittingly have made a case for the

inference that a substantial part of the high profits earned by drug companies is really due to advertising- and promotion-created barriers to entry, rather than risk. This, of course, coincides with the conclusion of nearly every economist who has carefully studied the drug industry.

Upon completing our analysis of the Conrad-Plotkin-Markham-Cootner explanation of risk and profits in the drug industry, I recalled the admonition once given by the great classical economist and logician John Stuart Mill. Mill cautioned economists against the pitfall of the multiplicity of causes. We must always be skeptical of simple statistical associations among complicated economic phenomena. Professor Kenneth Boulding put it well when he said:

> Some of us, perhaps, still have to learn that arithmetic is a complement to, not a substitute for, thought, and that what my spy in IBM calls the "gigo principle"—that is, garbage in, garbage out—is a sound approach even to the most elegantly computerized simulation.

This more or less capsules my findings in reviewing the analysis of drug profits and their possible association with risk. I find, to be very brief, that the high profit experience of the drug industry is related only minimally to risk and uncertainty in a casual way. On the other hand, the high profits of the drug industry are more closely associated with high barriers to entry of new competition. In other words, in the classic tradition, the market power enjoyed by drug firms has been achieved primarily because the leading drug companies have been able to fence themselves off from effective competition, and in this sheltered position they have garnered extremely high profits—profits which the economist would label as "abnormal" or "excessive," profits substantially above the competitive norm.

(The complete prepared statement and supplemental statement submitted by Dr. Mueller follows:)

STATEMENT OF DR. WILLARD F. MUELLER, DIRECTOR, BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION

Mr. Chairman and members of the Committee. It is a privilege and a pleasure to appear before this committee. I am accompanied today by two members of the staff of the Bureau of Economics, my assistant, Dr. Russell C. Parker, and Mr. William H. Kelly.

My appearance today is in response to the request of your chairman that I submit testimony on the subject of profits in the drug industry, as well as present an independent analysis of the study *Risk and Return in American Industry—an Econometric Analysis*, presented to this committee on December 19, 1967. The study was sponsored by the Pharmaceutical Manufacturers Association and prepared by Gordon R. Conrad and Irving H. Plotkin of Arthur D. Little, Inc., in consultation with Professor Jesse W. Markham and Professor P. J. Cootner. Hereafter we shall refer to the study as the Conrad-Plotkin study.

Before turning to the study, we shall first place in perspective the profits of drug manufacturers by comparing them with those earned by business enterprises in other American industries.

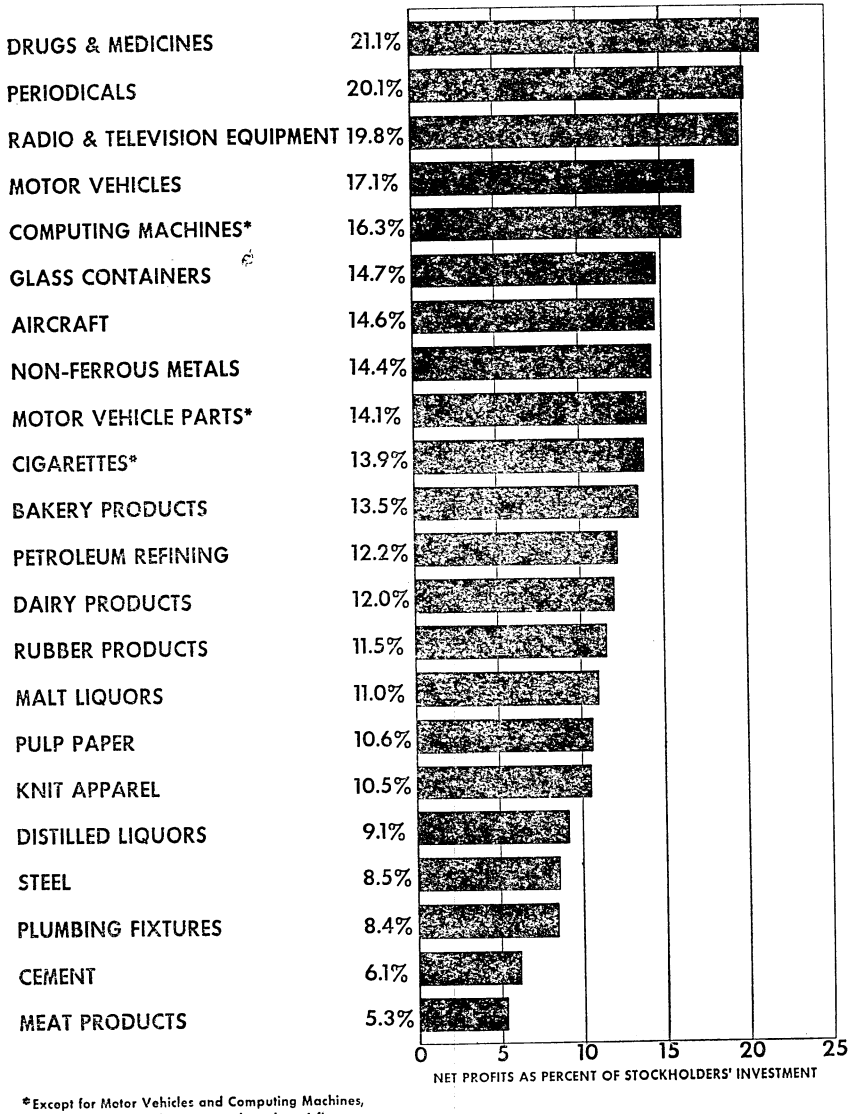
PROFITS IN THE DRUG INDUSTRY

Figure 1 shows for 1966 the average rate of return on stockholders investments of leading firms in 22 important American manufacturing industries.[1] Profit

[1] This information is based on the Federal Trade Commission reports on *Rates of Return for Identical Companies in Selected Manufacturing Industries*. The industry average is based on the 12 leading companies in each industry. The 22 industries shown in Figure 1 are those where the 8 largest corporations had combined assets of $1 billion or more in 1966, thereby excluding 15 smaller industries appearing in the FTC Report. None of the excluded industries had profits as high as did the drug industry.

FIGURE 1

RATES OF RETURN OF 12 LEADING FIRMS IN SELECTED INDUSTRIES, 1966



*Except for Motor Vehicles and Computing Machines, based on 8 firms; and Cigarettes, based on 4 firms.

SOURCE: Federal Trade Commission - Rates of Return For Identical Companies In Selected Manufacturing Industries, 1957-1966.

rates of leading drug manufacturers exceeded those of large firms in the 21 other industries. In fact, drug industry profits were twice as great as one-third of the remaining industries; were 44 percent or more above those of all but 4 other industries; and they exceeded even such traditionally high profit industries as motor vehicles and computing machines.

Nor was 1966 an exceptional year. Table 1 compares over the period 1950–1966, the average profits of *large* drug companies and *large* companies in the 22 industries shown in Figure 1. Several points are of special interest. First, in the early years, 1950–1955, average drug company profits were about equal to or somewhat above the average of other large manufacturers. Second, beginning in 1956, however, average profit rates of drug companies were well above the average of other large companies. Finally, since 1956 drug companies have consistently ranked either first or second [2] among all large manufacturing industries. This indicates that during the last decade large drug companies have occupied an especially advantaged position relative to large companies in other American industries. Table 2 summarizes profit data of *all* drug companies and *all* manufacturing companies for the period 1956–1967. Over the period covered it shows essentially the same picture as Table 1. Since 1956 drug manufacturers have failed to occupy first place in only one year.

TABLE 1.—RATES OF RETURN OF LEADING DRUG MANUFACTURERS AND ALL LEADING MANUFACTURERS, 1950-66

Year	Drug industry [1]	All manufacturing [2]	Ranking of leading drug companies among all leading manufacturing companies
1950	19.6	17.3	6
1951	15.7	14.6	7
1952	12.7	12.7	11
1953	12.3	13.2	12
1954	12.8	12.8	8
1955	15.4	15.5	8
1956	18.2	13.8	2
1957	21.5	12.8	1
1958	20.2	9.3	1
1959	20.3	10.8	1
1960	18.4	10.3	1
1961	17.6	9.8	1
1962	17.1	10.6	2
1963	17.8	11.5	2
1964	18.9	12.3	2
1965	21.0	13.4	2
1966	21.1	13.3	1

[1] Based on 8 largest companies from 1950 to 1953 and 12 largest companies from 1954 to 1966.
[2] Based on the 8 largest companies from 1950 to 1953 and the 12 largest companies from 1954 to 1966 in each of the 22 industries shown in fig. 1 with the exception of the computer and motor vehicle industries in which the 8 largest firms were used for all years and cigarettes in which the 4 largest firms were used for all years.

Note: Rate of return after taxes as a percent of stockholders' investment.

Sources: Report of the Federal Trade Commission, "Rate of Return for Identical Companies in Selected Manufacturing Industries, 1955-66" and Moody's Industrial Manual, 1952-54.

This pattern of persistently high profits indicates that large drug companies occupy a unique position in the American economy. And they appear to have become increasingly unique since the mid-1950's.

Before turning to an analysis of the Conrad-Plotkin-Markham-Cootner explanation of high profits in the drug industry, I shall review briefly what appears to be a virtual concensus of opinion among researchers in the field of industrial organization concerning the causes of high profits of drug manufacturers.

In this connection I would like to emphasize the crucial role which Congressional hearings have played in developing the facts necessary for scholars to study the organization and performance of the drug industry. Prior to the Kefauver drug hearings on administered prices in 1959–1961, not a single article concerning the American pharmaceutical industry had appeared in a professional economic journal.[3]

[2] In each case they ranked second to automobile manufacturers.
[3] Hugh Douglas Walker, "Market Power and Price Levels in the Ethical Drug Industry," Unpublished Ph.D. dissertation, Vanderbilt University, June 1967, pp. 2–3.

TABLE 2.—RATES OF RETURN OF DRUG MANUFACTURERS AND ALL MANUFACTURING INDUSTRIES, 1956–67

Year	Profits after taxes as a percent of stockholders' equity		Profit rank of the drug industry among all manufacturing industries [1]
	All drug manufacturers	All manufacturers	
1956	17.6	12.3	2
1957	18.6	11.0	1
1958	17.7	8.6	1
1959	17.8	10.4	1
1960	16.8	9.2	1
1961	16.7	8.8	1
1962	16.8	9.8	1
1963	16.8	10.3	1
1964	18.2	11.6	1
1965	20.3	13.0	1
1966	20.3	13.5	2
1967 (3 quarters)	18.6	11.5	1

[1] Rank among the 26 industries for which profits are reported separately in Quarterly Financial Reports.
Source: Federal Trade Commission and Securities and Exchange Commission, Quarterly Financial Report.

Since the first such article appeared in 1962, there has been a growing volume of research literature on the subject, all of which has drawn heavily on the Kefauver and subsequent Congressional hearings. The facts developed by this committee have made another enormous contribution to the fund of knowledge concerning the drug industry. I am confident that scholars will be sifting and winnowing the facts for years.

THE CAUSES OF HIGH PROFITS IN THE DRUG INDUSTRY

The preponderance of economic evidence argues that the persistently high profits of the drug industry are the result of the absence of effective price competition in the sale of many products. Price competition in drugs in ineffective for several reasons. Concentration in the production of many drugs is high because of the patent privilege.[4] And even where there are relatively many sellers, as well as many potential sellers (for example, in the case of unpatented drugs sold under generic names), effective price competition often is muted by vast advertising, promotion, and other selling effort which differentiates in the minds of consumers the products of the largest drug manufacturers selling under their own brand or trade names from those of other manufacturers.[5] Hence, manufacturers selling chemically identical drugs under generic names frequently have difficulty in selling them at any price. The resulting wide price spread between advertised and generic drugs often applies to unpatented as well as patented

[4] The Kefauver committee staff analyzed concentration for 51 products in the major drug groupings: antibiotics, hormones, diabetic drugs, sulfas, vitamins, and tranquilizers. These products represented at least two-thirds of the total value of ethical drugs in 1958. The 15 leading drug companies controlled the production of these important products as follows:

"In 27 of the products, or more than one-half the entire U.S. output is produced by 1 of the 15 companies. . . . In sulfa drugs, one company accounts for 100 percent of the output in eight of the nine products. In tranquilizers the condition of monopoly prevails in six of the seven products. In antibiotics (other than penicillin) the total output is produced by one company in five of the nine products, and in hormones and vitamis, each, in three out of the nine. In 8 additional products concentration takes the form of "duopoly"—control by 2, while in 10 others the entire output is produced by 3 companies. Against the typical structure of concentration in manufacturing industries, it is indeed remarkable that in only 6 of the 51 products are there as many as 4 producers."

Report No. 448 of the Committee on the Judiciary, U.S. Senate, made by its Subcommittee on Antitrust and Monopoly, 87th Cong., First Sess., *Study of Administered Prices in the Drug Industry,* June 27, 1961, pp. 68–69.

[5] It well recognized that advertising and promotion effort in the drug industry is greater than it is in nearly all other large American industries. See, for example, William S. Comanor and Thomas A. Wilson, "Advertising, Market Structure, and Performance: An Empirical Analysis," *Review of Economics and Statistics,* November 1967, Appendix Table 2. Of the 41 industries studied by Comanor and Wilson, all but two had lower advertising-to-sales ratios than did drug manufacturers. Comanor and Wilson further point out that advertising outlays represent less than half of the total selling expenditures of drug companies.

drugs. These factors shelter the leading concerns, or any concern with a highly differentiated drug product, from effective price competition.[6]

This explanation of high drug profits is not novel. Nearly all researchers who have analyzed the drug industry in detail have come essentially to the same conclusion.[7] Similarly, empirical studies which cut across many industries have identified the elements of market structure that are primarily responsible for high noncompetitive profits.[8] These elements are high seller concentration, high barriers to entry, and product differentiation. One or more of these factors are present in the sale of all drugs where price competition is ineffective. Perhaps the most pervasive factor blocking effective price competition in drugs is the presence of substantial product differentiation of branded drug items. A recent econometric study demonstrates that advertising- and promotion-created barriers to entry are the single most important explanation for differences in profit rates in American industry.[9] The drug industry was among the industries included in that study.

Professor Seymour Harris of Harvard University pretty well summarizes the conclusions of academic scholars concerning the organization and performance of the drug industry:

"Many are concerned that an industry which comes close to being a public utility achieves the highest profits in relation to sales and investment of any industry; is highly concentrated in its control of the market; reveals serious monopolistic trends; increases the cost to consumers by differentiating the product at a dizzy pace, with the differentiated product usually similar to or identical with existing products; and greatly inflates the cost through record expenditures on selling. The competition among companies to overwhelm the doctors by repetitious and often misleading advertising, and a failure to give as much publicity to the bad side effects as to the immediate beneficial effects, are unfortunate. Thus competition[10] forces even highly moral firms to become less ethical in their behavior. In the drug industry the relation of labor to total costs is minimal; and like the soap and tobacco industries, using similar selling techniques, their relation of labor to value added is a minimum—selling expenditures and profits are the large items in gross receipts.

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[6] In a highly important study, Professor Hugh Douglas Walker of the University of Indiana measures the extent to which drug prices have been raised by the market power created by patents and brand advertising. He estimates that the gross benefits of the removal of both brand names and patents would amount to $617 million per year. Since the removal of patent protection might have an adverse effect on research effort, he estimates that the net benefits to society after allowing an additional research subsidy of $192 million (the total amount financed by Industry in 1961) would be $425 million. Professor Walker summarized his finding in a paper before the Econometrics Society meetings, December 29, 1967. His complete analysis appears in his unpublished doctoral dissertation, "Market Power and Price Levels in the Ethical Drug Industry," Vanderbilt University, June 1967.

[7] Report No. 448 of the Committee on the Judiciary, U.S. Senate, made by its Subcommittee on Antitrust and Monopoly, 87th Cong., First Sess., *Study of Administered Prices in the Drug Industry,* June 27, 1961. Federal Trade Commission, *Economic Report on Antibiotics Manufacture,* June 1958. Leonard G. Schifrin, "The Ethical Drug Industry: The Case for Compulsory Patent Licensing," *The Antitrust Bulletin,* Fall 1967, pp. 893–915. Henry Steele, "Patent Restrictions and Price Competition in the Ethical Drugs Industry," *Journal of Industrial Economics,* July 1964, pp. 198–223. Henry Steele, "Monopoly and Competition in the Ethical Drugs Market," *The Journal of Law & Economics,* October 1962, pp. 131–164. Seymour Harris, *The Economics of American Medicine,* 1964. William S. Comanor, "Research and Competition Product Differentiation in the Pharmaceutical Industry in the United States," *Economica,* November 1964; William S. Comanor, "Research and Technical Change in the Pharmaceutical Industry," *The Review of Economics and Statistics,* May 1965. Frank Cacciapaglia, Jr. and Howard B. Rockman, "The Proposed Drug Industry Antitrust Act—Patents, Pricing, and the Public," *The George Washington Law Review,* Vol. 30, June 1962, pp. 875–949. For a dissenting view see Jules Backman, "Economics of Propietary Drugs," *Annals of the New York Academy of Sciences,* July 14, 1965.

[8] See, for example, Joe S. Bain, "Relation of Profit Rate of Industry Concentration: American Manufacturing, 1936–40," *Quarterly Journal of Economics,* August 1951; Joe S. Bain, *Barriers to New Competition,* Harvard University Press, 1962; L. W. Weiss, "Average Concentration Ratios and Industrial Performance," *Journal of Industrial Economics,* July 1963. Norman R. Collins and Lee Preston, "Concentration and Price Margins in Food Manufacturing Industries," *The Journal of Industrial Economics,* July 1966, p. 226. A report by the staff of the Federal Trade Commission, *The Structure of Food Manufacturing,* Technical Study No. 8, National Commission on Food Marketing, June 1966, pp. 202–210. H. Michael Mann, "Seller Concentration, Barriers to Entry, and Rates of Return in Thirty Industries, 1950–1960," *Review of Economics and Statistics,* August 1966, pp. 296–307. Unpublished study by Norman R. Collins and Lee Preston, "Concentration and Price-Cost Margins in Manufacturing Industries," April 1, 1966. William S. Comanor and Thomas A. Wilson, "Advertising, Market Structure, and Market Performance," *Review of Economics and Statistics,* Nov. 1967.

[9] William S. Comanor and Thomas A. Wilson, *ibid.*

[10] Professor Harris is referring to nonprice rather than price competition.

"The cost of drugs is too high. I say this, though I am aware that the research contributions of the industry are important and that the lives saved, the suffering averted, and the acceleration of recoveries are worth more than the $4 billion spent on drugs. But the cost could be substantially less." [11]

Does this mean that risk plays no role in high drug profits? Not necessarily. Although these high profits can be explained by the structural characteristics of the industry—high concentration, high entry barriers, and a high degree of product differentiation—it is conceivable that risk also played some part. Conrad, Plotkin, Markham and Cootner testified that they believed high drug prices and profits were due primarily to uniquely high risks assumed by large drug manufacturers, and that the Conrad-Plotkin study measured the magnitude of this risk. The relevant question, of course, is how much of total profits can be attributed to the risk factor. Let us therefore turn to the empirical evidence on this subject.

THE RELATIONSHIP BETWEEN RISK AND HIGH DRUG PROFITS

The investment analyst's view of the drug industry

One way of gaining insight into the question of "risk" is to look at what investment analysts tell investors about the drug industry. This may seem to be a rather homespun approach to the problem, but after all it is what investors *believe* about an industry that determines investment decisions.

A perusal of studies by investment analysts indicates that they generally advise investors that the drug industry is a rapid growth, high profit industry where established firms hold a strong position relative to small companies and potential entrants. The industry is frequently described as "depression resistant" because, as one analyst put it, "Illness is no respecter of business cycles, and Americans have shown that they will buy the medicine they need regardless of economic conditions." [12] These characteristics are considered to make drug stocks good "defensive" investments. As a result, drug stocks sell at relatively high price-earnings ratios, indicating that investors are confident of a high future payout. A Standard & Poor's analysis of drugs summed up the factors affecting drug stocks as an investment as follows:

"Shares of drug equities have historically sold at relatively high price-earnings ratios, owing to the industry's recission-resistant characteristics, its above-average earnings growth rate, and its strong underlying position. Moreover, it is difficult to enter the drug field." [13]

Investment analysts generally emphasize that the high earnings of drug companies make drug stocks a good buy. This is not to imply, of course, that investment analysts view the industry as completely riskless. The staff of Moody's Investors Service, after explaining a number of reasons why drug stocks were a good investment, stated:

"The drug industry cannot be risk-free. The postwar years have seen periods of slowdown, and individual companies have suffered temporary setbacks. The causes have been many. Competition has led to price-cutting in popular products, such as penicillin, where capacity has been overexpanded. Occasionally, a profitable new drug is found to have unsuspected and unfavorable side effects. This, however, is less of a problem than product obsolescence or the expiration of patents on major drugs that have been exclusive with one company. In recent years, government regulation has been tightened at the drugmakers' expense. Finally, the ebb and flow of respiratory diseases often causes sharp fluctuations in drug sales." [14]

But after enumerating the above points, the Moody's analysts continued, "The impact of such development has caused only temporary deviations in a growth curve that has pointed strongly upward." [15] Thus, while the drug industry faces uncertainties and problems, from an investor's standpoint these "risks" apparently are no greater than those found in many other industries. On the contrary, drugs are considered a sound growth investment.

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[11] Seymour Harris, *The Economics of American Medicine,* The MacMillan Company, 1964, p. 6.

[12] "No Cycle for Drugs," analysis prepared by the staff of Moody's Investor Service for *Dun's Review,* October 1967, p. 127.

[13] Standard & Poor's Industry Surveys, *Drugs, Cosmetics—Basic Analyses,* May 4, 1967, p. D 24.

[14] "No Cycle for Drugs," analysis prepared by the staff of Moody's Investor Service for *Dun's Review,* October 1967, p. 127.

[15] *Ibid.*

Investment analysts frequently make mention of the fact that drug profits may be adversely affected by factors that will increase price competition and thereby erode high profits. The most frequent reference of this sort is the observation that anything threatening to increase the use of generic drugs as opposed to brand name drugs threatens high profits. An analysis by *Value Line* of the possible effects of "medicare" on drug profits is typical of investment analysts' views on the subject. After explaining that "medicare" very probably would increase drug sales, *Value Line* concluded that drug profits would not go up by a corresponding amount because,

"Hospitals and institutions usually, wherever possible, buy generic name drugs rather than brand names in order to reduce costs. *The most profitable business for the drug manufacturers is that which comes through drugstores, where drugs are prescribed on a brand name basis.*" [16] [Emphasis added.]

This observation, of course, is concerned with how medicare might affect competition because of the increasing use of generic drugs; it is not explaining profits associated with risks. In sum, there is no reason to conclude, on the basis of advice being given investors by investment analysts, that the drug industry is a uniquely risky industry. On the contrary, the generally glowing reports of investment analysts suggest that large drug companies should have little difficulty obtaining adequate capital should they choose to go into the market for it. Actually, however, their profits are so large that drug companies seldom need go to the capital market for equity capital. And there is no reason to expect that drug companies would have difficulty getting adequate capital even if they enjoyed profit rates comparable to most other American industries.

But perhaps this is a too prosaic approach to the problem. Let us, therefore, turn to the Conrad-Plotkin-Markham-Cootner "econometric" explanation of high profits in the drug industry.

Conrad-Plotkin study of risk and profit rates

My comments today concerning the Conrad-Plotkin analysis will be limited to an evaluation of the testimony presented to this Committee last month. Arthur D. Little, Inc., has promised to provide us with the underlying data used in their analysis. With your permission, we will provide a brief supplemental memorandum to the Committee should we have any additional observations after reviewing these data.

You will recall that Conrad and Plotkin attempted to test the hypothesis that the level of an industry's profit rate is positively correlated with the degree of risk faced by firms within the industry. In other words, the more risky an industry, the higher its average profits.

The concept of risk in investment decision making theory refers to situations where it is impossible to predict with certainty the outcome of particular economic events. The presence of uncertainty is assumed to affect investors' decisions. A common assumption is that investors must be paid a "risk premium" if they have an aversion to assuming risks. "Risk aversion" has been an underlying assumption in a number of recent theoretical works, particularly in the area of portfolio selection and monetary theory.[17] However, the assumption of "risk aversion" is not a universal economic law. One need only view the crowds at the race track paying for the privilege of taking a gamble to infer that some persons regard risk taking as furnishing positive rather than negative satisfaction. These individuals may be viewed as "risk lovers." As a group, these risk lovers lose money at the race track. This is also the case with persons gambling in commodity futures markets.

In order to explain why individuals will both purchase insurance to guard against large losses and undertake gambles with remote probabilities of achieving high returns, Friedman and Savage have argued that the same individual may be both a risk averter and a risk lover.[18]

This, in a nut shell, is what risk aversion theory is all about. But note two important points. First, the size of the risk premium is an empirical question. The theory tells us nothing about the amount of the premium, nor even whether it is

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[16] "Medicare: Bad for the Drug Makers?", *The Value Line Investment Survey,* Edition 4, February 12, 1965, p. 426.

[17] See H. M. Markowitz, *Portfolio Selection,* John Wiley and Sons, New York, 1959, and James Tobin, "Liquidity Preference as Behavior Towards Risk," *Review of Economic Studies,* February 1958.

[18] M. Friedman and L. J. Savage, "Utility Analysis of Choices Involving Risk," *Journal of Political Economy,* Vol. 56, August 1948, pp. 279–304.

positive or negative.[19] Second, central to the hypothesis that it is necessary to offer a positive premium to investors in order to attract adequate capital into a risky industry is the idea that risk may cause firms to incur losses as well as to enjoy abnormally high profit rewards. Hence, risky industries would be characterized by the presence of both zrms with abnormally high profits and firms with abnormally low profits. It would be inconsistent with risk theory if nearly all firms in an industry made very high profits and few or none ever suffered losses.

The Conrad-Plotkin measure of risk misses this point. Risk is quantified by Conrad and Plotkin by measuring the variance of individual companies' rates of return about the industry average in a given year and computing a simple average of these values for the sixteen-year period 1950 to 1965.[20] This measure assumes that the greater the *variation* in the profit rates of firms about the industry average, the *riskier* the industry. The chief conceptual shortcoming of this measure is that it does not necessarily tell us anything about the probability of incurring losses. In truth, using this measure an industry may be defined as risky even though all firms in it earn excessively high profits; on the other hand, this measure may define an industry as having very low risk even though all firms are making little or no profit. An example will illustrate this point. By the Conrad-Plotkin measure, the drug industry is a high risk industry and the aluminum industry is a low risk industry. Conrad and Plotkin's estimates of the average rate of return, standard deviation, and variance for the two industries are as follows:

[In percent]

	Average rate of return	Standard deviation [1]	Risk (profit variance) [2]
Drugs	17.5	8.6	74.2
Aluminum	7.8	1.3	1.6

[1] The standard deviation is defined as the positive square root of the variance. In a normal distribution 68 percent of the observations fall within 1 standard deviation, plus or minus, of the average; 2 standard deviations about the average include 95 percent of the observations.

[2] Variance measures the dispersion of observations about an average. It is computed by taking a simple average of the squared deviations of the observations from the average.

The drug companies in their sample experienced an average rate of return of 17.5 percent over the period 1950–1965.[21] The standard deviation in profits around this average was 8.6 percent. This means that the profit ratio of roughly two-thirds of the companies in the industry fell in the range, 8.9 percent to 26.1 percent.

On the other hand, the average rate of return of a group of aluminum companies was 7.8 percent, with a standard deviation of 1.3 percent. This means that two-thirds of the time aluminum company profits fell in the range, 6.5 percent to 9.1 percent.

Thus, according to Conrad and Plotkin, the drug industry is riskier than the aluminum industry because of the greater standard deviation in the profit rates of drug manufacturers.

Just what do these facts concerning the variation in profits tell an investor about the relative profit expectations in these two industries? They say, in effect, that there is a two to one chance that profit rates in the drug industry will fall in a range from 8.9 percent to 26.1 percent, whereas there is a two to one chance in the aluminum industry that profit rates will fall in a range from 6.5 percent to 9.1 percent. Can anyone seriously argue that investors would prefer to place new capital in the aluminum industry rather than in the drug industry? The only risk that the aluminum investor is saved from is the high probability that aluminum companies will earn less than 9 percent—there is only one chance in six of getting more than 9 percent. On the other

[19] See, for example, Professor Bain's discussion of the effect of risk on average profit rates of an industry. He concludes that, "a weighted average profit rate for all firms in the economy or in the industry (all losers as well as all winners being included) should include a true net risk return of roughly zero—and there should be no obvious risk reward explanation of group-average excess profits." Joe S. Bain, *Industrial Organization,* 1959, p. 375.

[20] Gordon R. Conrad and Irving H. Plotkin, *Risk and Return in American Industry,* p. 12.

[21] Conrad and Plotkin's computations of industry variance and profits in 59 industries have been reproduced in Appendix Table 1.

hand, the "risk" the investor in the drug industry faces is that the chances are poor that drug companies will earn a rate of return as low as the average return in the aluminum industry. In fact, there is only one chance in six that they will earn a rate of return of below 9 percent, whereas there are four chances out of six that they will earn between 9 and 26 percent, and one chance in six that they will earn over 26 percent. Clearly, then, it is nonsense to infer from the Conrad-Plotkin variance measure of risk that the drug industry is riskier than the aluminum industry in terms of attracting new capital.

Losses, or even low profits, are practically unheard of among large drug companies. In this respect the drug industry is practically unique among important American industries. Figure 2 shows for 22 major industries the percent of the time the 8 largest companies fell in various profit rate categories during the period 1954–1966.[22] Large drug companies not only earned a higher return than any other of the major manufacturing industries shown, but none of the drug companies ever experienced losses during the period, nor did any companies experience profit rates below 5 percent. Only two other industries enjoyed this distinction, petroleum refining and cigarettes.

Companies in most manufacturing industries had profit rates ranging between 5 percent and 15 percent. By considering this range to represent a sort of "norm," we can visualize the extent to which large drug manufacturers departed from it. Over the period 1954–1966, the 8 largest drug manufacturers were in this range about 25 percent of the time and none ever fell below it. On the other hand, 75 percent of the time the leading drug manufacturers earned profits exceeding 15 percent, and fully 17 percent of the time they had profit rates exceeding 25 percent.

No other industry matched drugs in the frequency with which companies had profit rates exceeding 15 percent. In only three other industries—motor vehicles, computing machines and aircraft—did large firms have profit rates exceeding 15 percent more than 50 percent of the time. On the other hand, all but four of the remaining 18 industries had profit rates exceeding 15 percent less than one-fourth of the time. Finally, some companies in all but two of the 21 industries outside drugs earned below 5 percent at least part of the time. These contrasting patterns cast serious doubt on the proposition that large drug companies face a serious risk of incurring losses.

Figure 3 illustrates the profit experience of leading drug companies in each year during the 1954–1966 period. Most importantly, it shows a pattern of persistently high profits. None of these large companies earned below 5 percent in any year, and in only four years did any company earn between 5 percent and 10 percent; three of these years were in the beginning of the period—1954, 1955, and 1956. Since then, only in 1962 did a company earn below 10 percent. And in the last three years only a small percentage earned below 15 percent.[23]

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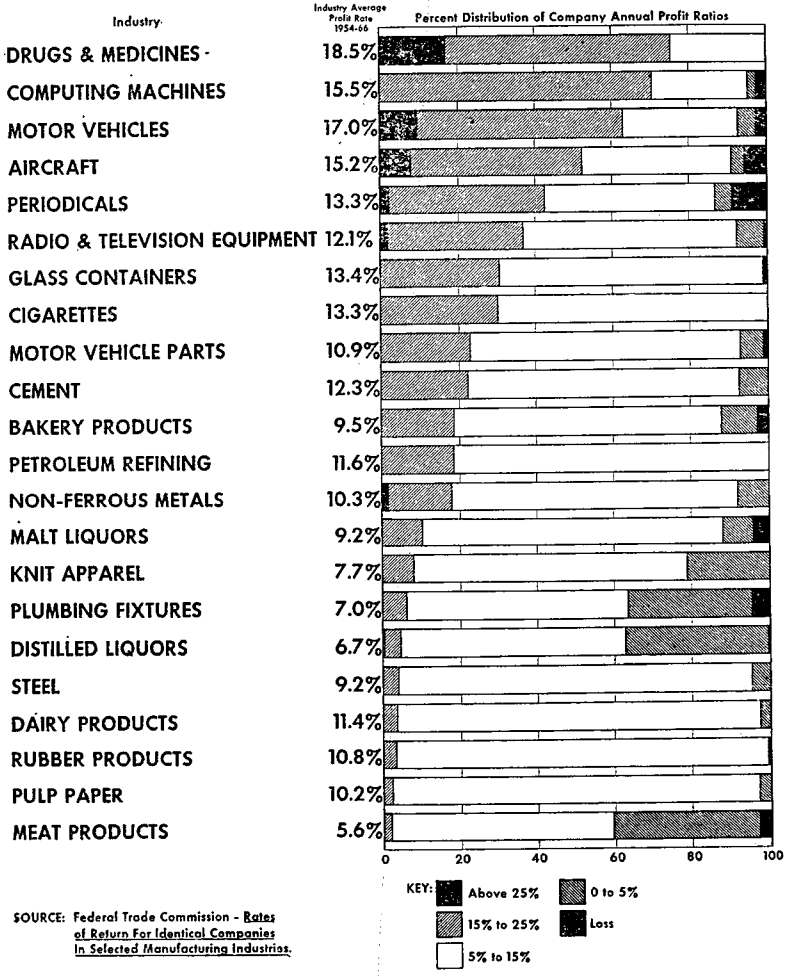
[22] This information was obtained from the Federal Trade Commission reports on *Rates of Return for Identical Companies in Selected Manufacturing Industries.* The same industries were used as for Figure 1; namely, those in which the 8 largest companies had combined assets of $1 billion or more in 1966. The total assets of the 8 largest firms in each industry were grouped in 5 profit categories for each year, 1954 through 1966. The combined assets of all firms within each category were totaled over the 13-year period and divided by the total combined assets in all categories over the period. The result was a weighted percentage of the number of companies among the 8 largest firms in each industry earning profits in each of the 5 profit categories during the period 1954–1966.

[23] The profit experience of the 29 drug companies used in the Conrad-Plotkin analysis does not differ materially from that of the eight leaders. In only two years (one company in each case) did any of the companies earn less than 5 percent. Over the period 1954–1965, the 29 companies fell in the various profit rate categories as follows:

Profit Rate (Percent):	*Percent of time companies in category*
25 and over	22.5
20 to 25	13.6
15 to 20	31.8
10 to 15	19.3
5 to 10	12.7
Below 5	0.04

FIGURE 2

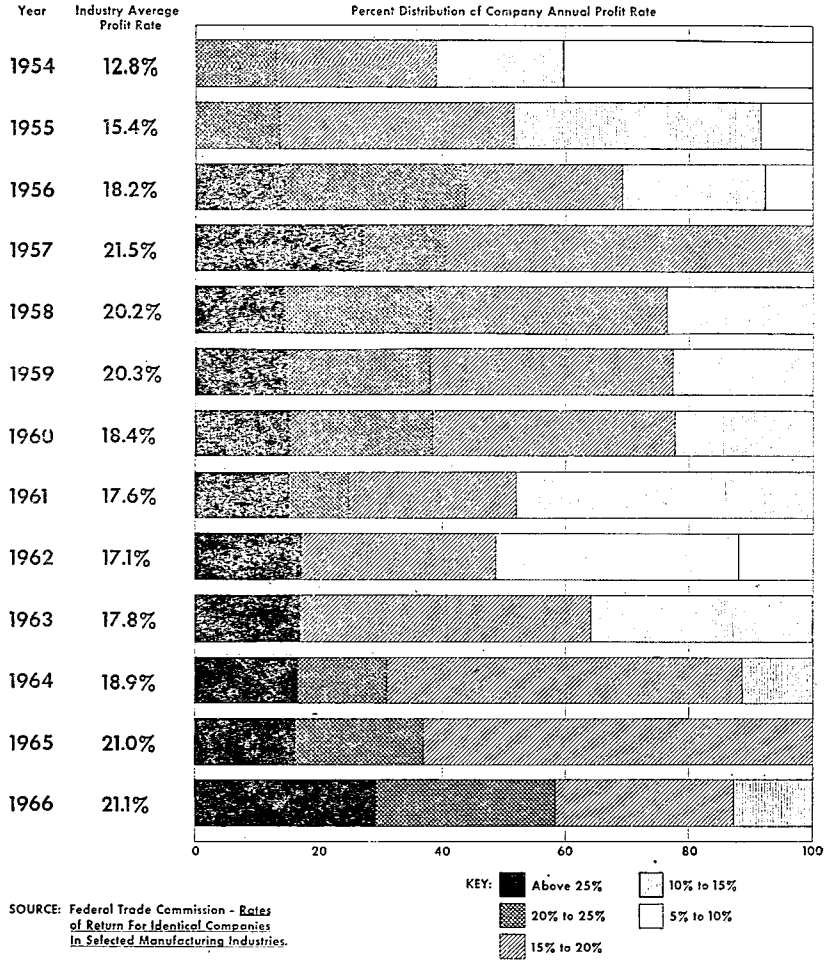
DISTRIBUTION OF RATES OF RETURN OF 8 LARGEST FIRMS BY PROFIT RATE CATEGORY 22 MAJOR MANUFACTURING INDUSTRIES, 1954 - 1966



SOURCE: Federal Trade Commission - Rates of Return For Identical Companies In Selected Manufacturing Industries.

FIGURE 3

DISTRIBUTION OF RATES OF RETURN OF 8 LARGEST FIRMS IN THE DRUG INDUSTRY, 1954-1966



SOURCE: Federal Trade Commission - Rates of Return For Identical Companies In Selected Manufacturing Industries.

This actual profit experience seems to fly in the face of the Conrad-Plotkin-Markham-Cootner inference that drug manufacturing is a uniquely risky business. The explanation, of course, is to be found in their definition of risk. Using a different definition of risk, Dr. Irving N. Fisher and Dr. George R. Hall of the Rand Corporation concluded that risk accounts for a very small portion of the high profits of drug companies.[24] The findings are shown in Table 3. They show that for the period 1959–1964 drug companies earned an average return of 18.32 percent. Fisher and Hall attributed 1.68 percent of this to risk. They concluded that the "risk premiums" for drugs are "very low," and that the explanation for high drug profits "must be sought in factors other than risk." [25]

It is true that Conrad and Plotkin have found a statistically significant relationship between their measure of risk and industry profits. But they have misinterpreted the casual factors responsible for their statistical relationship.

TABLE 3.—FISHER & HALL ESTIMATES OF AVERAGE INDUSTRY RISK PREMIUMS

[In percent]

Industry group	Average observed rate of return	Risk-adjusted rate of return	Average risk premium
Drugs	18.32	16.64	01.68
Aerospace	15.70	13.35	02.45
Chemicals	14.09	11.31	02.78
Petroleum	11.47	10.26	01.21
Rubber	10.96	10.21	00.75
Food	10.72	09.15	01.57
Electrical machinery	11.96	08.57	03.39
Automotive	14.77	07.54	07.23
Office machinery	14.08	07.24	06.84
Steel	08.25	07.03	01.22
Textiles	07.89	05.94	01.95

Source: Irving & Fisher and George R. Hall, "Risk and Corporate Rate of Return," paper presented before the Econometrics Society, Dec. 29, 1967.

Upon close analysis, the Conrad-Plotkin measure of risk turns out to be a better proxy of relative market power than of risk. Their measure assumes the existence of "homogeneous" industries; that is, "industries in which all the firms produce similar products, compete in the same markets and, in general, face the same elements of risk and uncertainty." [26] In fact, however, when broad industry definitions are used, such as those in the Conrad and Plotkin study, the constituent firms within each "industry" are frequently highly differentiated from one another by a variety of factors.[27] Hence, each firm in the industry may face different risks and other factors having a bearing on profits. This is particularly true in consumer, service, and other so-called differentiated product industries. Because of advertising and other factors, some firms in such industries have a pronounced and persistent advantage over others. As a result, the most advantaged firms earn persistently higher profits than the less advantaged firms. Such a difference between the profits of the most advantaged and least advantaged firms in an industry may provide a rough measure of the height of the entry barriers into the industry.[28] Economic theory predicts and empirical analysis verifies that the higher an industry's entry barriers, the higher its profits.[29]

[24] Hall and Fisher, "Risk and Corporate Rate of Return," paper presented at the meetings of the Econometrics Society, December 30, 1967. Their complete study appears in *Risk and the Aerospace Rate of Return,* The Rand Corporation, Santa Monica, California, December 1967. Hall and Fisher measure risk as the variance of the profit rates of companies overtime taking into account trends in profit rates.

[25] Hall and Fisher, *op. cit.,* p. 16.

[26] Fisher and Hall, *Risk and the Aerospace Rate of Return, op. cit.,* p. 31. Fisher and Hall conclude that not only does Conrad and Plotkin's measure of risk involve serious practical measurement problems, but that it also "does not fully agree with a reasonable theoretical notion of risk." *Ibid.*

[27] *Ibid.*

[28] Joe S. Bain, *Barriers to New Competition,* 1962. The difference in the profits of the most advantaged and least advantaged firms most accurately measures the height of entry barriers when the least advantaged firms earn only a "normal" profit.

[29] *Ibid.*

Hence, if intra-industry profit variance measures the height of entry barriers, we may expect a positive statistical association between industry variance and average industry profit rates. Thus, it is not surprising that Conrad and Plotkin find some statistical association between intra-industry profit variance and average industry profit rates. Unfortunately, they misinterpreted the significance of their own findings.

The effect of product-differentiation-created intra-industry profit variance on the Conrad-Plotkin analysis is obvious by inspection of specific industries with a high degree of product differentiation. Automobiles, for example, show up as a very "risky" industry in the Conrad-Plotkin study. This is the case because of the wide disparity in profits between the strongest, most entrenched firms and the weakest, marginal ones. For example, during the last five years automobile companies enjoyed average profits as follows: General Motors, 21 percent; Chrysler, 15 percent; Ford, 14 percent; American Motors, 6 percent. During most of the 1950's while Studebaker was in the industry it operated in the red. I think nearly all students of industrial organization will agree with Bain [30] that the reason for the high *average* profit rates in the automobile industry is the high degree of market concentration and the very great barriers confronting potential entrants. Thus, the persistently high average profit rates of the automobile industry are primarily due to the structure of the industry not its risk.

Nor are automobiles the exception. On the contrary, of the industries included by Conrad and Plotkin, eight of the nine with average profit rates exceeding 14 percent were industries characterized by substantial differentiation advantage among even the largest firms, and in each case the most advantaged firms held a substantial and persistent profit advantage over the less advantaged firms.[31]

The drug industry is an especially poor candidate for the explicit assumption of the Conrad-Plotkin model that industries must be homogeneous. There are great product differences among even the 29 drug companies they studied. They produce varying mixes of ethical and proprietary drugs,[32] varying proportions of branded and generic drugs, and they enjoy varying degrees of differentiation for their branded drugs. All of these factors, as well as a number of others, result in persistently higher profits for some drug companies than others. American Home Products, for example, not only earned average profits well above all other drug companies, but over the entire period 1954–1966, it had profits higher than every other firm. On the other hand, over the same period, Rexall Drug had the lowest profits among the top eight companies in all but two years, when it was second lowest.

Although a number of factors affect the profit differential among drug companies, the degree of advertising-achieved product differentiation plays a big role. Table 4 classifies the 29 drug companies used in the Conrad and Plotkin study by the volume of their advertising outlays. The five companies with advertising outlays in excess of $50 million in 1966 enjoyed an average rate of return of 29.2 percent during 1961–1965; those with advertising outlays between $10 million and $50 million had an average rate or return of 19.7 percent; and those spending less than $10 million earned 17.3 percent. Significantly, all of the top 5 advertisers earned in excess of the average return of those spending between $10 million and $50 million.[33]

The preceding reveals that much of the profit variance which Conrad and Plotkin found among leading drug companies is the result of the product differentiation advantage held by some firms in the industry.

If we are correct in believing that differences in intra-industry profit variance actually measures differences in the degree of product differentiation rather than risk, then Conrad and Plotkins' correlation results may have been heavily influenced by the inclusion of highly differentiated industries. We now turn to an examination of this possibility.

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[30] *Ibid.*, p. 169.

[31] The industries are: radio-TV broadcasters, book publishing, drugs, cosmetics, automobiles, radio-TV manufacturers, confectionary and soft drinks.

[32] It is generally recognized that profits are more stable for highly differentiated proprietary drugs than for ethical drugs. See, for example, James Bolog, "Forecasting Drug Earnings," *Financial Analysts Journal*, July-August 1966, p. 39.

[33] Some companies below the top five earn persistently high profits because they enjoy a strong position in one or two products. Smith, Kline and French has consistently earned high profits, in recent years averaging over 30 percent. Its two specialty items are Thorazine and Compazine, made and sold under license from Rhone-Paulenc of France. Schifrin, *op. cit.*, p. 911.

TABLE 4.—ADVERTISING OUTLAY AND AVERAGE EARNINGS OF 29 DRUG MANUFACTURERS

Advertising expenditures in 1966	Number of companies	Advertising as percent of sales	Average earnings on stockholder investment [1] (percent)	Standard deviation (percent)
Over $50,000,000 [2]	5	24.1	29.2	5.8
$10,000,000 to $50,000,000 [2]	9	11.9	19.7	6.6
Under $10,000,000	15	(3)	17.3	8.3
Total	29		20.1	8.6

[1] Simple average of after-tax earnings for the period 1961–65.
[2] Drug companies included in the Conrad-Plotkin study with advertising expenditures of $10,000,000 or more in 1966, as reported in Advertising Age, Aug. 28, 1967, p. 36.
[3] Not available.

Relationship between product differentiation and profits

To test the hypothesis that product differentiation caused profit variance is largely responsible for the statistical association uncovered by Conrad and Plotkin, we have analyzed separately their consumer goods and producer goods manufacturing industries. Product differentiation, of course, shows up primarily in consumer goods.

Figure 4 shows all the industries used by Conrad and Plotkin. They find a modest degree of correlation between intra-industry profit variance and profits using one measure of profit rates.[33]

Figure 5A shows the plotted observations of the consumer goods industries used in the Conrad-Plotkin analysis, and Figure 5B shows the plotted observations of the producer goods industries.[34] Among consumer goods industries there is a quite strong positive relationship, whereas among producer goods industries the relationship is very weak, and is not statistically significant.

[33] Conrad and Plotkin test their theoretical analysis against a number of measures of rates of return and risk. They report the results of fitting eight distinct models in Appendix Tables D–1 and D–2 of their report and refer to others in the text. Most of the discussion and the conclusions of the report, however, are based primarily on the two measures which resulted in the best fitting models.

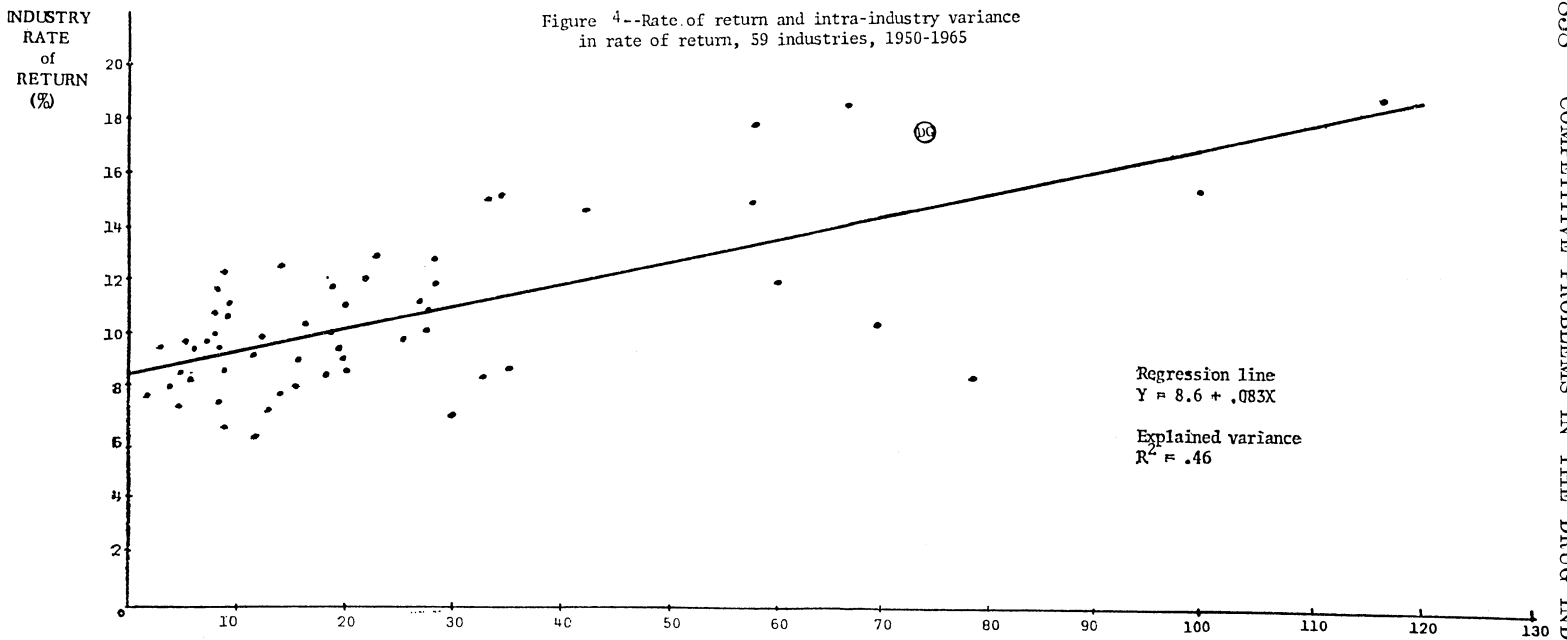
The first and most important of these is a model in which rate of return is defined as net profit plus fixed charges over total capitalization. The risk coefficient is the average yearly intra-industry variability of company profit ratios for the period 1950–1965. The mechanics of computation were to calculate a variance of company profit ratios about the industry average profit ratio in each year of the 16-year period and then compute a simple average.

Conrad and Plotkin used the coefficient of determination (R^2) to evaluate the goodness of fit of their simple correlation-regression models. The R^2 for the first model was .46. This means that 46 pecent of the difference in industry profit levels was associated with the intra-industry variance in profits. Corresponding R^2 values for two other models using book value rates of return were .31 (net income as a percent of total assets) and .18 (net income as a percent of common equity).

In addition to the models using book value measures of rates of return, Conrad and Plotkin also apply their analysis to returns to stockholders calculated as a percent of the market value of outstanding stock. This ratio is defined as the total of dividends, fixed charges, and the change in market value of shares of common stock during the year divided by the market value of common shares outstanding at the beginning of the year. The risk coefficient computed on the basis of this earnings ratio is suggested as a measure of the market risk to present and prospective purchasers of outstanding shares of stock. There is apparently no claim that it is an indicator of the company's ability to attract new investment financing or that it indicates the way in which real resources in the economy should be allocated efficiently between industries. We concur with this. The relevant comparison in evaluating an industry's ability to attract new capital should be expected earnings relative to cost of capital. The market value of outstanding stock may bear little relationship to a company's earning on invested capital because the market value of outstanding stock has capitalized into it expected future income resulting from monopoly profits. Because of this, a firm enjoying the benefits of monopoly and earning profits well in excess of the cost of capital may exhibit only a normal rate of return per dollar of equity measured at market prices.

[34] We have excluded the following industries from our analyses because none, strictly speaking, is a manufactured product: Radio-TV broadcasters, book publishing, publishing, trucking, eating places, department stores, apparel retailers, air transport, shipping, variety retailers, food retailers, and financial institutions. Leading firms in all of these industries, with the possible exception of shipping and trucking, enjoy varying degrees of product differentiation. Therefore these industries do not meet the homogeneity assumption of the Conrad-Plotkin model. They therefore most appropriately should be grouped with the consumer goods industries shown in Figure 5A. When the above 12 industries are included with the 15 consumer goods industries plotted in Figure 5A, the resulting R^2 is 0.63.

Figure 4--Rate of return and intra-industry variance in rate of return, 59 industries, 1950-1965



Industry rate of return = (net income + fixed charges)/total capitalization

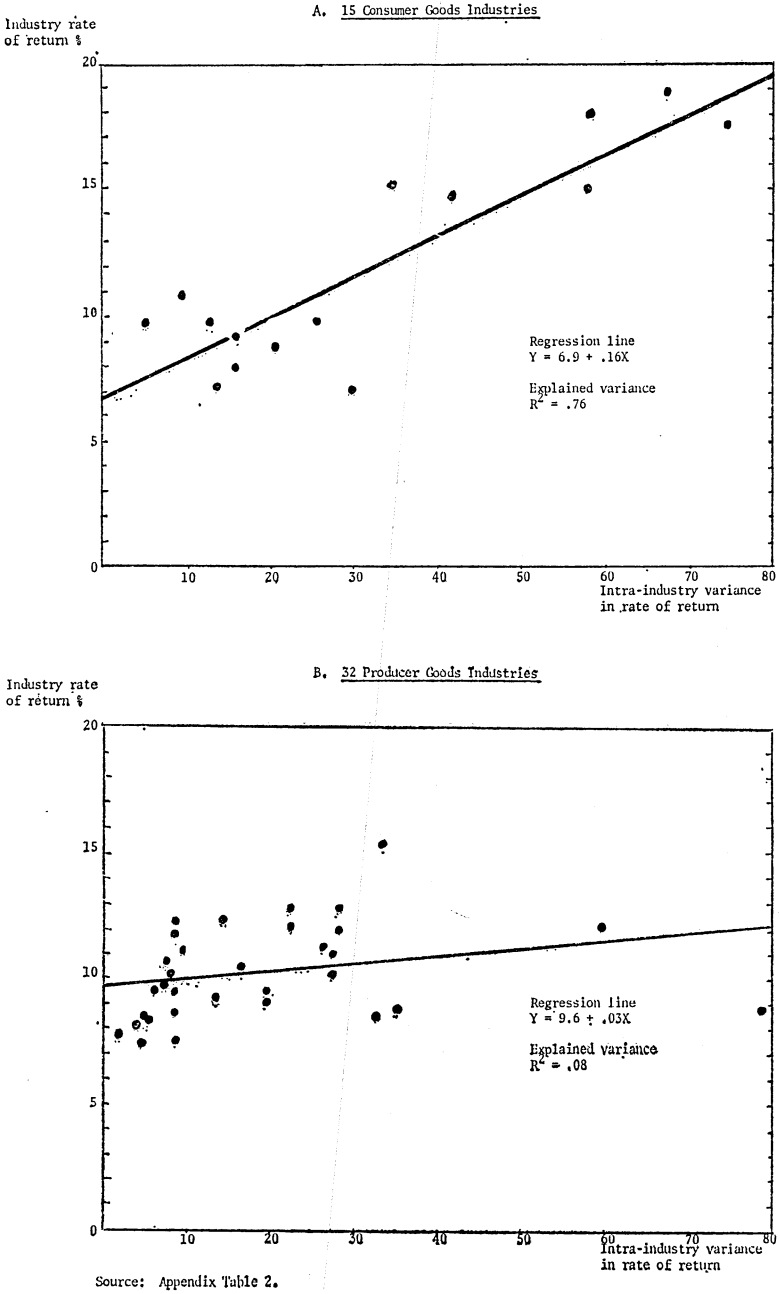
Intra-industry variance is the 16-year simple average of the variances of company profit rates about their industry views in each of the years.

DG represents position of pharmaceutical industry.

Source: Gordon R. Conrad and Irving H. Plotkin, Risk and Return in American Industry, Figure 1, p. 1. The plotted observations appear in Appendix Table 1 of this statement.

FIGURE 5

Relationship between industry average rate of return and intra-industry variance in rate of return



Source: Appendix Table 2.

In consumer goods, 76 percent of the variation among average industry profit rates is associated with the variance of intra-industry profit rates. Additionally, the slope of the regression line fitted to the observations is quite steep, which means industry profit rates rise sharply with high intra-industry profit variance.

On the other hand, when only producer goods industries are used in the analysis, the statistical relationship is extremely weak. Only 8 percent of the variation in industry profit rates is associated with variation in intra-industry profit variance. Moreover, the regression line is much less steeply inclined, indicating that average industry profit rates increase very slightly with increases in intra-industry profit variance. These findings are extremely significant. They demonstrate that the statistical relationship found by Conrad and Plotkin was due almost entirely to the consumer goods industries in their sample. The fact that no significant statistical relationship remains when only producer goods industries are used to test their model is especially damaging to the Conrad-Plotkin analysis. A basic assumption of their method of measuring intra-industry risk is that the industries analyzed be homogeneous. Producer goods manufacturing industries are, of course, much more homogeneous than are consumer goods industries. Hence, according to their assumptions the "purest" relationship between "risk" and profits should have been uncovered in the analysis of producer goods industries.

The close statistical relationship existing in consumer goods industries very probably results because intra-industry profit variance in consumer industries is a rough proxy for the height of entry barriers. Thus, Conrad and Plotkin unwittingly have made a case for the inference that a substantial part of the high profits earned by drug companies is really due to advertising- and promotion-created barriers to entry, rather than risk. This, of course, coincides with the conclusion of nearly every economist who has carefully studied the drug industry.

CONCLUSION

Upon completing our analysis of the Conrad-Plotkin-Markham-Cootner explanation of risk and profits in the drug industry, I recalled the admonition once given by the great classical economist and logician, John Stuart Mill. Mill cautioned economists against the pitfall of multiplicity of causes. We must always be skeptical of simple statistical associations among complicated economic phenomena. Professor Kenneth Boulding put is well when he said, "Some of us, perhaps, still have to learn that arithmetic is a complement to, not a substitute for, thought, and that what my spy in IBM calls the 'gigo principle,' (that is, garbage in, garbage out) is a sound approach even to the most elegantly computerized simulation." [35]

This more or less capsules my findings in reviewing the analysis of drug profits and their possible association with risk. I find, to be very brief, that the high profit experience of the drug industry is related only minimally to risk and uncertainty in a causal way. On the other hand, the high profits of the drug industry are more closely associated with high barriers to entry of new competition. In other words, in the classic tradition, the market power enjoyed by drug firms has been achieved primarily because the leading drug companies have been able to fence themselves off from effective competition, and in this sheltered position they have garnered extremely high profits—profits which the economist would label as "abnormal" or "excessive," profits substantially above the competitive norm.

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[35] Kenneth Boulding, "The Economics of Knowledge and the Knowledge of Economics," *American Economic Review*, May 1966, p. 10.

APPENDIX TABLE 1.—INDUSTRY VARIANCE AND RETURN BASED ON BOOK VALUE

Industry	Variance (risk)	Mean (return)
1. Radio-TV broadcasters	116.859	18.929
2. Publishing books	99.085	15.477
3. Gold mining	78.783	8.797
4. Drugs	74.213	17.524
5. Publishing	69.936	10.552
6. Cosmetics	67.284	18.726
7. Aerospace	59.901	12.231
8. Automobile	58.127	17.989
9. Radio-TV manufacturers	57.631	15.042
10. Confectionery	41.800	14.699
11. Building materials, heat	34.965	8.754
12. Beverages, soft drinks	34.338	15.214
13. Lead and zinc	33.259	15.275
14. Miscellaneous metalwork	32.866	8.532
15. Watches	29.705	7.114
16. Auto parts accessories	28.321	12.949
17. Oil, crude, producers	28.217	11.950
18. Electrical products	27.486	10.959
19. Machinery	27.426	10.121
20. Metals, miscellaneous	26.777	11.348
21. Beverages, brewers	25.412	9.831
22. Electronic products	22.822	12.949
23. Chemicals	21.306	12.144
24. Shoes	20.535	8.698
25. Trucking	19.873	11.107
26. Machinery, metal fabrication	19.580	9.019
27. Copper	19.528	9.493
28. Eating places	18.637	11.852
29. Retail, department stores	18.599	10.002
30. Retail, apparel chains	18.312	8.547
31. Container, paper	16.111	10.396
32. Home furnishing	15.485	8.007
33. Food products	15.476	9.199
34. Air transport	14.330	7.878
35. Office and business equipment	14.170	12.453
36. Auto trucks	13.321	9.242
37. Beverages, distillers	13.320	7.209
38. Textile apparel manufacturers	12.497	9.849
39. Shipping	11.812	6.224
40. Tobacco	9.259	10.764
41. Building materials, roof	9.219	11.137
42. Retail, variety stores	8.948	6.625
43. Vending machines	8.769	12.177
44. Building materials, cement	8.708	11.666
45. Blast furnaces	8.682	8.591
46. Textile products	8.477	7.519
47. Paper	8.157	9.443
48. Abrasive products	8.061	10.082
49. Retail, food chains	7.804	10.819
50. Oil	7.494	10.634
51. Forest products	7.255	9.689
52. Paint	6.018	9.531
53. Coal, bituminous	5.331	8.304
54. Tire and rubber	5.080	9.673
55. Steel	5.014	8.534
56. Railroad equipment	4.521	7.410
57. Containers, metal and glass	3.709	8.091
58. Financial	2.899	9.546
59. Aluminum	1.579	7.778

Source: Gordon R. Conrad and Irving H. Plotkin, Risk and Return in American Industry, table F–1, p. 78.

APPENDIX TABLE 2-A.—CONSUMER GOODS INDUSTRIES RATES OF RETURN AND INTRA-INDUSTRY VARIANCE IN RATE OF RETURN, 1950-65 [1]

Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]
Drugs	17.5	74.2
Cosmetics	18.7	67.3
Automobile	18.0	58.1
Radio-TV manufacturers	15.0	57.6
Confectionery	14.7	41.8
Beverages, soft drinks	15.2	34.3
Watches	7.1	29.7
Beverages, brewers	9.8	25.4
Shoes	8.7	20.5
Home furnishings	8.0	15.5
Food products	9.2	15.5
Beverage, distillers	7.2	13.3
Textile apparel manufacturers	9.8	12.5
Tobacco	10.8	9.3
Tire and rubber	9.7	5.1

[1] Rate of return is defined as net income plus fixed charges divided by total capitalization.
[2] The variance is the simple average of intra-industry variances for each year of the period, 1950-65.

Source: Gordon R. Conrad and Irving H. Plotkin, "Risk and Return in American Industry," Arthur D. Little, Inc.; appendix table F-1, p. 78.

APPENDIX TABLE 2-B.—PRODUCER GOODS AND MINING INDUSTRIES RATES OF RETURN AND INTRA-INDUSTRY VARIANCE IN RATE OF RETURN, 1950-65

Industry	Average rate of return, 1950-65 [1]	Intraindustry variance in rate of return [2]
Gold mining	8.8	78.8
Aerospace	12.2	59.9
Building materials, heat	8.8	35.0
Lead and zinc	15.3	33.3
Miscellaneous metalwork	8.5	32.9
Auto parts, accessories	12.9	28.3
Oil, crude, producers	12.0	28.2
Electrical products	11.0	27.5
Machinery	10.1	27.4
Metals, miscellaneous	11.3	26.8
Electronic products	12.9	22.8
Chemicals	12.1	21.3
Machinery, metal fabrication	9.0	19.6
Copper	9.5	19.5
Container, paper	10.4	16.1
Office and business equipment	12.5	14.2
Autotrucks	9.2	13.3
Building materials, roof	11.1	9.2
Vending machines	12.2	8.8
Building materials, cement	11.7	8.7
Blast furnaces	8.6	8.7
Textile products	7.5	8.5
Paper	9.4	8.2
Abrasive products	10.1	8.1
Oil	10.6	7.5
Forest products	9.7	7.3
Paint	9.5	6.0
Coal, bituminous	8.3	5.3
Steel	8.5	5.0
Railroad equipment	7.4	4.5
Containers, metal and glass	8.1	3.7
Aluminum	7.8	1.6

[1] Rate of return is defined as net income plus fixed charges divided by total capitalization.
[2] The variance is the simple average of intra-industry variances for each year of the period, 1950-65.

Source: Gordon R. Conrad and Irving H. Plotkin, "Risk and Return in American Industry," Arthur D. Little, Inc.; appendix table F-1, p. 78.

SUPPLEMENT TO STATEMENT OF DR. WILLARD F. MUELLER, DIRECTOR, BUREAU OF ECONOMICS, FEDERAL TRADE COMMISSION

In my statement on January 18 before the Monopoly Subcommittee I raised a number of questions concerning the theoretical and empirical credibility of a study to Messrs. Conrad and Plotkin of Arthur D. Little, Inc.[1] Most importantly, whereas their study concluded that differences in the level of profit rate among industries are explainable by differences in the degree of risk faced by firms within the industries, my analysis demonstrated that their statistical findings were the result of the inclusion of consumer goods industries with a high degree of product differentiation.

At that time I promised to provide a brief supplemental memorandum analyzing the underlying data used by Conrad and Plotkin in their study. The results of this further analysis give added support to the finding that the differences in profit rates among industries result almost exclusively from the inclusion of differentiated consumer goods industries in the sample. Such industries are characterized both by high average profits and by high intra-industry variance in profits.

EFFECT OF GROUPING SOME INDUSTRIES

Conrad and Plotkin, in choosing the sample of industries to be used in their analysis, grouped together a number of industries which are defined separately in both the Census of Manufacturers and in the data source from which they computed their regression variables.[2] One is immediately puzzled by the reasoning behind such an apparently arbitrary grouping procedure.[3]

This grouping procedure is particularly questionable with regard to the "Food Products" and "Machinery" industry groups. In the case of "Food Products" seven 4-digit SIC industries are grouped together; yet several other industries which Census defines as food industries are excluded from the grouping and included in their analysis as separate industries.[4] Data for the seven industries were provided separately in the basic data source used by Conrad and Plotkin, and six of the seven had numbers of companies equal to or greater than the numbers of companies which were included as separate industry observations. Therefore, to be consistent these six should be included as separate observations in the sample rather than combined into a single observation.

The seven industries included in the food group are listed in Table 1 along with their individual intra-industry profit variances and average profit rates. As Table 1 shows, there are wide differences in both profit variances and average profit rates among the seven food products industries. Average profit rates ranged between 5.561 and 12.481, and the variances of industry profit rates ranged between 2.190 and 32.698.

In the case of "Machinery" Conrad and Plotkin arbitrarily combined eight 4-digit SIC industries into a single observation. Table 2 shows the variances in profit rates and average profit rates of these eight machinery industries. These industries are clearly distinct and should be treated as separate observations. As is the case with food products, both the profiit variance and the average profit rate vary greatly among the various machinery industries. Intra-industry profit variance ranged between 9.372 and 41.005 and average profit rate ranged between 8.212 and 14.552.

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[1] Gordon R. Conrad and Irving H. Plotkin, *Risk and Return in American Industry*, Arthur D. Little, Inc., May 1967.

[2] *Ibid.*, Appendix C, pp. 34–35.

[3] Data were not submitted which could be used to determine the effect that the grouping of certain industries had on the regression and correlation models reported by Conrad and Plotkin. There is a suggestion, however, that the grouping may have produced higher correlation coefficients by the fact that observations computed on an unweighted basis had that effect. From the data submitted it was possible to compute simple or unweighted variance coefficients. Using these, the explained variance or the R^2 of the equation with grouped data was slightly higher than an equation with only ungrouped observations.

[4] Conrad and Plotkin combined the seven industries shown in Table 1 as one observation, and used confectionery, soft drinks, beer and distilled liquor as separate observations. For unexplained reasons Conrad and Plotkin excluded the sugar industry from their analysis although information was available on the industry. In addition to sugar refining, Conrad and Plotkin excluded three other industries for which the Standard & Poor's Compustat Tape of 1967 contained five or more companies and ten industries which contained either three or four companies. These latter ten industries are significant because in some cases Conrad and Plotkin combined industries that contained as few as two companies into grouped observations.

TABLE 1.—INTRAINDUSTRY PROFIT VARIANCES AND AVERAGE PROFIT RATES OF 7 FOOD PRODUCTS INDUSTRIES

Industry category [1]	Number of companies [2]	Industry profit rate [3]	Intraindustry profit variance [4]
Food products combined	43	9.075	24.463
Packaged foods	9	12.481	23.878
Meatpackers	7	5.561	12.590
Dairy products	7	9.190	2.190
Canned foods	7	7.215	18.004
Bread and pastries	6	9.458	32.698
Cookies and crackers	5	10.134	9.112
Corn refiners	2	9.964	8.632

[1] Industry category as defined in the basic source used by Arthur D. Little, which was Standard & Poor's compustat industrial tape.
[2] Number of companies in the Arthur D. Little sample.
[3] Net income plus fixed charges as a percent of total capitalization (total assets minus current liabilities). The ratios shown are the 16-year (1950–65) simple averages of profit ratios for firms included industries.
[4] The 16-year simple average of annual unweighted intraindustry profit variances. Weighted intraindustry profit variances could not be computed from the data submitted by Arthur D. Little.

Source: Data provided by Arthur D. Little, Inc.

TABLE 2.—INTRAINDUSTRY PROFIT VARIANCES AND AVERAGE PROFIT RATES OF 8 MACHINERY INDUSTRIES

Industry category [1]	Number of companies [2]	Industry average profit rate [3]	Intraindustry profit variance [4]
Machinery combined	62	11.165	33.954
Specialty machinery	16	11.450	41.005
Industrial machinery	10	12.181	21.386
Machine tools	8	10.906	21.054
Construction and materials handling machinery	7	10.580	9.372
Oil well machinery	6	13.096	14.280
Agricultural machinery	6	8.212	33.349
General industrial machinery	5	14.552	38.282
Steam generating machinery	4	9.912	17.478

[1] Industry category as defined in the basic source used by Arthur D. Little, which was Standard & Poor's compustat industrial tape.
[2] Number of companies in the Arthur D. Little sample.
[3] Net income plus fixed charges as a percent of total capitalization (total assets minus current liabilities). The ratios shown are the 16-year (1950–65) simple averages of profit ratios for firms included in industries.
[4] The 16-year simple average of annual unweighted intraindustry profit variances. Weighted intraindustry profit variances could not be computed from the data submitted by Arthur D. Little.

Source: Data provided by Arthur D. Little, Inc.

The grouping procedure used by Conrad-Plotkin cannot be justified because of the fewness of firms in the separate 4-digit SIC industries within these two groups. The criterion which they used for including an industry in their analysis as a separate observation was that the industry contain at least five companies. Nine of their sample industries contained the accepted minimum of five companies. As Tables 1 and 2 show, in only one of the seven grouped food products industries were there fewer than five companies, and in only one of the eight grouped machinery industries were there fewer than five companies.

These arbitrary groupings conflict with Conrad and Plotkin's testimony before the Committee that they had not "massaged" the data.[5] Their arbitrary groupings also violate one of the basic assumptions of their theoretical model that the industries analyzed be homogeneous, i.e., that the companies within each industry grouping are subject to the same demand and supply conditions.

Whatever their rationale for grouping these industries, the process of ungrouping provides an additional test of the hypothesis that the positive relationship between intra-industry variance and industry average profit rate results pri-

[5] Plotkin testified on this point, "We have not changed one iota of their data, including their industry classifications as to which companies belong to which industries." Transcript, Tuesday, December 19, 1967, p. 2745.

marily from the inclusion in the sample of consumer goods industries characterized by product differentiation.[6]

Turning first to consumer goods, the separation of the food products group into its separate 4-digit SIC industries enables us to expand the number of consumer goods observations from 15 to 20. Using data supplied by Arthur D. Little, two regression equations were computed expressing the relationship between intra-industry profit variance (X) and industry average profit rate (Y). The first regression was computed using the sample of 15 consumer goods industries included among the industries analyzed by Conrad and Plotkin.[7] The resulting regression equation is:

Equation I $Y=9.3+0.038X$

with explained variance $R^2=0.26$.[8]

A second regression equation was computed based on a sample of 20 industries. The increased number resulted from replacing the food products group by the six food products industries having at least five sample companies.[9] The regression equation using the adjusted sample is:

Equation II $Y=8.9+0.042X$

with explained variance $R^2=0.30$.

Increasing the size of the consumer goods sample raises from 26 to 30 percent the variation among industry average profit rates associated with the variance of intra-industry profits. In addition, the expansion of sample size increases the slope of the regression line from 0.038 to 0.042, indicating a greater response of industry profit rates to changes in intra-industry profit variance.[10] These results substantiate our earlier finding that in the consumer goods sector a strong relationship between intra-industry profit variance and industry average profit rates does in fact exist.

Turning now to the producer goods and mining sectors, the separation of the machinery group into its 4-digit SIC industries enables us to expand the size of the producer goods and mining sample in the same way as we did for consumer goods. Using the Arthur D. Little data two regression equations were computed—the first using essentially the same producer goods and mining industries as were included in the Conrad-Plotkin sample, and the second using an expanded sample adjusted by ungrouping the machinery industries and replacing the single machinery group observation by the seven machinery industry observations containing at least five sample companies.[11]

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[6] The process of expanding the number of observations increases the reliability of a statistical relationship. That is, all other things equal, a larger sample size reduces the probability that the relationship could have been due to chance. If, in addition, the increase in the size of the sample also increases the strength of the relationship between profit variance and average profit rate, one can even be more confident that such a relationship exists. If the relationship is weakened when the sample size is increased, the likelihood that such a relationship actually exists may be more suspect.

[7] Observations are listed in Appendix Table 1A.

[8] Intra-industry variance data used in this equation were computed on an unweighted basis. Data were not submitted by Arthur D. Little, Inc., to permit computing the additional values of the variables for Equation II on the weighted basis used by Conrad and Plotkin for *Risk and Return in American Industry*. The use of weighted variables by Conrad and Plotkin results in a higher R^2 for consumer goods than the ones shown in Equation I. (See Figure 5A of my January 18, 1968, statement before this Subcommittee.) There is no reason to believe that the use of weighted observations should reverse any of the relationships between Equation I and Equation II discussed below.

[9] Observations are listed in Appendix Table 1B.

[10] The statistical reliability of these relationships was increased because of both the higher correlation coefficient and the enlarged size of the sample. By adding the additional industry observation the statistical probability that the relationship could have occurred by chance was reduced from 2.5 percent to about .5 percent.

[11] See Appendix Tables 2A and 2B. Arthur D. Little did not furnish the underlying data on gold mining, lead and zinc, miscellaneous metals, or forest products. Hence, these observations were excluded from the two samples.

The regression equation for the unadjusted sample containing 26 observations is:

Equation III $Y=9.8+0.018X$

with explained variance, $R^2=0.17$.[12]

Computing a similar simple regression equation for the adjusted producer goods and mining sample containing 32 observations, the resulting equation is:

Equation IV $Y=10.2+0.016X$

with explained variance, $R^2=0.10$.[13]

Whereas the expansion of the sample size improved the statistical relationship between intra-industry profit variance and industry average profit rate in the consumer goods sector, exactly the opposite results occurred in the producer goods and mining sectors. The explained variance, R^2, decreased from 0.17 to 0.10, indicating that an even smaller percentage of the differences in industry average profit rates resulted from the variance in intra-industry profits.[14] Moreover, the slope of the regression line, which shows the response of industry profit rates to changes in industry profit variances, decreased from its already low level of 0.018 to 0.016.

In sum, the strong statistical relationship between intra-industry profit variances and industry average profit rates in the consumer goods sector proved to be even stronger when the size of the consumer goods sample was increased, while the already weak statistical relationship between variances in industry profit rates and industry profits in the producer goods and mining sample became still weaker when the size of the producer goods and mining sample was expanded. This finding is significant. Together with the findings I reported in my January 18, 1968 statement to this Subcommittee, it demonstrates conclusively that the statistical relationship reported by Conrad and Plotkin was due entirely to the differentiated consumer goods industries in their sample. As pointed out in my original statement, a basic assumption of their hypothesis is that the industries analyzed be homogeneous. The producer goods industries in their sample most closely approximate this assumption. Yet, when only these industries are analyzed, no significant statistical relationship exists between industry variance and profit rates.

PROFIT RATES OF LARGEST COMPANIES AND OTHER COMPANIES

The underlying data furnished by Arthur D. Little provide additional facts with which to test our hypothesis that the intraindustry variance in profit rates is really a measure of the advantage which some firms enjoy over others by reason of their success in differentiating their product. If we are correct that in many consumer goods industries product differentiation creates advantaged positions for the largest companies relative to smaller ones, then the largest companies may be expected to enjoy persistently higher profits than other companies.[15] On the other hand, we generally would not expect the largest firms in producer goods industries to enjoy a significant product differentiation advantage over other companies in the industry. So, unless such firms enjoyed some other advantage we would not expect the largest companies in such industries to earn persistently higher profits than the remaining companies in the industry.

To test the above hypothesis, the Arthur D. Little sample of companies in each industry was divided into two size classes on the basis of relative company size.

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[12] Values for X and Y in Equations III and IV are unweighted with respect to company size. Unweighted variables had to be used in measuring the effects of adding the 7 additional ungrouped observations because the company size weights employed by Conrad and Plotkin were not made available by Arthur D. Little. The effect of using unweighted values rather than weighted values can be seen by comparing the R^2 and the slope of Equation III with comparable values for the equation shown in Figure 5B of my January 18, 1968, statement before this Subcommittee. This comparison shows that the relationship between intra-industry profit variability and average industry profit rates is even less significant when Conrad and Plotkin's weighted values are used.

[13] *Ibid.*

[14] The statistical probability that the relationship could have occurred due to chance increased from 2.5 to 5 percent.

[15] Ideally, we should know the degree of product differentiation enjoyed by each firm in the industry. Lacking this information, we have assumed that the largest companies possess the most highly differentiated products. This assumption is generally valid because the leading companies in consumer products industries are also by and large the leading advertisers.

In each industry, the four largest companies based on total assets were grouped together to form one size class, while the remaining sample companies were grouped in a second size class. If there were fewer than eight sample companies in an industry, the sample was divided evenly between the two classes. The simple average of profit rates for the period 1963 through 1965 was computed for each size class of each industry. Table 3 summarizes the results of these tabulations.

TABLE 3.—SUMMARY OF RELATIVE PROFIT RATES OF LEADING COMPANIES AND OTHER COMPANIES, 54 INDUSTRIES

Type of industry [1]	Total number of industries [2]	The number of industries in which the leading companies earned [3]—		
		Higher profits than other companies	The same as other companies	Lower profits than other companies
Consumer goods	19	15	0	4
Producer goods	35	16	3	16

[1] Industries classified according to Federal Reserve Board listing for the Index of Industrial Production.
[2] Arthur D. Little did not submit data for several industries which Conrad and Plotkin used in their analysis reported in "Risk and Return in American Industry." For this reason the total number of industries is slightly fewer.
[3] Net income plus fixed charges over total capitalization. This is the profit ratio used by Conrad and Plotkin.

Source: Tables 3A and 3B.

For the period 1963 to 1965, the leading companies in fifteen of the nineteen consumer goods industries earned higher profit rates than the other companies in the idnustry as a group. In sixteen of the thirty-five producer goods and mining industries the group of leading companies had higher profit rates than the group of smaller companies; in another sixteen industries the group of smaller companies averaged higher profit rates than the group of leading companies; and in the remaining three industries both groups averaged exactly the same profit rates. Clearly, no great advantage accrued to producer goods or mining companies by reason of their being leading companies in their respective industries. The relationship between relative firm size and average profit rates was random.

The results of this test again support the proposition that the leading companies in consumer goods industries possess some unique advantages which do not acrue to the leading companies in producer goods and mining industries. It is our hypothesis that these advantages are the result of the largest companies' greater capacity to differentiate their products. As a result the companies which are most successful in achieving a highly differentiated product are able to charge higher prices and make higher profits than the less advantaged companies. In contrast, the products of producer goods and mining industries are more homogeneous. Consequently, relatively small firms [16] enjoy profit rates about equal to industry leaders.

DIFFERENCES IN PROFIT RATES AMONG CONSUMER GOODS INDUSTRIES

Economic theory posits that industries with a high degree of product differentiation will experience both higher average industry profits and greater differences in profits between the leading companies and the remaining companies in the industry than industries with a moderate to low degree of product differentiation.[17] We are now able to test this theory by employing the underlying data used in the Arthur D. Little study.

In Table 4 the consumer goods industries listed in Appendix Table 3A have been grouped into three categories on the basis of the total advertising expenditures of the four leading advertisers in the industry in 1964. It shows that there is a strong positive relationship between the absolute amount of an industry's advertising and its average profit rates. In the top category, containing industries whose products were highly advertised, the average profit rates of both

[16] The companies included in the Arthur D. Little sample generally included only large and medium size companies. Very small companies were excluded from the sample since it included only companies whose stocks were registered on principal stock exchanges.
[17] Joe S. Bain, *Barriers to New Competition*, Harvard University Press, 1956.

leading companies and all other companies were substantially higher than those in either of the other two categories. In fact, the smaller companies in the top category earned higher average profits than the leading companies in the second category containing industries characterized by moderate levels of advertising. As the level of industry advertising declined, the average industry profit rates also declined, dropping from 16.9 percent for the leading companies in the top category to 11.9 percent for the industry leaders in the second category and to 8.5 percent for the leading companies in industries in the lowest category.

TABLE 4.—RELATIONSHIP BETWEEN ADVERTISING, PROFIT RATES AND INTRAINDUSTRY PROFIT VARIABILITY FOR 19 CONSUMER GOODS INDUSTRIES

Advertising expenditures of 4 leading advertisers, 1964	Number of industries	Average of industry profit rates of leading companies, 1963–65	Average of industry profit rates of other companies in 1963–65	Absolute difference in profit rates	Average of intraindustry variance in profit rates 1950–65
Over $150,000,000	[1] 3	16.9	12.9	4.0	89.8
$50,000,000 to $150,000,000	[2] 11	11.9	10.0	1.9	43.1
Under $50,000,000	[3] 5	8.5	6.8	1.7	29.8

[1] Include drugs, automobiles, and tobacco.
[2] Include cosmetics, beer, soft drinks, confectionery, canned foods, liquor, tires, radio and TV, dairy products, bread and pastries, and biscuits and crackers.
[3] Include watches, shoes, home furnishings, apparel, and meat products.

Source: Tables 1B and 3A. Advertising data were tabulated from Advertising Age, Jan. 3, 1966, p. 46.

Greater absolute expenditures on advertising not only lead to higher average industry profit rates but to greater variances in intra-industry profit rates. This occurs, as explained above, because the leading companies enjoy an advantaged position relative to those companies less capable of sustaining large advertising expenditures. Table 4 shows the difference in average profit rates between the class of leading companies and the class of other companies in each advertising category. In the top advertising category the profit rates of the leading companies averaged 4.0 percent higher than the profit rates of smaller companies. In the second category the leading companies' profit rates exceeded those of the smaller companies by an average of only 1.9 percent. In the third category this difference declined to 1.7 percent. The persistently higher profits of leading concerns resulted in greater variances in profits. As shown in Table 4, the average of intra-industry variance in profit rates was 89.9 for the top category. For the second category the variance dropped to 43.1, and it declined still further to 29.8 for the lowest category.

These results again verify our earlier findings that the advertising-achieved product differentiation advantages held by leading firms in an industry affect both the higher dispersion of profit rates within the industry and industry average profit rates.

CONRAD AND PLOTKIN'S UNDISCUSSED FINDING

Conrad and Plotkin did not discuss before the Subcommittee their statistically most significant finding.[18] The regression models appearing in Appendix Table D–2, page 40, *Risk and Return in American Industry*, show that company profitability is negatively related to profit variability. That is to say, the more profitable a company, the more stable are its profits. This finding is in direct contradiction to their principal hypotheses that high profit firms earn such profits as a reward for the "risk" associated with varying profit levels. Conrad and Plotkin gave no explanation for their strange silence regarding this potentially significant finding.

CONCLUSIONS

Our analysis of the underlying data for the Conrad-Plotkin study supplied by Arthur D. Little provides further support for the hypothesis that the dif-

[18] The explained variances (R^2) and the simple regression coefficients for temporal variances in Conrad and Plotkin's models analyzing returns on total capitalization and net income to common equity (Model II, page 40, *Risk and Return in American Industry*) are statistically more significant than those discussed in their text.

ferences between average profit rates among industries studied resulted primarily from the impact of product differentiation on industry profit rates. The intra-industry variance in profit rates is really a rough measure of the size of the product differentiation barrier to entry in an industry and not a measure of industry risk. It measures the difference in profit rates between the most advantaged firms and the least advantaged firms, this difference increasing as the level of product differentiation increases. Hence, the Conrad-Plotkin study unwittingly supports the inference that in consumer goods industries high industry profits are caused by product differentiation-created barriers to entry. On the other hand, careful statistical analysis reveals that their risk hypothesis has no empirical foundation.

TABLE 1A.—RATES OF RETURN AND INTRAINDUSTRY VARIANCE IN RATE OF RETURN FOR 15 CONSUMER GOODS INDUSTRIES, 1950-65

Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]	Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]
Automobiles	11.129	168.889	Tire and rubber	9.914	31.367
Cosmetics	17.852	101.583	Shoes	9.528	26.143
Drugs	17.998	90.827	Beverages, distillers	9.057	25.591
Radio-TV manufactures	13.721	90.226	Food products	9.075	24.463
Watches	7.335	70.392	Textile apparel manufactures	10.655	23.115
Beverages, brewers	11.966	67.558	Home furnishings	7.874	16.878
Confectionery	13.018	50.358	Tobacco	9.627	9.824
Beverages, soft drinks	12.424	45.950			

[1] Rate of return is defined as net income plus fixed charges divided by total capitalization.
[2] The variance is the simple average of unweighted intraindustry variances for each year of the period, 1950-65.

Source: "Underlying Data for Study" by Conrad and Plotkin, "Risk and Return in American Industry."

TABLE 1B.—RATES OF RETURN AND INTRAINDUSTRY VARIANCE IN RATE OF RETURN FOR ADJUSTED SAMPLE CONTAINING 20 CONSUMER GOODS INDUSTRIES, 1950-65

Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]	Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]
Automobile	11.129	168.889	Shoes	9.528	26.143
Cosmetics	17.852	101.583	Beverages, distillers	9.057	25.591
Drugs	17.998	90.827	Food, packaged foods	12.481	23.878
Radio-TV manufacturers	13.721	90.226	Textile apparel manufacturers	10.655	23.115
Watches	7.335	70.392	Food, canned foods	7.215	18.004
Beverages, brewers	11.966	67.558	Home furnishings	7.874	16.824
Confectionery	13.018	50.358	Food, meatpackers	5.561	12.590
Beverages, soft drinks	12.424	45.950	Tobacco	9.627	9.824
Food, bread and pastries	9.458	32.698	Food, cookies and crackers	10.134	9.112
Tire and rubber	9.914	31.367	Food, dairy products	9.190	2.190

[1] Rate of return is defined as net income plus fixed charges divided by total capitalization.
[2] The variance is the simple average of unweighted intraindustry variances for each year of the period, 1950-65.

Source: "Underlying Data for Study" by Conrad and Plotkin, "Risk and Return in American Industry."

TABLE 2A.—RATES OF RETURN AND INTRAINDUSTRY VARIANCE IN RATE OF RETURN FOR 26 PRODUCER GOOD AND MINING INDUSTRIES, 1950-65

Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]	Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]
Electrical products	11.292	174.584	Textile products	7.843	18.754
Aerospace	12.628	113.246	Copper	9.842	15.673
Building materials—heating, air conditioning	11.886	71.494	Auto trucks	10.301	14.543
Paper	10.753	64.410	Building materials, cement	12.558	13.214
Oil, crude producers	12.608	47.690	Steel	8.830	12.418
Office and business equipment	12.871	46.056	Building materials, roof and wall	10.609	10.839
Miscellaneous metal work	8.447	35.774	Paint	10.096	9.855
Machinery, metal fabricating	9.360	34.644	Vending machines	12.493	8.406
Auto parts and accessories	12.749	34.287	Oil	10.087	7.937
Machinery	11.165	33.954	Containers, metal and glass	8.066	7.871
Abrasive products	11.814	32.161	Coal, bituminous	8.368	7.449
Containers, paper	10.638	19.228	Railroad equipment	8.149	6.318
Chemicals	10.492	18.759	Aluminum	7.938	2.812

[1] Rate of return is defined as net income plus fixed charges divided by total capitalization.
[2] The variance is the simple average of unweighted intraindustry variances for each year of the period, 1950-1965.

Source: "Underlying Data for Study" by Conrad and Plotkin, "Risk and Return in American Industry."

TABLE 2B.—RATES OF RETURN AND INTRAINDUSTRY VARIANCE IN RATES OF RETURN FOR ADJUSTED SAMPLE OF 32 PRODUCER GOOD AND MINING INDUSTRIES, 1950-1965

Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]	Industry	Average rate of return 1950-65 [1]	Intra-industry variance in rate of return [2]
Electrical products	11.292	174.584	Chemicals	10.492	18.759
Aerospace	12.628	113.246	Textile products	7.843	18.754
Building materials—heating, air conditioning	11.886	71.494	Copper	9.842	15.673
Paper	10.753	64.410	Auto trucks	10.301	14.543
Oil, crude producers	12.608	47.690	Machinery oil well	13.096	14.280
Office and business equipment	12.871	46.056	Building materials, cement	12.558	13.214
Machinery, specialty	11.450	41.005	Steel	8.830	12.418
Machinery, general industrial	14.552	38.282	Building materials, roof and wall	10.609	10.839
Miscellaneous metalwork	8.447	35.774	Paint	10.096	9.855
Machinery, metal fabricating	9.360	34.644	Machinery, construction and material handling	10.580	9.372
Auto parts and accessories	12.749	34.287	Vending machines	12.493	8.406
Machinery agricultural	8.212	33.349	Oil	10.087	7.937
Abrasive products	11.814	32.161	Containers, metal and glass	8.066	7.871
Machinery, industrial	12.181	21.386	Coal, bituminous	8.368	7.449
Machine tools	10.906	21.054	Railroad equipment	8.149	8.318
Containers, paper	10.638	19.228	Aluminum	7.938	2.812

[1] Rate of return is defined as net income plus fixed charges divided by total capitalization.
[2] The variance is the simple average of unweighted intraindustry variances for each year of the period, 1950-65.

Source: "Underlying Data for Study" by Conrad and Plotkin, "Risk and Return in American Industry."

TABLE 3A.—PROFIT RATES OF LEADING COMPANIES AND OTHER COMPANIES IN 19 CONSUMER GOODS INDUSTRIES, 1963–65

Industry	Size classes [1]			
	Leading companies		All other companies	
	Number of companies	Average rate or return 1953–65 [2]	Number of companies	Average rate or return 1963–65 [2]
Cosmetics	4	22.7	7	14.3
Drugs	4	20.4	25	19.3
Automobiles	2	19.0	3	10.0
Confectionery	2	16.2	2	9.8
Radio-TV manufacturers	4	15.5	4	8.8
Soft drinks	3	13.4	3	19.8
Tobacco	4	11.4	6	9.5
Apparel	4	10.8	7	13.2
Dairy products	3	10.5	4	9.0
Canned foods	3	10.3	4	4.0
Malt liquors	4	9.9	13	9.5
Shoes	3	9.2	4	9.1
Biscuits and crackers	2	9.1	3	10.1
Home furnishings	4	8.7	5	7.8
Tires and rubber	4	8.3	7	7.8
Distillers	4	7.8	7	11.1
Bread and pastries	3	7.3	3	5.7
Watches	2	6.9	3	.3
Meat products	3	6.7	4	3.4

[1] The group of leading companies consists of the 4 largest companies except when fewer than 8 companies are included in the sample for an industry. In this case, the sample companies are divided evenly between the 2 groups with the largest firms going into the group of leading companies. If there is an odd number of companies in industries having less than 8 sample companies, the median company is placed in the all other company category.

[2] A 3-year simple average of company profit ratios.

Note: The packaged food products category was excluded from the group of consumer goods industries for this analysis because it was too broadly defined, and hence contained a number of sample companies which did not compete with one another.

Source: "Underlying Data for Study" by Conrad and Plotkin," Risk and Return in American Industry—An Econometric Analysis.'

TABLE 3B.—AVERAGE PROFIT RATES OF LEADING COMPANIES AND ALL OTHER COMPANIES IN 35 PRODUCER GOOD AND MINING INDUSTRIES, 1963-65

Industry	Leading companies [1]		All other companies	
	Number of companies	Average rate of return 1963-65 [2]	Number of companies	Average rate of return 1963-65 [2]
Chemicals	4	15.7	39	10.0
Aerospace	4	15.5	13	11.1
Machinery, construction, and material handling	3	13.7	4	9.6
Office and business equipment	4	13.0	10	10.9
Machinery, general industrial	2	12.9	3	10.9
Electronic products	4	12.2	26	10.6
Electrical products	4	12.0	26	12.0
Oil	4	12.0	21	9.1
Vending machines	3	12.0	3	11.7
Miscellaneous metalwork	3	11.9	4	7.2
Machinery, oil well	3	11.7	3	11.7
Auto trucks	2	11.5	3	12.5
Oil, crude producers	4	10.7	5	10.7
Machine tools	4	10.6	4	11.4
Auto parts and accessories	4	9.9	13	12.7
Machinery, steam generating	2	9.6	2	3.9
Abrasive products	3	9.6	4	8.7
Textile products	4	9.4	11	9.6
Building materials, roof	4	9.4	6	8.8
Copper	3	9.0	3	10.7
Machinery, industrial	4	9.0	7	10.8
Containers, paper	4	8.7	7	10.2
Coal, bituminous	3	8.7	4	7.9
Paint	2	8.6	3	10.6
Machinery, metal fabricating	4	8.6	9	9.2
Railroad equipment	4	8.4	7	9.2
Building materials, cement	4	8.4	6	7.7
Paper	4	7.9	13	10.7
Containers, metal and glass	3	7.9	3	10.0
Machinery, agricultural	3	7.8	3	14.1
Steel	4	7.6	19	8.0
Machinery, specialty	4	7.5	12	12.3
Building materials, heat	4	7.0	11	11.3
Blast furnaces	2	7.0	2	5.6
Aluminum	2	6.3	3	6.0

[1] The group of leading companies consists of the 4 largest companies except when fewer than 8 companies are included in the sample for an industry. In this case, the sample companies are divided evenly between the 2 groups with the largest firms going into the group of leading companies. If there is an odd number of companies in industries having less than 8 sample companies, the median company is placed in the all other company category.

[2] A 3-year simple average of company profit ratios.

Source: "Underlying Data for Study" by Conrad and Plotkin, "Risk and Return in American Industry—An Econometric Analysis."

Senator NELSON. Thank you very much, Dr. Mueller, for your very instructive presentation.

Do you have any questions, Senator Scott?

Senator SCOTT. If your conclusions are correct, that the high profits of the drug industry are due primarily to the high entry barriers—your table 1 shows three industries where the industry variance in return based on their book value exceeds drugs—would you therefore conclude that the profits of radio broadcasting, book publishing, and gold mining are also high because of the high entry barrier characteristic of those industries?

Dr. MUELLER. First, I do not think gold mining was among these, but in these other industries I think the high entry barriers go a long way toward explaining the level of their profits. But I have not studied them individually as I have drugs.

Senator SCOTT. There is an old quotation in the publishing business, "Making many books, there is no end."

And there are new publishing companies in the field all the time. I know of one within the last 6 months. Is it so difficult to enter the publishing field?

Dr. MUELLER. I think we would have to make a distinction here. These are the profits of leading concerns which Arthur D. Little have included, and it is hard to enter, I would say, magazine publishing and make a profit return comparable to Time and Look and the others in the industry that have a very strong position. If you write a book, you can find someone who will publish it for you. You would not very likely end up with these industry leaders, however.

Senator SCOTT. Over the last 20 years, perhaps the easiest industry to get in has been the radio broadcasting industry, as an example. Would your parallels apply to this? Because if they do, it is some sort of a criticism of the Federal Communications Commission, it seems to me.

Dr. MUELLER. I would not want to be in the position of being up here criticizing another regulatory agency. I would rather be criticizing my own bureau, which I know best. And we all can stand some criticism, I am sure.

But, again, I think what this measure that I am referring to here, the product differentiation entry barrier, captures the fact that the industry leaders that have a very strong position—say the networks. I do not have the numbers with me, but I looked at them in making this analysis. You have something comparable to automobiles where you have very strong firms at the top of the heap which earn persistently high profits, and then you have a range coming down to the weaker ones, and then there are a large number of firms which are making rather modest profits. I simply took the Arthur D. Little data, which showed profits for leading firms essentially and not for all firms in the industry. It is completely consistent with this analysis to find a number of enterprises which have very strong positions because of product differentiation. In drugs a number of enterprises can enter the easy-entry part of the business, say, producing penicillin under a generic name. Here you do not make much money because it is extremely competitive.

Senator SCOTT. You have said that the concentration of the drug industry is high because of the patent privilege. Would you suggest to the committee an alternative to the existent patent policy?

Dr. MUELLER. I am not up here today making any such suggestion on patent policy. I might say on that point, after listening to the testimony of Professor Markham and several of his colleagues last month, in which they spoke of the short-life cycle of drugs, one might draw the inference that 17 years is an extremely long period to enjoy the patent privilege in this industry.

Senator SCOTT. Because if they were testifying before the Patent Committee their life cycle might grow longer.

Dr. MUELLER. I expect they might have.

In the case of specific drugs, such as tetracycline with which I am somewhat familiar, the patent privilege is still valuable, even though it has only a few years to run.

Senator SCOTT. Would you recommend that Congress impose limitations on advertising in the drug industry, or for that matter in any other area?

Dr. MUELLER. I would not make this recommendation for any area in American industry.

I would hope there are other alternatives to this.

Senator SCOTT. I am glad you said that, because if there were to be limitations recommended on the drug industry, it would seem to me they would apply to other industries similarly situated, such as motor vehicles, computer machines, and aircraft.

I do not know whether or not—I realize that the purpose of your testimony is a reply to other testimony, but are you inferring that you, yourself, in your official position, would be happier if the drug companies were making less profits than they are? Is that the point you are making?

Dr. MUELLER. I am certainly never in the position of being happy just because someone is making less money. Our system is built on the profit motive, and we use profits as an allocator of resources; but my own response on that point is that I would like to see the drug industry exposed to more of the competitive pressures that are so commonplace in the great bulk of American industry. They are an exception, and I certainly would not want to be interpreted as implying somehow that this is characteristic of American industry. It is an exception. And there are very few industries like this.

Senator SCOTT. What I am thinking here is this: The Government runs on taxes. Taxes are the result of income and profits. And the President last night asked for more taxes, which would imply that he would like to see more income in the country, and I am wondering whether the desire for more income and more taxes on the one hand is wholly consistent with the criticism of those industries which are producing the income which provides the taxes which pay your salaries and mine and even the President's. I just wonder whether or not the purport of some of the hearings in Congress do not say on the one hand "We want to stop some people from making as much income", and immediately when they do, the people who would be hurt would be the Government which takes a great part of it. That is not very good economics, perhaps, but it is certainly awfully good commonsense.

Dr. MUELLER. My only answer would be that we have a tax policy which takes 50 percent of the profits of corporations that are earning, say, 5 percent, or 10 percent. The average of American industry is 12 percent. And to argue that some industries should be immune to any kind of public policy criticism just because, in addition to exploiting of consumers, they are giving half of this back to the Government.

So, I think that in a sort of a commonsense way, this is not a very good rationalization for not doing anything about the industries which present a public policy problem.

Senator SCOTT. Then, in your judgment, is an automatic public policy problem only part of which industry makes a profit, a high profit?

Dr. MUELLER. I think we have to make a distinction between industries and individual companies making very high profits. Some industries earning below average industry profits, say in meat packing which happens to be a very competitive, low return industry averaging 6 percent on equity in many years. In meat packing there are some companies, however, that are extremely efficient and better managed and more aggressive, and they make high profits. Iowa beef packers is the prime example. They are up here with the average of drug companies, 20 percent. On the other hand, other companies make considerably less, the ones for one reason or another just are not able to cut it. But that is the way things are in a competitive industry. And as long as the average return in the industry is adequate to attract capital, the system works well.

So it is not that some companies are making a profit, no one objects to that, but it is the persistently high profits for the entire industry that are an indicator of poor performance.

Senator SCOTT. I am probing to find out whether there is any law or regulation which says that a company can't make a profit, even a high profit.

Dr. MUELLER. Certainly not.

Senator SCOTT. Therefore, why is a Government agency anxious to show that it is critical of some companies making profits higher than other companies?

Why does that become a matter of Government policy?

Dr. MUELLER. The only point that is relevant here is that high profits are indicative of the presence of market power, and upon analysis of the reason for the high profits we find that they are due to a certain clog on competition.

Senator SCOTT. Now, if there is any fault in the area of market power, is that not covered by the antitrust statutes?

Dr. MUELLER. I think not. I think, as I explained in the beginning of my statement, the consensus of economists is that the source of market power is a combination of the patent law and the vast amounts spent on promotion and advertising, which in this industry create the so-called product differentiation entry barrier. So that insofar as there are solutions, it is something outside of the existing antitrust law.

Senator SCOTT. This is the strongest country economically in the world, and the strength of this country economically is built, in part, upon advertising, upon promotional genius, and upon management. Why, then, would a Government agency come in and be critical of the consequences of these elements which in other areas we rush up to praise?

Dr. MUELLER. First, since this area of advertising is especially a sensitive one for anyone in public office, I want to make clear that I am not here speaking for five Federal Trade Commissioners who have emphasized many times that they are not critical of advertising. I am here as Chief Economist, the Bureau of Economics. And I am not being critical of advertising as such either. Public policy has long been concerned with advertising, as has the advertising profession. The advertising profession now claims the major credit for helping to get the Federal Trade Commission started, and I think they did play some

small part. The point is that we have responsibilities now to keep advertising honest. And we put up with a lot of puffing, and so on, but there are already safeguards in this respect.

But I am here simply to try to help identify the problem in this industry, and I am not at all in disagreement with you that advertising can play and has played an extremely important role in many industries in the American economy. But recognizing this, I can't bind myself to the possibility that in certain areas it creates problems.

Senator SCOTT. What kind of problems does advertising create?

Dr. MUELLER. I think it mutes the voice of competition. The fact that it has prevented the purchase of drugs on the basis of their inherent qualities. It has prevented the purchase on this basis, and the advertising has prevented, in effect, competition from working as we ordinarily hope it would. It has gone far beyond the informational aspects that we are most interested in.

Senator SCOTT. Let us see if the corollary of your argument holds water—I do not know whether a corollary is intended to hold water—if you are arguing that advertising in the drug industry is so used as to muffle competition, and to muffle the opportunity for the public to have more information on the nature of the drugs it is buying, would it therefore follow that if you would advertise less the public would know more?

That is a hard one to answer.

Senator NELSON. May I interrupt?

I have an answer for that. It is not a question of the public knowing more or less. The public, in fact, knows nothing, and advertisements in this industry are not addressed to the public; they are addressed to the man in the medical profession exclusively.

I have an example which I think explains the point and may be helpful to the Senator.

We have a case with regard to the drug prednisone where advertising very clearly was not helpful to the public at all, nor to the doctor himself, in terms of his patient's welfare. The company that discovered prednisone and got it patented is the Schering Corp., which gave it the trade name "Meticorten."

A large number of companies went into the marketplace with the drug under license from Schering. The prices on prednisone, according to the Medical Letter of June 2, 1967, ranged from 59 cents for 100 tablets to the pharmacist by one company to $17.90 a 100 to the pharmacist by another company. The latter is the highest priced prednisone on the market. The Medical Letter stated that these drugs were of comparable therapeutic value, and advised the doctors to prescribe the lower priced generic named drug.

Now, here is a case where tremendous advertising by one company convinced the doctor—not the public, because the public had no notion about it—convinced the doctor that he ought to continue to prescribe Meticorten even though there were 21 other drugs in the marketplace that the Medical Letter said were of equal therapeutic value, one selling for 59 cents a 100, one for 72 or 73 cents a 100, Deltra for $2.20 a 100, Meticorten for $17.90 a 100, and Paracort for $17.88 a 100.

So, here is a case where the advertising is to the medical profession and not to the public and has not enlightened anybody, but rather

resulted in tremendous expenditures by patients in this country for a drug that was available on the market at a fraction of the price.

And I think the classic result of the publicity which was brought out before this committee occurred when one company reduced its price dramatically 2 months after we examined their pricing structure and showed them the Medical Letter. They reduced their price from $17.90 a 100 to $10.50 a 100, and the second company reduced theirs from $17.88 a 100 to about $3.45 a 100. Now, that is a clear case where the advertising was doing a disservice to the medical profession and the public in terms of economics.

Senator SCOTT. Isn't Dr. Goddard currently looking into the whole question of whether drugs are chemically and therapeutically equivalent?

That has not been finally established, has it?

Senator NELSON. He is examining that, drug by drug, as I understand it.

Senator SCOTT. If the investment opportunities in the brand name drug manufacturing industry are so fabulous, would you tell me why the prices for the stock of these companies are not constantly skyrocketing? And is not that because of the constant threat of congressional investigation and threats of further regulatory action?

Dr. MUELLER. You mean they keep going up, skyrocketing?

Senator SCOTT. If their profits are so big, why doesn't the stock keep going up?

Dr. MUELLER. Why does it not?

Senator SCOTT. Why does it not skyrocket if profits are as fabulous as you have indicated?

Dr. MUELLER. Well, first, the stock earnings ratios on drug stocks are extremely high, they are among the highest of any American industry, indicating that stockholders and investment analysts expect drug stocks to keep going up—of drug companies to continue to make high profits in the future.

Now, as an investor, of course, you may buy into the market at any point, and you are not necessarily going to make vast amounts on your investments in stocks because the market for drug stocks is a very competitive one. How well an individual does in the market is not any indication of how profitable the industry is. Were you referring to the variation?

Senator SCOTT. I am not familiar with these figures, but were you to take, again, the eight leading companies, would their securities, their common stock, on the market today be higher or lower than it was a year ago or the year before?

Dr. MUELLER. I misunderstood you. I thought when you said skyrocketing, that it was going up. But you are talking about it coming down as well, and whether this is associated with——

Senator SCOTT. What I am talking about is the feeling that I have—not the knowledge—that actually drug securities in the market have not been skyrocketing or increasing in their market prices recently. I am not sure, though.

Dr. MUELLER. They are not, of course, entirely unique. The market has been a very mixed kind of one this year. But is response to your——

Senator SCOTT. Machinery stocks, IBM, Xerox, and others like that have gone up fantastically.

Dr. MUELLER. In response to your question as to whether the stock market prices are responsive to public policy actions in the drug industry, I would say they are. As I indicated in my discussion of the investment analysts' views of the drug industry, one thing they discuss is that if there is increasing use of generic drugs, profits will come down. In other words, what they are predicting is: If your industry becomes more competitive profits are going to come down, and drug stocks are coming down, and this is true, I suppose, with respect to any public policy action that is going to affect drug prices.

So, I would not be at all surprised if this association exists. I ran across such comments in preparing this statement, as I looked at the way in which investment analysts viewed the industry. This is something they talked about.

Senator SCOTT. I notice there is no chart here which would tend to bear out or theorize—there is no chart of a steady rise in the valuation of these drugs. We are discussing only profits.

Dr. MUELLER. As I pointed out in the beginning, the stocks over this period have—stock prices relative to earnings have been very high. These ratios are far above the average of American industry. And I did not really think it was important for my comments to show the trends in stock prices. Over this period, however, they reflected the profit situation very accurately.

Now, it is possible—and it has happened—that there are variations——

Senator SCOTT. Maybe I have not made my point clear in these hearings. Because if this industry or any other is doing anything they ought not to be doing, we want to know about it. If there is anything that is statutorily wrong, we want to know about it. If corrective legislation is needed, we want to know about it.

But I get a little bit fed up, after 25 years of residence down here in this cave of winds, with the constant plea of Government to industry to produce more, make more money, give us more taxes, and then have other agencies of the Government beating them over the head all the time they are doing it.

Now, it seems to me that if the people are doing something wrong, let us know about it. But I do not think it is wrong to make a profit in this industry, and I have not yet heard a single witness in 25 years that convinced me that it was.

Dr. MUELLER. Well, I certainly will say nothing here today to try to convince you that it is improper. I am not carrying a club to beat any American industry. I have a job at the commission, and my part of it is to try to make our system work fair and competitively; that is all.

Senator SCOTT. I only wish some Government agencies would come before some senatorial committees occasionally in praise of industry, in praise of business, and not always appear in such an antibusiness aspect.

Dr. MUELLER. I agree with you 100 percent, Senator. And before the full committee——

Senator SCOTT. Because business is jobs, and if you praise business, you are praising job-making.

Dr. MUELLER. And before the full committee last June, with Senator Long and Senator Morse presiding, I appeared along with Mr. Turner of the Justice Department, Professor Adams of Michigan State University; we had a dialog with Professor Galbraith. At that hearing I went to considerable length to explain as accurately as I could that our competitive system is working extremely well. People have been selling it short. There are exceptions. But Professor Galbraith has exaggerated their frequency. In that dialog, he kept emphasizing the automobile industry. He kept telling Mr. Turner that, "Unless you solve automobiles, you have to concede my point that the system has had it."

Senator SCOTT. That is the affluent Mr. Galbraith; isn't it?

Dr. MUELLER. The very affluent. And the point, though, is that the problem industries that are discussed most before congressional committees are the exceptions in our economy. The great bulk of the economy works very well and, unfortunately, we do not come up here and tell you "This industry is working perfectly," because you do not hold hearings on industries that do not have problems. But our silence should not be interpreted as implying that we do not think the system is—the greater part of it—is working very effectively.

Senator SCOTT. I am glad you are always proud of it, because I think we ought to be proud of the system. I have seen some of the others. I have been in England quite recently, and when I see the mess they have made of things it has made me more inclined to defend our own.

Dr. MUELLER. And the more we see of other country's problems the more tolerant we become of the imperfections in our system.

Senator SCOTT. Thank you.

Senator NELSON. I am sure the Senator knows that Dr. Mueller came here at the request of the committee.

Senator SCOTT. I did not mean to imply that Dr. Mueller came up here to wage a vendetta against industry. I was speaking broadly and generally about wanting more Government witnesses to find occasion to praise the capitalistic system, because it needs all the friends it can get, especially around income tax time.

Senator NELSON. We asked him specifically to analyze the testimony of other economists who had testified here and give his viewpoint.

And I think part of his testimony was directed specifically at the question of factors that make it possible for prices to be held artifically high.

Mr. GORDON. Dr. Mueller, at our hearings last month, when Dr. Markham was here, our chairman stated to Dr. Markham on page 2775, line 18 of the transcript:

> Senator NELSON. As one who majored in economics when I was in school and listened to the arguments in those days, I just learned enough to discover that you could find any point of view you wanted from any set of economists any place in the United States. And from my discussions with my friends today, I find that this is still true.
>
> Dr. MARKHAM. If I may intrude on the dialogue, Senator, I think you are quite correct when you went to school, and that was true when I went to school, too.
>
> If this analysis means anything, it means I think, what precisely Professor Cootner and the rest who have testified here have said, and that is as Professor Plotkin has said, this takes the issue really out of the area of opinion; it puts it in the area of quantitative fact.

First of all, how new is this, really?

Is this really new?

Dr. MUELLER. The econometric approach which they used?

Well, actually, all econometrics involves the application of mathematical and statistical techniques in testing economic relationships. Economists have been doing this for many years. The chief advantage of this technique today is that it permits us to analyze vast volumes of data with modern electronic computers in a short period of time, test many relationships. Actually, the Arthur D. Little study is a very simple one. It involves a study of only two relationships, the so-called risk factor and profits. It does not introduce any other variables such as market structure or competitive variables, as have some other studies of risk.

These techniques have been used long before I was born; they came into prominence in the twenties as simple and multiple regression techniques. So they are not anything new or novel. The whole point of it is that you can't take, as Professor Boulding pointed out—you can't take data that are very crude and send them through a machine and come out with something that is better than the input. In addition, you have to know what it is you are putting in.

So, simply using a sophisticated technique does not give you any good new answers to difficult questions unless you have a good conceptual framework and you have good data.

And, as we point out, when you really understand what Conrad and Plotkin are measuring, their data show nothing at all in the so-called producer goods industries; there is no significant statistical relationship present. And, as a result, when we test their theory with, in effect, better data than they used, we find no relationship. That is what the scientific method is all about. As Cootner explained in his opening statement, he had hoped this is the way science operated, the testing of alternative hypotheses, and so on. And this is what we have tried to do in our analysis, really test what it was they thought they had come up with.

Mr. GROSSMAN. Dr. Mueller, two questions:

First of all, I would like to ask you just as an economist to comment on one of the statements that Dr. Whitney made at our last meeting. He said:

"If a $5 prescription, or six of them, will keep a patient from losing a couple of days' pay or spending a night in the hospital, the price is reasonable."

What do you think of this "market-will-bear" type of philosophy?

Dr. MUELLER. It, in effect, permits a rationalization of anything that you see. It is like saying: "We would all be willing to pay more for our newspapers." Certainly we buy the Star, the Post, and the New York Times, and we pay only 10 or 15 cents for these fine newspapers. We would be willing, however, to pay more; but competition pushes the price down; and, as a result we get more than our moneys' worth. The economist refers to this as a consumer surplus. So, merely because there is a great value received, a greater value received than someone would be willing to pay, does not prove anything in terms of the effectiveness of our market system, our competitive system.

Senator NELSON. As I understand that testimony given a few weeks ago, what the economist was really saying was that if you are scuba

diving and are under 50 feet of water and run out of oxygen, any price you pay for it is good.

Dr. MUELLER. That is right, and you can't argue with that.

Mr. GROSSMAN. One final question, and this is more in the way of summation——

Dr. MUELLER. If I may interject, I think you have devised a new theory of value, Senator. We will call it the "scuba theory of value."

Mr. GROSSMAN. In the way of summation, when I asked you about what you thought a fair and profitable return was, you talked in terms of more competition rather than a specific figure. And when Senator Scott asked you about changes in patent policy, you said: "No", perhaps, but you had nothing specific to recommend. With regard to advertising, you had nothing specific——

Dr. MUELLER. I never answered the question, I do not think.

Mr. GROSSMAN. I wondered whether you could tell us, since we have to rely on your expertise on this, what exactly do you recommend?

In other words, you talk about competition. And I would like to know specifically what you think should be done.

Dr. MUELLER. My testimony and my part in these hearings is a very small one. I was asked primarily to analyze the significance of the Conrad-Plotkin study. But this committee and its predecessors which have investigated the drug industry have put their fingers on the key problem, which is the beginning of understanding. Advertising-created-product differentiation is certainly a key point. And something—I am not recommending anything particularly today—but there should be something that can be done to erode this power. One possibility is the greater use of generic drugs—anything that helps to bring this development about may help; perhaps something designed to simply give consumers, in this case doctors, more information about what it is they are prescribing for their patients. There are different ways of doing this, some private and some public perhaps.

On the patent question, I am sure that you will get other witnesses who would be more willing than I to take a particular position on that point.

But that is the other key point.

And many other countries take a different position on this than does the United States.

Mr. GROSSMAN. Thank you.

Senator NELSON. Thank you very much, Dr. Mueller, for your thoughtful presentation to the committee and the very valuable reference work you did. And if you wish to present supplemental material in the future, as you stated earlier that you may, we will be happy to look at it. And, as I understand you, you said if you thought it worthwhile, you would be happy to come back before the committee and present it personally?

Mr. MUELLER. Yes, sir.

Senator NELSON. Thank you very much.

We will adjourn until 10 o'clock tomorrow morning.

(Whereupon, at 11:55 a.m., the subcommittee adjourned, to reconvene at 10 a.m., Friday, January 19, 1968.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

FRIDAY, JANUARY 19, 1968

U.S. SENATE,
MONOPOLY SUBCOMMITTEE OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:15 a.m., in room 318, Old Senate Office Building, Senator Gaylord P. Nelson (chairman of the subcommittee) presiding.

Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. We will open the hearings of the Subcommittee on Monopoly with Prof. Leonard Schifrin, head of the department of economics at the College of Williams and Mary.

Professor, we appreciate very much your taking time to come here this morning. I have read your statement. It is a very well documented, very well reasoned statement. We appreciate the time you have taken to assemble this material.

You may present your statement in any fashion you see fit. If you find it most effective to read it, you may. If you wish to extemporize or add to it as you go along, that is perfectly satisfactory. I trust you will have no objection if we occasionally interrupt you with some questions.

STATEMENT OF LEONARD G. SCHIFRIN, PH. D., DIRECTOR, DEPARTMENT OF ECONOMICS, COLLEGE OF WILLIAM AND MARY, WILLIAMSBURG, VA.

Dr. SCHIFRIN. I would like to read my statement, Senator Nelson, because it represents a general condensation of a very vast quantity of material.

Senator NELSON. Very well. Go ahead, Professor.

Dr. SCHIFRIN. My name is Leonard Gerald Schifrin, and I am presently associate professor of economics and head of the department of economics at the College of William and Mary in Williamsburg, Va. I received my bachelor's and master's degrees from the University of Texas, and my doctorate from the University of Michigan. I taught at the University of Michigan and at Yale University before coming to William and Mary in 1965. Within the field of economics my areas of specialization are industrial organization, problems of competition and monopoly, and governmental policy toward business. My particular research interest in recent years has been the economics of the ethical drug industry.

I thank the members of this committee for affording me the opportunity of presenting to them some of the salient aspects of my studies of the operation of this industry.

First, let me speak to what the economist calls industry performance—a concept of many facets, but one that essentially deals with the effectiveness with which the industry, in its operations, serves the goals of society. Industry performance thus deals with such matters as technological progress, the development of new products, changes in production levels to correspond to changes in the pattern and size of consumer demand, the efficiency with which development, manufacture, and marketing are done, and the reasonableness of prices charged consumers.

The different dimensions of performance in the ethical drug industry fall under two headings—"product performance" and "market performance." Product performance may be measured by such things as (a) the magnitude and quality of the industry's effort to develop new and better products, (b) the tangible results of this effort, i.e., the number of discoveries and new products flowing from research and development, and (c) the human and economic impact—better health, longer life, and greater productivity—resulting from these tangible results of industry research and development.

In this regard, it is apparent that the drug industry is a highly research conscious industry, in basic research as well as in applied research and development. It has made available to the public over the years a large number of new and better products; and these products, together with advances in other areas of health, have had dramatic impact on our mortality rates, our longevity, and on our general well-being. Many dangerous illnesses have been brought under control; much of the discomfort and even the hopelessness of illness have been checked. The drug industry, along with other sectors of the health industries, deserve credit for the contributions it has made in this respect.

But the record also shows clearly that the product performance of the industry needs qualification and contains serious flaws. A number of authorities have demonstrated that the research performance of the industry is exaggerated by industry officials so as to justify the very large profits of the large drug firms (an illogical argument, by the way). Furthermore, the R. & D. performance is quite small compared to the promotional and advertising outlay, which generally runs four times as large. Beyond questioning its magnitude, critics have contended convincingly that much of the research is imitative, wasteful, and aimed at patent procurement rather than progress. Further, many of the so-called "new drugs" coming to market represent duplications of existing drugs, combinations of drugs representing no therapeutic improvement over their components taken separately, or new items that are the result of molecule manipulation rather than substantive therapeutic advancement. We have heard or seen cases of ineffective drugs, harmful drugs, drugs without adequate warnings, dangerous drugs coming to the market as part of the "new drug flow" for which the industry claims credit.

Senator NELSON. May I interrupt a moment?

Dr. SCHIFRIN. Yes, sir.

Senator NELSON. You say beyond questioning its magnitude, critics have contended convincingly that much of the research performed by the industry is imitative, wasteful, and aimed at patent procurement rather than scientific progress.

Do you have any specific examples of people who have made this criticism?

Dr. SCHIFRIN. Yes, sir; I do. Dr. Walter Modell in his own professional articles and in testimony before several Senate committees has made this point rather convincingly. Dr. Claude Forkner has published in several medical journals, including the New England Journal of Medicine, about the drug mixtures in that respect, the "shotgun therapy," as he puts it. Dr. Dale Console, formerly with Squibb Laboratories, has talked about such questionable practices of the drug industry.

Senator NELSON. You have the articles in which they made their criticisms?

Dr. SCHIFRIN. Yes, sir; I have these and other articles and I would be glad to submit them for the record.

Senator NELSON. If you would submit those to the committee counsel, we will print them in the record.

Dr. SCHIFRIN. Yes, sir.

(The material referred to follows:)

[From the *New England Jounal of Medicine* 259:438–439 (Aug. 28), 1958]

MEDICAL INTELLIGENCE—DRUG MIXTURES[1]

(By Claude E. Forkner, M.D.[2])

Much of the success in modern treatment of disease resides in advances in chemistry, physiology and pharmacology. This has resulted in the isolation of many chemical and biologic substances that have specific and sometimes powerful effects.

For example, twenty years ago there was 1 sulfonamide available to the medical profession—namely, sulfanilamide. Today, according to the sixth edition of the *Modern Drug Encyclopedia*, 200 different products are listed as sulfonamide preparations. Many of these contain 1 or more of the sulfonamides in combination with other drugs, often without any indication in the name of what is actually in the drug. For example, few people would guess that Eskadiamer is a combination of 2, Neotrizine a combination of 3, Ray-Tri-Mides a combination of 3 and Terfonyl a combination of 3 sulfonamides, Powdalator is a combination of penicillin G and sulfanilamide and Thizodrin is a combination of 3 drugs, 1 of which is sulfathiazole.

I suspect that few physicians use more than 3 or 4 of the sulfonamides and that they would like them to be marketed under standardized names rather than under a series of arbitrary combinations of letters making meaningless and nonexistent words that add nothing but confusion, add greatly to the cost of medical care and promote serious errors in treatment.

Who is it that wants all this nonesense on the market? Is it the doctors? No. Is it the patients? No. Is it the drugstores? No. Is it the hospitals? No.

A couple of decades ago only a handful of antispasmodics were available, and only 2 or 3 of these were very useful. Today over 200 differently named products are on the market. A few examples are Alubelap, containing a mixture of aluminum hydroxide gel, phenobarbital and belladonna, Amesec, containing aminophylline, epherdrine hydrochloride and amobarbital, Atralose, containing homatropine methylbromide, phenobarbital and methylcellulose, Bunesia, containing

[1] Presented at the convention of the American Medical Association, New York City, June 4, 1957.

[2] Professor of clinical medicine, Cornell University Medical College; attending physician, New York Hospital.

homatropine methylbromide, butabarbital and magnesium hydroxide, and Kolantyl, containing 5 drugs, none of which have any relation to the name of the product.

I have no doubt that physicians would rather use a few drugs of known composition sold under their own names, such as belladonna, phenobarbital, aminophylline, curare and atropine, to 200 different combinations of products sold under names that have little or no relation to the chemical compositions of the drugs.

A few years ago one had available 3 or 4 good antihistaminics, which are as useful today as any of the 130 marketed products, which for the most part contain a variety of mixtures with which physicians cannot hope to become familiar.

There are today over 100 antacid compounds on the market for sale in drugstores, most of which contain combinations of drugs. One of these drugs picked at random is called X. It contains magnesium carbonate, calcium carbonate, colloidal kaolin, tricalcium phosphate, sodium bicarbonate, bismuth subcarbonate, papain and diastase. I do not believed that any good gastroenterologist, any good internist or any good scientist would find use for such a drug. It is like the medieval prescriptions written hundreds of years ago. Such concoctions, of which there are hundreds in drugstores, should have no place in modern therapy.

Fifteen years ago there were only 2 or 3 antibiotics. Today, a dozen or slightly more have been shown to be of special value, and more than 270 different preparations are on the market, many of which are combinations and duplications.

A few decades ago, before medicine became as precise and scientific as it is today, doctors' prescriptions often consisted of 6, 8 or more ingredients, many of which were more or less inert. The prescriptions were written in Latin, and the mystery of the ingredients constituted part of their virtue. Gradually, most of this sort of unscientific and meaningless procedure was abandoned; professors of medicine and of pharmacology taught students to use simple drugs, for precise reasons and for definite periods. Gradually, with the intense developments of chemotherapy, of antibiotic therapy, of antihistaminic therapy, of endocrinologic therapy and of vitamin therapy there has been a mushrooming of drug manufacturers who are in desperate competition. The commercialistic factor has crept into therapeutics to such an extent that physicians everywhere are confused and misled by the literally thousands of drugs increasing in number daily. Dozens of expensive commercial brochures, sample drugs and elegant preparations reach one's office daily and are promptly disposed of in the wastebasket. Many of these modern preparations are mixtures of drugs, some of which are dangerous, some of which are useless, and most of which would be more intelligently given as separate drugs rather than in a shotgun capsule.

There are today over 300 preparations on the American market listed as hematinics designed to increase the red-cell count and hemoglobin. This, of course, is ridiculous. It is well known to every hematologist that not more than 8 or 10 useful drugs are necessary to treat anemia. For the vast majority of cases only 1 of 2 or 3 drugs is necessary or desirable.

Shotgun therapy with multiple drugs usually is unscientific, often means that the doctor does not know what he is doing, invariably is more expensive for the patient and not infrequently results in tragedy both for the patient and for the doctor. An example of such shotgun therapy is the use of drugs containing vitamins, including B_{12} and folic acid, along with iron, thereby masking bleeding from an otherwise asymptomatic neoplasm until the tumor has become incurable. Many students believe that folic acid administered to patients with pernicious anemia may precipitate an acute and serious exacerbation of the neurologic symptoms.

There are about 450 vitamin preparations currently on the market. Many of these are so-called fortified vitamins. In addition to this, milk, bread, fruit juices and other foods are today fortified with vitamins. Many of the preparations contain a dozen or more items, including copper, iron, cobalt, iodine, phosphorus, calcium, manganese, molybdenum and zinc, in addition to 8 or 10 vitamins.

Every year I am told that Americans buy over the drugstore counters about $250,000,000 worth of vitamins. It is safe to say that at least $240,000,000 of this is wasted. No reason whatever exists for the taking of vitamins by any healthy adult American on an adequate diet. There is good reason often for correcting

the diet of people who have faulty eating habits. The giving of vitamins in no sense is a substitute for a faulty diet in an otherwise normal person. Vitamin B_{12} is being pumped into people by the gallons all over the country by doctors who are not aware of the fact that vitamin B_{12} is of no value whatever except in one group of rare diseases, the macrocytic anemias.

My plea is merely the restatement of a very old and sound principle: no medicine, and that includes vitamins, should be prescribed unless there is a good reason for doing so. When drug mixtures are prescribed, one should remember that one is getting into dangerous territory.

Fifty years ago there were over 300 medical schools in this country. A study was made. More than 200 of these schools were found to be poor and were forced to close. The American Medical Association did much to promote that improvement in medical education. Today, many thousands of useless drug and vitamin preparations exist, thousands being duplicates under misleading names. Doctors, patients, the proprietors of legitimate drugstores, the people generally and hospitals deplore this situation. Exploitation of the public by the existence of such a situation constitutes an important item in the high cost of medical care. Who is going to devise a remedy for the insidious disease?

[From the New York Herald Tribune, Thursday, April 14, 1960]

EX-DRUG OFFICIAL CHARGES "QUESTIONABLE" PRACTICES

WASHINGTON, April 13 (UPI).—The former medical director of a major drug firm accused the drug industry today of profiteering and other questionable practices and urged Congress to crack down with restrictive legislation.

Dr. A. Dale Console, of Princeton, N.J., told Senate investigators he saw little hope of the drug companies dropping practices he said they engaged in.

Dr. Console, medical director for Squibb Laboratories until he left to re-enter private practice, said that "unless sweeping reforms are instituted, a truly ethical (drug) house cannot survive in the present competitive wrangle."

CHARGES LISTED

In a severe indictment of the industry, Dr. Console charged before the Senate Anti-trust subcommittee:

That doctors and the public are subjected to a constant "barrage" of new drugs, some of which are worthless and others which have "a greater potential for harm than for good." He said that "since so much depends on novelty, drugs change like women's hemlines."

That more than half of the drug companies' research effort is directed toward projects that are really not worthwhile but "are pursued simply because there's profit in it."

That the industry has high-pressure sales techniques based on the maxim, "If you can't convince them, confuse them."

That most medical leaders and educators "face the problem with denial, complacency or a sense of futility" because the industry "is unique in that it can make exploitation appear a noble purpose."

The subcommittee also heard Dr. Frederic H. Meyers, of San Francisco, a University of California expert on drugs, challenge the American industry's contention that it leads the world in discovering new drugs.

"Far from leading in drug progress," Dr. Meyers said, "it appears that our industry has usually followed and often after a clear lag."

He said that much of the laboratory work by American drug firms was centered on "exploiting and marketing" foreign discoveries. Because of this, he belittled the American industry's assertion that the cost of its research justifies high drug prices in this country.

Dr. Meyers also criticized practices used in advertising new drugs. He said many drug ads were "at best incomplete and at worst dishonest."

"Some ads become so expensive that they approach 'payola'," he said.

[From Time Magazine, May 26, 1961]

TOO MANY DRUGS

Prescription drugs would be cheaper and more effective if manufacturers would market fewer of them, says Dr. Walter Modell of Cornell University Medical College, one of America's foremost drug experts. He also believes that this is the way to bigger profits for the companies.

Writing of pharmaceutical chemists in *Clinical Pharmacology and Therapeutics*, Dr. Modell asked: "Will they realize that there are too many drugs for the patient, for the physician, and, surprisingly enough, for the pharmaceutical industry?" No fewer than 150,000 preparations are now in use, of which 90% did not exist 25 years ago, and 75% did not exist ten years ago. About 15,000 new mixtures and dosages hit the market each year, while about 12,000 die off.

These figures, says Dr. Modell, reflect the fact that new drugs are often introduced not because they are better than existing drugs or because there is a real need for them, but "to horn in on a market which has been created by someone else's discovery." He denounces as "structural roulette" the game of making a minor change in the molecule of a competitor's drug, to get around patent restrictions, and rushing the resultant analogue to market. He points to one manufacturer "who sells one drug entity in this country and a congener [close chemical relative] in another country," and argues that "each is the best for the same purpose. Since more than one drug cannot be the best for the same indication, we simply don't have enough diseases to go around. At the moment the most helpful contribution is the new drug to counteract the untoward effects of other new drugs; we now have several of these."

Dr. Modell recommends that manufacturers exercise self-restraint by making and marketing only the single best drug for each purpose, and cross-license one another to spread both risks and profits. One of the most successful of all U.S. companies, he says, introduces the smallest number of new drugs and does the least "molecule manipulation." The others, Dr. Modell suggests, should do the same—to their own advantage as well as that of bewildered doctors and patients.

Senator NELSON. Now, you comment in the next statement that there are many so-called new drugs coming to the market which represent duplications of existing drugs, combinations, and so forth.

Do you have some specific examples of these duplicative drugs and those resulting from molecule manipulation?

Dr. SCHIFRIN. May I answer that question this way: The usual statistics cited on this come from the product survey put out by Paul de Haen. In this survey that he updates annually, he not only lists the total number of so-called new drugs coming to the market, but a breakdown as to those that represent duplicates of drugs existing on the market, those that represent combinations of drugs already on the market, and then how many of these are clearly new drugs—that is, items containing drugs that have not appeared on the market previously. The large majority of the total so-called new drugs come from the duplications and the combinations category. I would be glad to submit the data I have on the De Haen product survey along with this other material.

Senator NELSON. Please hand it to the reporter.

(The material referred to follows:)

TABLE 6.—PHARMACEUTICAL PRODUCTS INTRODUCED NATIONALLY

	Number of firms	New single chemicals	Duplicate single products	Compounded products	(a) Total new products	(b) New dosage forms	Cumulative total (a and b)
1966	52	13	16	53	82	26	5,618
1965	65	23	23	73	119	22	5,510
1964	82	17	34	111	162	41	5,369
1963	89	18	43	152	213	52	5,166
1962	108	28	47	180	255	84	4,901
1961	111	41	33	191	265	106	4,562
1960	109	45	64	202	311	98	4,191
1959	106	63	49	203	315	104	3,782
1958	126	44	73	253	370	109	3,333
1957	127	51	88	261	400	96	2,884
1956	126	42	79	280	401	66	2,388
1955	124	31	90	282	403	96	1,921

Note: New single chemicals indicates products that are new single chemic l entit es not previously known and developed by one manufacturer.
Duplicate single products include products such as dexamethasone or griseofulvin put out by various manufacturers.
Compounded products comprise any product having more than one active ingredient.
New dosage form: if a product has originally been marketed in tablets and is now offered in ampules, suppositories, etc., the latter are considered new dosage forms.

Source: Paul de Haen, New York City.

Senator NELSON. Now, you also stated in this same paragraph that we have heard about or seen cases of ineffective drugs, harmful drugs, drugs marketed without adequate warnings, and dangerous drugs coming to the market as part of the "new drug flow" for which the industry claims credit.

Do you have specific examples of such harmful drugs, those without adequate warnings, and so forth?

Dr. SCHIFRIN. Yes, sir; I think the most harmful example of a new drug coming to the market was MER 29, which was withdrawn from the market because of its harmful effect on people taking it. Also in these hearings, the question of inadequate advertising has come up. I believe the Chlormycetin case is probably the most important one there. A highly promoted drug came to the market, a potent drug, with dangerous side effects, and the information as to the side effects was fully understood only after the problems of use of the drug had been so serious that it was withdrawn from the market for a year for a very careful study.

So I cite that as the most outstanding example of a drug, a dangerous drug, with inadequate information.

There are quite a number of other examples. The Merrell Co. was cited for false claims with MER–29. This is an article from the New Haven Register of December 20, 1963, that I happen to have here. That is just one of several examples I could name.

Senator NELSON. If you would submit that last article from it, we will print it in the record.

(The material referred to follows:)

[From the New Haven Register, Dec. 20, 1963]

DRUG FIRM INDICTED ON FALSE CLAIMS

WASHINGTON (AP).—The William S. Merrell Co. was indicted by a Federal Grand Jury today on charges of making false statements to the government about the anti-cholesterol drug, MER/29, and tests made to determine its safety.

The indictment returned here said the company and three of its research scientists "concealed and covered up, by trick and scheme, material facts important to the Food and Drug Administration." The scientists named are Harold W. Werner, Evert F. Van Maanen and William M. King.

Mr. GROSSMAN. Could I ask you a question here?

On Page 4, you talked about the proliferation of products that confuses rather than proves drug selection or drugs inadequately tested or whose side effects are minimized in the race to market for the consumer's dollar.

Are you criticizing the FDA here, as well?

Dr. SCHIFRIN. I am not criticizing——

Mr. GROSSMAN. In other words, in order for these drugs to get to the market, they have to somehow get past the FDA, do they not?

Dr. SCHIFRIN. Let me read that part of my statement that covers that point you raised there. That discusses the point.

Mr. GROSSMAN. Surely.

Senator NELSON. We are not above criticizing a Federal agency, you know.

Dr. SCHIFRIN. I consider many of these criticisms valid. I offer them as important qualifications of the industry's product performance. But many aspects of this product performance warrants praise, and this must be recognized, criticisms and qualification notwithstanding.

The other half of the picture is what I refer to as "market performance," and deals with the efficiency with which the industry uses society's scarce resources; that is, the extent to which economic resources are used to enhance consumer well being and other economic goals. In this regard, the important questions that must be answered are these: Is there enough competition to place a premium on efficiency and penalize waste? Is there enough competition to compel firms to pursue only those activities that benefit consumers? Can firms incur costs for activities that do not benefit consumers yet charge consumers, in the prices they pay, for such activities? Is there enough competition to keep prices in realistic relation to costs, providing profits adequate for maintaining or expanding desirable activities but not profits derived from the exercise of monopoly power?

To generalize from the vast quantities of evidence available, I believe that the characteristics of the drug-product marketing and distribution systems are such that effective competition does not prevail. As a result, firms are free to engage in many practices—most notably in promotion and advertising but in research and development also—that serve their own profit goals but provide no benefit to society. A largely wasteful promotional effort costing in the hundreds of millions of dollars per year; misdirected research; rivalry in novelty, in capturing the attention of physicians; all this represents costs of large magnitude passed on in full to the consumer, but without any corresponding benefit—and perhaps some harm, such as a proliferation of products that confuses rather than improves drug selection or drugs inadequately tested, or whose side effects are minimized, in the race to market for the consumer's dollar. Yet these practices and the factors contributing to them have become part of the industry—woven deep into the design of its fabric.

Now, if I may comment on that question, I would say that to a considerable extent, in recent years, the Food and Drug Administration has been doing much, much better in watching out for the advertiser than trying to do something about the proliferation of drugs that may not really contribute to drug therapy. The Kefauver-Harris amendment in 1962 made a great contribution in this respect and I think the FDA has administered that law very capably and effectively. My main criticism is not so much that the Food and Drug Administration can cure the problems of this industry as much as that a system prevails, an informational system, a distributional system—the whole process by which information about products comes onto the market; that is, the information largely comes from the drug firms and it is aimed at the physicians. Thus the new products and the claims about them, the information regarding their use all come from the same source. I believe this is a cause of many of these abuses in product development and product promotion.

Now, as far as the FDA, there is one—there are certain changes in what the FDA can do that will be very helpful and if the FDA has not done the job that I would like it to do, its failure is in not pressing hard enough, I believe, for certain further changes that would make it more effective.

Mr. GROSSMAN. There could not be this proliferation of products, certainly, without FDA approval. If the FDA did not approve it, they just would not be marketing it.

Dr. SCHIFRIN. That is true, the FDA—as far as the proliferation of products goes, that is true. The FDA is playing a permissive role in this, certainly. But understand me, when I cite here the large number of new products, I am not really criticizing the industry's performance just because of the quantity of its new products here. I am criticizing the new products in this respect; the industry takes credit for putting out a tremendous number of new products and representing these things as therapeutic advancements. Most of these new products are not therapeutic advancements. They are new items duplicating those already existing on the market. These may be useful for competitive purposes, but it represents no advancement of drug therapy. Thus if the industry is saying, "Look, one of the manifestations of our research and development effort is this tremendous number of new products," we are concerned with the industry's operations and must understand just how much of a contribution these are or are not.

Senator NELSON. If I may interrupt the minority counsel, the Kefauver-Harris Amendment of 1962 for the first time gave the FDA the authority to disapprove a New Drug Application unless the drug was proved efficacious; is that correct?

Dr. SCHIFRIN. Yes.

Senator NELSON. Now, if there is a molecular manipulation that gives you a product, which has the same therapeutic result as an already existing drug, does the FDA presently have the authority to deny the company the right to market that drug?

Dr. SCHIFRIN. No, sir. Before 1962, the FDA could deny a New Drug Application only if the product were harmful—that is, if it did not hurt the patient, that product could be marketed. Now a product has to be efficacious. But it does not need to be of superior efficacy to products already on the market to be cleared by the FDA.

Senator NELSON. If it is just a product differentiation, as the phrase is used——

Dr. SCHIFRIN. Yes, sir.

Senator NELSON. And if it does duplicate a product on the market and is efficacious, does the FDA have the authority to prevent the firm from marketing it?

Dr. SCHIFRIN. No, sir.

Mr. GROSSMAN. One further point on this:

If it is efficacious and if the FDA is agreeable to let it go on the market, you pointed out when you used the word "it will provide competition"—isn't that something we are trying to do here? In other words, if it is going to be a competitive drug, does it not have some value as far as our inquiry is concerned?

Dr. SCHIFRIN. That may be a contribution.

Mr. GROSSMAN. That is a pretty important point.

Dr. SCHIFRIN. Yes, but it may be offsetting negative contributions. In other words, these drugs that are duplicated may be very heavily promoted. I think that is a waste of resources that could be used for other purposes.

Secondly, they may be promoted under brand names, which creates confusion and the fact that they are duplicates may be obscured in the promotional literature. They may be represented as new therapeutic factors when in fact, a large majority are not.

Senator NELSON. The only way in which a company can come onto the market with a duplicate but differentiated product is if a patent has expired on the one they are duplicating. Is that not correct?

Dr. SCHIFRIN. I would say that is the usual way. There are rare circumstances under which it could obtain a license, usually as the result of some antitrust activity.

Senator NELSON. But that is a license from the patentholder?

Dr. SCHIFRIN. The patentholder, yes.

Senator NELSON. But usually in that case, if it is a differentiated product, it is a product, as I understand it, of the same chemical composition with some insignificant difference and then is put on the market and advertised to the medical profession as something better or something——

Dr. SCHIFRIN. Yes, sir, the differentiation is nominal. It is not in its chemical composition and many opinions maintain that it is not in its therapeutic action, either. It is a nominal differentiation, and therefore the professional thrust is to make a claim that this is a new and better product. But it is really an identical product to many products already on the market.

Senator NELSON. So that the reason for doing it really is to benefit the company in a competitive situation?

Dr. SCHIFRIN. Yes, because if the product is made from a drug whose patent has expired or is not patented, there are likely to be many such items on the market and an item comes out to fill out a company's catalog and will get promoted. The company, hopefully, will want this thing selected by its brand name. They will put a high price on it, very often; but it does not give the doctor additional medicine to use for his patients.

Senator NELSON. What I do not have clear in my own mind is whether product differentiation by definition is another product with

the same chemical composition, as was testified yesterday—I assume that is correct. Is that what a product differentiation is?

Dr. SCHIFRIN. I would not define it that narrowly, as an economist.

Senator NELSON. But in any event, as to the chemistry involved, I think the testimony was that a differentiated product was of the same chemical composition as the one that is being duplicated.

Dr. SCHIFRIN. That is a common usage of the term, yes. That is the way it has been used.

Senator NELSON. What I do not have clear is why should the company go to the bother of creating a product differentiation, whatever that really means, when all they would have to do is just duplicate the product on the market, the same compound, and give it their brand name and advertise it on the market under their brand name?

What is the reason not following that procedure instead of going to what is called product differentiation?

Dr. SCHIFRIN. Well, Senator, I think there are two types of product differentiation. One is an actual difference in the product, a physical difference. That may be a small difference. That is what the term "molecule manipulation" refers to, to differentiate a product, chemically, and that is done very often, to get a patent on a product that is very much like the product of some other company that is already patented. That is a way of entering their market.

The second way of differentiating a product is really to produce something just like the other firms are producing but to differentiate it by calling it some other name, a trade name differentiation.

Why would a firm do either of these? Well, to have the physical differentiation, they would do it for the sake of acquiring a patent and then having an exclusive item that they could promote under a trade name, hopefully have it prescribed heavily and have these prescriptions filled, as they are at a very high price.

Perhaps a company duplicates a drug that is already on the market; first of all if it were a small firm, in the hope that through being an active price competitor, it could gain large sales. A large firm would do it in hopes of making that trade name stick and thus having physicians prescribe it by its trade name designation and those prescriptions would be filled at much higher prices and thus it would be profitable for the large firm to attempt this nominal differentiation, if it could make that trade name stick for this differentiated product.

Senator NELSON. So in this case, where they simply duplicate the drug already on the market, the differentiation involved is only the differentiation so far as identification by a brand name is concerned, is that correct?

Dr. SCHIFRIN. Yes.

Senator NELSON. And the hope in that case is that by effective advertising, they will be able to get into the market and compete. Is that it?

Dr. SCHIFRIN. Well, to get into a market and compete, but also, here we get into the whole practice of trade names, by promoting under a trade name, of course, they are popularizing the specific trade name they are promoting. They are also engaging in promoting the practice of prescribing by trade names

Now, the promotion serves both of these purposes. There may be many, many firms producing that product. But only the larger ones

that can popularize these trade names become the effective ones and thereby become insulated against the generic firms who are in the market and selling at a lower price. So there are very large profits to be gained by a larger firm entering the market, even for an unpatented product.

Senator NELSON. So then you are describing a situation where a company, because of its distinction, can then effect a nominal differentiation simply by the use of a brand name and then, by effectively advertising its brand name to the medical profession—because that is where they advertise—convince the majority of the profession to prescribe that brand name. Once a firm is able to do that, it can artificially set the price higher. Is that what you are saying?

Dr. SCHIFRIN. Yes, sir.

Senator NELSON. And continue to compete because there is no price competition. There is merely promotional brand name competition in the head of the physician who knows the name?

Dr. SCHIFRIN. That is right.

Senator NELSON. Is that what you are saying?

Dr. SCHIFRIN. Yes, sir. The people who have appeared here, many of them, have referred to this, the competition that you are talking about, as the competition for the ear and the eye of the physician.

Senator NELSON. To give you a hypothetical case, you could very well have an unknown minor company that is not established by reputation—that is, by name reputation. It may be a very fine company, but it is not known widely to the medical profession. That small company could discover a new and very good drug and go into the marketplace with that drug. Even though they will get some kind of a reputation based upon this one drug, it would not be a reputation that could match the reputation of 50 or 100 years of advertising and standing in the medical community achieved by the big companies. So then theoretically, you could have a case where a brand name company that is established, could move in, once the patent has expired, and get a position in the marketplace because of their acceptance by the medical profession, charge an artificially high price and occupy a large percentage of the market even though they would be selling exactly the same product as the small firm which developed the drug.

Dr. SCHIFRIN. Yes.

Senator NELSON. Even though the originating company may put their product out at a much lower price and other generic companies may come in at a still lower price. Is that what you are saying?

Dr. SCHIFRIN. Yes, and going beyond that—the example posed by this hypothetical case, is something that could result after the patent had expired.

But supposing a smaller company did have this development you are talking about. The larger company would not have to wait until the patent expired. Through molecule manipulation, they could come up with a drug with a different chemical structure which would warrant a separate patent, but still be very close to the drug marketed by the smaller company. And shortly after the development made by the smaller firms, the larger firm could come out with its product, which is not an improvement now, and through very heavy promotion, take away even those initial gains that the small firm hoped to make. So the

small firm may be jeopardized by the promotion of the large firm during the period when the smaller firm's patent may be valid.

So it could be effective around it, but not over it.

Senator NELSON. You think that the reason the major companies continue to emphasize very heavily the brand name rather than the name of the company is that they can effectively compete, then, in the retail market, where there is no price competition. They can compete effectively against equivalent quality generic drugs that are available at a much lower price.

Dr. SCHIFRIN. I would like to change that a little bit and I will agree with you 100 percent. The large firm can keep the small firm from competing with it, because the large firm, you see, which has popularized trade name use, renders the small firm, which can't promote under trade name, an ineffective competitive factor.

I think we are saying essentially the same thing.

Senator NELSON. You are aware that very frequently, the generic drug producer does compete very effectively against a major firm in competitive bidding situations; the city of New York, for example, purchasing for the public hospitals and the welfare department, asks for competitive bids and is well equipped to test the drugs—and generic firms do compete in that situation.

Dr. SCHIFRIN. Yes, sir.

Senator NELSON. Or would it be more apt to put it the other way around, that in that area, the brand name companies decide to compete with the generic firms by reducing their prices substantially. For example, we have cases where within the same 2- or 3-month period, a brand name is being sold across from city hall in New York to a community pharmacist for $8 a hundred and so forth, and then in the same period, the same company moves in and bids to New York City at $1.10 a hundred because they know they have to meet the competition the other brand names who are willing to compete, plus the generic people who are in that market, too.

Dr. SCHIFRIN. Yes, sir.

And I come to this point in my statement, but to the extent the large firms can shift the competition from price to promotional competition—that is, they can shift the burden from the selection of generic equivalents on a price basis—to have that selection done on a trade name basis, they render the small firm very impotent in competition, you see. Perhaps this chart——

Senator NELSON. Just one moment before you get to that.

Does that explain in part, at least, why the highest price charged by the manufacturer in every example I have seen, is always the price charged to the community pharmacist? In other words, if you look at a listing of all drugs by all companies—I have seen no exceptions—at the start you will see that the price charged the pharmacist is the highest price charged in America.

Then you look at bids all over the country to the Defense Supply Agency, the Veterans' Administration, hospitals all over America, cities and counties—and in almost every single instance, the price asked by the same company for the same drug is lower, many times one-fifth, one-tenth, one-twentieth as low as the price they charge to the community pharmacist. And in those instances where we find a

purchaser in a nonprofit institution, a municipal hospital, paying the same price as the pharmacist does, if you will look a little further, you will see that they did not purchase on a system of competitive bidding.

Dr. SCHIFRIN. Yes, sir.

Senator NELSON. So, the brand name identification in the mind of the doctor, in part at least, accounts for the higher price consistently charged the community pharmacist. The industry is not afraid that an unknown firm's drug would be prescribed. Is that the situation?

Dr. SCHIFRIN. Absolutely.

Mr. GORDON. May I interrupt at this point?

Dr. SCHIFRIN. Yes, sir.

Mr. GORDON. Can I conclude that even if a small company has a patent, it cannot really protect itself against the large company?

Dr. SCHIFRIN. That is true, because as I say, the large company can frequently obtain a patent on a therapeutic equivalent of slight chemical difference, you see. The difference in chemical structure would warrant the patent application and then it would have a therapeutic agent here to rival that of the small firm and through its promotional effort could in fact get the bulk of the market and the small firm, although having come up with a significant development and having acquired a patent, may not succeed very well financially in obtaining innovational profits for the accomplishment.

Senator NELSON. If a new chemical compound is discovered by a small company and patented, can another firm actually take that compound, do some molecular manipulation, and end up patenting the slightly modified product? I have some serious doubt about that without knowing anything about it.

Dr. SCHIFRIN. Well, it seems to me that when the small firm acquires the patent for its development, the patent comes at the price of significant disclosure. That disclosure, of course, can serve as the basis for a structural change that the large firm might accomplish to come up with its rival therapeutic agent.

Secondly, I think a lot of the development occurs simultaneously. That is, there is a lot of literature in the professional journals about progress, technology, chemical manufacture and so on. It may only be that the small firm may beat the large firm at certain times just by a very narrow margin in the development of its product. The large firm is almost up to the small firm and when it sees the small firm has a patent, it can do a little sidestep and obtain a patent on a slightly different chemical substance.

Mr. GORDON. Do you have examples of that?

Dr. SCHIFRIN. The only case I can think—it is a little bit different. For example, meprobromate. We know that it has been an enormous financial success for Carter and Wyeth. But meprobromate was actually discovered by Dr. Berger in England. Rather than initiate production as a small manufacturer, he went with his discovery into the employment of Carter and entered the market through a large firm. I think this reflects the very unstable and uncertain position that a small firm making a development would face in the market. That was avoided in that case by going directly to the large firm.

Senator NELSON. In some of these developments where a number of researchers and companies around the world are working on the

same problem, seeking the same solution, progressing at a similar rate, is there evidence that because of the fear of a legal contest of the patent by one versus the other, they reach some agreement that one will get the patent and that he will license the others?

Dr. SCHIFRIN. Very much so. When Patent Commissioner Ladd appeared before the Kefauver committee, he pointed out that patent interferences—that is, where companies contest a patent application made by another company—are more frequent in chemical and chemical-related industries than any other industry. That is fact one.

The second fact, and this came from, I think, Mr. Federico, who was with Commissioner Ladd, is that a patent interference results in a very careful scrutiny of a patent application. In a high proportion of these cases, it turns out that the result is unpatentability. That is, a decision that the patent should not be awarded. Large firms are researching along these similar lines. They attempt to test the patent application, because rewards for getting a patent are very high in this industry. Hence, the major firms that have pursued parallel lines of research, often permit a patent applicant to go ahead unchallenged and to get his patent. But the other large firms, for not challenging that patent, will get licenses to produce it. In other words, they will share the patent among three or four firms rather than have nobody get the patent. So licensing is a result of these agreements not to test patents by the large firms.

Senator NELSON. When you say they share the patent, you do not mean that three companies, more than one company, gets the patent in their name?

Dr. SCHIFRIN. No, but as a condition for withdrawing from the interference, the companies that withdraw get licensing privileges.

Senator NELSON. Is that a violation of the antitrust laws in any way?

Dr. SCHIFRIN. Well, I would say that in a considerable number of these cases, the licensing agreements have been accompanied by price-fixing agreements. We have seen that in meprobromate, and in tetracycline. We have seen it several times through the industry, that the cooperation involved in cross-licensing is a very tempting circumstance to lead to a—if not an overt, at least a tacit price-fixing agreement. The tetracycline is a notable example of these things.

Senator NELSON. I notice that there is more than one type of case. I have seen instances where one company gets the patent and licenses two others who have been working in the same area, doing parallel research. Then there are cases where one company gets the patent and licenses anybody who wants to be licensed for all practical purposes.

Dr. SCHIFRIN. Those are rare.

Senator NELSON. There are some; are there not?

Dr. SCHIFRIN. Yes, reserpine, I think, is the outstanding example.

Mr. GORDON. Dr. Schifrin, if the large companies will not test the validity of the patents owned by other large companies, and if small companies can't do it because of the litigation expenses, then who is going to protect the public against the possibility of invalid patents being used to reap monopoly profits?

Dr. SCHIFRIN. Mr. Gordon, as of now, the answer to that is nobody does. The FTC, in its tetracycline case a few years ago, under section 5 of the Federal Trade Commission Act, did consider a fraudulent pa-

tent application to be an unfair method of competition. So to the extent they are willing to do it, they can. They have been the only ones who have done this, and of course, these are infrequent examples. There is no regular mechanism by which the true validity of patents can be watched over and ascertained right now. One of my proposals is related very closely to that point.

Senator NELSON. You mean, then, that if a company has what appears to be a new product and there is doubt in the minds of other companies that it is really patentable, in order to avoid free competition, they just do not challenge its patentability; so that it then becomes patented and some companies become licensed and then, for 17 years, there is an artificially high price paid by the consumer because there a patent has been granted, which, if challenged, would not have been granted in the first place?

Dr. SCHIFRIN. Correct. In other words, market domination by a few firms that exercise a monopolistic type of interest comes to exist, yes.

Senator NELSON. And you say there is no effective protection in behalf of the public by any public agency against this kind of occurrence?

Dr. SCHIFRIN. At present, there is not.

Senator NELSON. It rather shocks me that you could have a situation where something that may be shown to be not really patentable if challenged becomes patented and no public agency is prepared to protect the public interest.

Dr. SCHIFRIN. Well, the most careful scrutiny of a patent's validity occurs in the court, not at the Patent Office. Thus, things for which patents are issued by the Patent Office may, if contested, be found to be invalid. The patent may be found to be invalid if contested. Thus the burden is put on usually some small firm. And the small firm, as Mr. Gordon correctly pointed out, usually can't bear the expense of litigation.

Senator NELSON. And you are advocating that some mechanism to protect the public interest in this kind of instance be established?

Dr. SCHIFRIN. Yes, sir; I think an advisory panel to the Patent Office, reflecting the highest degree of expertise in the medical field should be established, and should give these patents the very careful scrutiny that would never arise otherwise.

Senator NELSON. Are you satisfied that there is no mechanism under the present law by which any Federal agency could, on its own motion, challenge the patentability of a product?

I do not mean challenge a conspiracy to monopolize or any such thing, but challenge just the patentability of a product?

FDA, Federal Trade Commission, anybody?

Dr. SCHIFRIN. I am not positive as to the interpretation that these agencies give their own enabling legislation, but I will say this: If any such organ exists, it certainly is not used rigorously, if at all.

Senator NELSON. Do you think that your proposal is feasible as a practical matter? That is, would it really put into the hands of public representatives adequate tools to protect against this specific circumstance?

Dr. SCHIFRIN. Yes, sir; because I believe that much of this expertise, and from time to time, several related important functions, have

been filled by people who are in private industry—I should say mainly in medicine. Many of our people who are outstanding physicians, who teach in medical schools, certainly are competent to assist in this matter.

Senator NELSON. You certainly would not give this kind of group final authority; would you?

Dr. SCHIFRIN. No; but I would hope, sir, that their expertise would be recognized by the Patent Office in determining patentability; that these people serve as a rather influential body of experts.

Senator NELSON. And what is the next step in the event that this independent body that you would establish made a recommendation which they felt very strongly about but was not accepted by the Patent Office. Would you provide a mechanism then, which would allow the Government to go into court to challenge the patent?

Dr. SCHIFRIN. That is one alternative. I would consider that as feasible; yes. There is another alternative that is coordinated with that one.

I know we have wrestled with the problem of patent standards very often in our industry, and since the drug industry occupies a rather unique position in American industry, I would not be opposed to a unique patent law applying to drug patents, with clearly different and higher standards than are now provided by our general patent law. I think the drug industry warrants separate treatment.

Senator NELSON. If this is, as I believe, a serious problem, and it may very well be, would you not be reluctant to place the final arbitrary authority in a commission or committee such as you recommend, or even in the Patent Office itself? In other words, would you not think that if you had a commission and they made a recommendation that an item was not patentable and the Patent Office did not agree with that conclusion, that the legal arm of the Government, the Justice Department, ought to be able to move to test it? Or if the Patent Office did agree and the patentholder did not, they still ought to have a right to go to court?

In other words, should you not have as the final resort for both the Government and the company or companies involved the right to go to court?

All you are trying to suggest here is that the public interest be protected by establishing some agency with the authority to challenge the patentability of drugs and with the ultimate authority, in behalf of the public, to recommend to the Justice Department that the patent issuance be challenged in the courts?

Dr. SCHIFRIN. Ultimately; yes.

Senator NELSON. Go ahead.

Dr. SCHIFRIN. I have mentioned about the practices and the factors that have become a part of the industry's operation. Now let me describe how this design came into being, this product and market performance that I have reviewed now.

In the late 1940's and early 1950's the major drug firms became alarmed by vigorous price competition in the sale of drugs, most notably penicillin and streptomycin. They sought to insulate themselves from further price competition for these and other products through the device known as the "specialty" item—that is, finished

products sold under unique trade names and, to the maximum extent possible, made from drugs for which patents had been acquired. These two devices—the trade name and the patent—have, to an astounding degree, eliminated competitive conditions from the markets in which drug products vie for sales. The vast majority of all new drugs have been covered by patents, sometimes of questionable validity.

Patents monopolize the sale of products for a single seller or, in some cases, for it and a limited number of licensees. Even for products sold by many firms, the popularization of the use of trade names in prescription writing has led to the dominance in those markets by the few major companies in that product line who can promote through massive advertising outlays the trade names of their specialities. Monopoly or oligopoly has thus become the usual situation—in the antibiotics, the hormones, the mental drugs—and down the list of areas of drug therapy. The competition among firms in the market is no longer one in which producers of comparable items seek customers through more attractive prices, but one in which a single seller often exists alone, or, if he shares the market with a few rivals, that rivalry is in advertising, claims, and trade-name repetition—certainly not in price.

This is a large, costly, and wasteful competition. It is excessive, confusing, and largely ignored, but it does serve its purpose. It popularizes particular trade names and strengthens the use of trade names in general, thereby rendering price competition ineffectual. Such advertising adds little if anything to drug therapy, yet is a large cost, easily shiftable to the consumer.

To some extent the peculiar dependency of the physician on the drug firm for information places some of this activity above ordinary advertising—but even this "promotional" literature often has contained misleading, insufficient, exaggerated, or otherwise inadequate information.

The same features that encourage such wastes and enable drug firms to charge their costs fully to consumers also condition the profit margins contained in drug prices. These margins provide for rates of return to the industry as a whole and to all the large drug producers far higher than for the economy as a whole, year-after-year. Furthermore, these extraordinary profit levels are remarkably stable. Year after year, the ethical drug industry is right up at the top of the industry profit ranking. Year after year the after-tax rates of return on stockholders' equity for large drug firms exceeds those of other firms; year after year the ranking in "Fortune" show a disproportionate frequency of drug firms among the most profitable large firms in the economy; year after year the FTC–SEC profit data in manufacturing reveals the outstanding performance of drugs. The high profitability reflects the absence of competition. The stability of profits demonstrates the absence of risk to investors. If risk were to exist, one would expect to see the high gains of some firms accompanied by occasional losses—to themselves or to others—but such evidence of risk is virtually nonexistent. Unable to exploit the "risk" justification for its profit levels, spokesmen for the industry have tried to rationalize the great profits with the "research" argument—that high profits are necessary to finance the industry's research effort.

This is an illogical theme, however, since profits exist only after all costs, including research, have been covered. A firm that breaks even, or earns only a normal profit, is financing its research just as fully and capably as is the firm earning profits far above normal.

As that argument folds, the industry turns to the "growth industry" argument—that is, that the drug industry is a so-called growth industry and that high profits are needed to finance that growth. In response to that theme I contend that reinvesting your earnings instead of taking them as dividends is one thing; but exacting from consumers a double profit and more, to sustain and even increase dividends, on the one hand, and simultaneously to finance capital expansion and stockholders' equity on the other hand, is uneconomic, unjustifiable exploitation. The consumer who purchases his prescription is thus paying in that price for these things—for activities necessary to bring that product to him; for activities that provided no benefit to him and hence were unnecessary; an attractive dividend to the stockholders, and some part of a new machine, a new plant, a piece of property that will belong to the stockholder. The dramatic expansion of the industry in the past 15 to 20 years has been almost entirely, if not totally, financed out of profits—yet the industry throughout this period has maintained a payout rate, dividends per invested dollar or per share of stock, that compares favorably with other industries. That, to me, is something like having your cake, eating it, and seeing it grow bigger all at the same time.

Thus the market performance of the ethical drug industry, measured against the criterion that "prices paid by consumers reasonably reflect the costs of efficiently providing useful activities" is seriously deficient. The prices paid by most consumers of drug products are excessive for two major reasons—they are inflated by wasteful cost elements, and they are further inflated by the excessive profits they provide.

The question that now arises is this: What features of drug markets render consumers so exploitable?

First, there is the peculiar importance of the product, more so than almost any other commodity; then there is the "prescription relationship," in which someone other than the consumer actually decides what will be bought—someone who may be unaware of the availability of alternative products, unaware of their relative prices, or indoctrinated in the practices of prescribing high-priced trade name specialties.

Second, given this vulnerability of consumers, to exploitation, is monopolization—the basis of the power to exploit the consumer. This monopolization is both result and cause of the wasteful competition in development and especially in advertising, and is a prime determinant of excessive profits, all of which the consumer bears. The large drug firms, as I have indicated, strive to create monopoly through patents and trade names. But what is it that permits them to succeed so impressively in that endeavor?

To answer that question we must distinguish two separate facets of the industry's operation—on the one hand there is the development and manufacture of drugs, i.e., the active chemical substances that go into pharmaceutical preparations. On the other hand there is the

manufacture of the finished dosage-form products or preparations containing those drugs. As breakthrough discoveries have opened up the fields of antibiotics, cortical steroids, mental drugs, antihistamines, vitamins and nutrients, antidiabetic drugs, and others, a pattern of specialization has emerged. Because of differences in their backgrounds, in their interests, in their early activities, and also because of their inability to pursue many diverse research lines simultaneously, the larger firms have focused their efforts and resources on one, or perhaps a few, areas of exploration. In most of these areas, perhaps with the exception only of mental drugs, developments after the breakthrough discoveries have been of a "stepladder" nature. Those firms first on the ladder have kept ahead of others; entry on the ladder is impossible for smaller firms and extremely difficult even for large firms once the early entrants have gained momentum and acquired patents, thereby protecting all the previous rungs as well as the ones they are now perched on, from being used by potential rivals.

Thus, scarcity of opportunities for entering into the manufacturing of drugs—the chemical substances—has closed entry into the manufacture of finished products, except in those few cases where the bulk drugs are available to all fabricators of preparations containing them.

In most drug product markets the only sellers are those large firms who hold the patents on the drug ingredients. In a few cases other large firms are licensed to use the patents; and the many small firms in the industry are thus limited to the manufacture and sale of products containing unpatentable drugs, drugs whose patents have expired, or drugs which are available because licensing by the patent holder is required as a consequence of antitrust guilt. But even in these few situations, the small firms are not equal competitors of the large ones—because the popularization of trade names (possible only for large firms) in prescriptions renders the generically designated items of the small firms as inconsequential competitive threats.

As a result of this specialization, patent acquisition, and the use of trade names, there have developed two different groups of drug-product markets, which I have depicted in this diagram.

Across the top, that says, I believe, "Products Made from Drugs that are," and then the lefthand column "Patented," in the righthand column, "Unpatented."

Since most drugs, most commercial items, are patented, I have that column to the left larger than the one to the right.

Now, reading down the column, the columns then show the products made from drugs that are patented on the left and on the right, the products made from drugs that are unpatented. Reading across, first we have the private prescription market. This is the market in which, you know, the family physician prescribes a medicine and the prescription is filled at the drug store.

Down below, I have the institutional market. Since approximately 70 percent of drugs—maybe 60 percent now—are sold in the private prescription market, I have made the first row across larger than the row below it.

(The diagram referred to follows:)

	PRODUCTS CONTAINING PATENTED DRUGS	UNPATENTED DRUGS	
"PRIVATE PRESCRIPTION MARKET"	A	A	
"INSTITUTIONAL MARKET"	A	A	where trade names are used
		B	where generic names are used

Dr. SCHIFRIN. Now, what does this show? Those areas on that diagram that are marked with "A" shows where monopoly power exists. If a product—that is, a preparation—is made from a patented drug, there will be very few sellers, perhaps only one, of that drug. Regardless of whether that drug then is purchased in the private prescription market or in the institutional market, there cannot be price competition because of an unavailability of competitive alternatives.

Thus, all the items in the first column will be "A," the absence of competition.

In the second column, we have drug products containing unpatented drugs. There will be many sellers here. But in the private prescription market, where selection is done by trade name, only those few large firms that can promote trade names are effective sellers. That is, they dominate the market. So they can continue to charge the high prices that accompany trade name products and thus, even though these products contain unpatented drugs, there is an effective monopoly or oligopoly nonetheless.

Now, for products containing unpatented drugs sold to institutional purchasers, I have both "A" and "B" there. If the institutional purchaser for some reason or other continues to do his prescribing, his purchasing, by trade name terms, then the small firms are still cut out of the market.

Thus, only in the institutional market, only for drug products made from unpatented drugs, and only where the purchaser—that is, the institution—considers these items to be generic equivalents and goes on a price basis—only in that small area, "B," is there a price competition in the market for ethical drug products. That represents approximately 5 percent of all drug sales in this country. In other words, all the areas in "A" represent 95 percent of dollar volume of drug sales.

The competitive sphere, "B" is 5 percent, approximately.

The largest two dozen firms account for the approximately 95 percent of total industry sales represented by markets labeled "A"; the remaining hundreds of smaller firms share the 5 percent of industry sales accounted for in market "B."

The past history of the industry can be described as largely one of creating and expanding "A" relative to "B." The continuing goal

of the large firms has been the enhancement of their individual and collective profitability by preserving and expanding those sectors of the market where effective competition does not prevail. This goal is sought in these ways—(1) by making sure that the new drugs that replace older ones, particularly unpatented ones, are protected by patents—even though their patentability might not stand close examination.

Mr. GORDON. You stated before, Dr. Schifrin, that there is a sort of gentleman's agreement among the large firms in the drug industry that, "you won't question my patent and I will not question your patent." Is that a fair summary of your position?

Dr. SCHIFRIN. That does not summarize my entire position.

Mr. GORDON. I mean in the existing situation.

Dr. SCHIFRIN. That is part of the existing situation, Mr. Gordon.

The second way in which the large firms try to enhance situation "A" is by avoiding patent interference suits, which are fairly frequent in the chemical technology industries because of parallel research by the specializing firms, through often elaborate cross-licensing agreements. These agreements, over and above the price fixing that not infrequently has accompanied them, are enacted to avoid the possibility that a party losing an interference suit may challenge the patentability of the discovery.

Mr. GROSSMAN. Dr. Schifrin, could I ask you to be specific about this? You stay that these agreements were made "over and above price fixing that not infrequently has accompanied them."

That is a strong allegation. Could you be specific about this frequent price fixing?

Dr. SCHIFRIN. Well, in recent years, two of the most successful drugs that have been developed, commercially successful and quite important with therapeutic significance, have been meprobromate, the tranquilizer, and tetracycline, the broad spectrum antibiotic. In the case of meprobromate, Carter had the patent. Wyeth had the detail men, et cetera. Carter entered into a licensing agreement with Wyeth for them to also be able to sell meprobromate and to promote it very extensively. Thus for many years the only two meprobromates on the market were Equanil and Miltown. Price fixing in these two companies was found by the courts in recent years and compulsory licensing of meprobromate resulted from that case.

The second of these two examples I use is tetracycline. Just recently, of course, the Federal court found that there was a Sherman Act violation as a result of price fixing. The Federal Trade Commission case that I cited earlier tied the price-fixing agreement very closely to the cross-licensing agreement that brought the five sellers into the market.

Mr. GROSSMAN. I am aware of those cases. You used the words "not infrequently." That is why I wondered if you had other examples and whether the Justice Department has prosecuted either civilly or criminally on price fixing frequently.

Dr. SCHIFRIN. I have a list—at one time, I did compile a list of such cases. They go back to 1940 and I would be glad to provide that information at a later time. It is just a matter of finding the appropriate footnotes.

But I think——

Mr. GROSSMAN. How do you define frequently?

Dr. SCHIFRIN. I would define frequently in that—in this way: have there been found to be enough price-fixing agreements in the industry so that the reasonable observer would examine carefully licensing agreements for instances of price fixing?

Have there been enough violations of the Sherman Act in order to warrant the assumption that there is certainly a definite possibility that price fixing accompanies cross licensing.

Mr. GROSSMAN. You will submit that for the record at a later date?

Dr. SCHIFRIN. Yes.[1]

Mr. GROSSMAN. One other question at this time: I think Mr. Squibb, when he testified, talked about the industry's desire to get into the teaching institutions and therefore to cut their prices to go into these hospitals, to make sure that the young doctors see their product or become familiar with them.

Do you think that the consumer, who I think more frequently buys the "A" products there, is paying for this activity by the industry?

In other words, he is paying a lot more because the industry is cutting these prices in the institutional areas?

Dr. SCHIFRIN. No. I do not believe that the prices to the consumers would be lower than they are if the drug firms did not engage in that activity; no. I believe that the consumer pricing is based, really, on—in fact, I have definite information on what consumer pricing is based on.

I have correspondence from people in drug firms going back quite a number of years and this you mention was never determinant as a factor in setting prices.

Mr. GROSSMAN. Do you think the drug companies make high profits on those sales to institutions at very low levels?

Dr. SCHIFRIN. Yes; I do.

You are familiar with marginal cost pricing. One reason for my belief that the consumer bears the expense of the research and development, bears the expense of the promotion, bears the expense of the large profit. The actual costs of manufacture of most drugs is very, very small. I am sure the price charged to virtually any person covers at least the direct cost of production. The firms are not losing money on those sales to hospitals.

Mr. GROSSMAN. Thank you.

Dr. SCHIFRIN. Careful scrutiny of patentability is a threat to drug firms because there is a sizeable chance that no patent may actually be deserved; without patent protection, many firms can manufacture or obtain the drug, produce preparations containing it, and sell it with subsequent price competition a possibility. In any case, the market will be shared by more sellers than otherwise.

(3) Even where patent protection has not been garnered, trade names accomplish a nominal differentiation largely accepted by phy-

[1] Dr. Schifrin subsequently stated, "In addition to the meprobromate and tetracycline cases, other price fixing cases have been: *U.S.* v. *Eli Lilly and Co.*, USDC (DC) 1941, (insulin); *U.S.* v. *Schering Corp., et al.*, USDC (NJ) Civil Action No. 1919, 1941 (hormone products); *U.S.* v. *Alba Pharmaceutical Co., et al.*, USDC (SDNY) 1941 (imports); *U.S. v. Eli Lilly and Co., et al.*, USDC (NJ) Cr. 173–58, 1959 (Salk polio vaccine)."

sicians, which effectively eliminates any possible competitive threat posed by the generically labeled output of the small firms. Trade names supplement patent monopoly where it exists and substitute for it where it does not.

Thus the large drug firms have used two devices, patents and trade names, to eliminate virtually all tendencies toward price competition. They have led to a different sort of competition—one in which the consumer comes up a loser. Not forgetting the contribution to better health and longer life made by the industry, there has emerged in it a new competition—one that rewards molecule manipulation, questionable patent tactics, excessive promotional claims, and oftentimes a product inadequately tested or cautioned. Such abuses are part of the industry's record, and have generated an increasing surveillance and regulation by the Food and Drug Administration.

Inevitably we come to the matter of public policy in regard to this situation. Specifically, the question as I see it is how to improve the market performance of the industry while not impairing and hopefully even improving its product performance, as I have used those terms. Stated in perhaps a more meaningful way, the question is: How can public policy restore effective competition to the manufacture and sale of ethical drug preparations and thereby make their prices more reasonable, while preserving sufficient incentives for the discovery and development of new and better products?

First, there is the matter of standards of drug patentability. Higher standards than those now prevailing are necessary to halt the routine issuance of patents whose validity is not substantiable in court. Higher standards of patentability will continue to reward true accomplishment and even induce more of it by affording it more protection than is now possible; patents for insignificant or substantial coattail developments or modifications would be eliminated. Such a change would greatly limit the financial gains available from molecule manipulation, but increase the gains from significant discovery, thus redirecting research and development funds away from imitative into innovational channels.

This is the context in which I suggested this commission of experts to assist the Patent Office. I believe they could provide a good deal of influence on this higher standard of patentability for drug patents.

Several years ago the Federal Trade Commission found that the tetracycline monopoly was built on patents obtained with "unclean hands and bad faith." Both the ability to acquire patents in such a manner and the economic motivation to do so must give way. My first specific recommendation, then, is that a special group, representing knowledgeable legal and medical expertise, serve as constultants to the Commissioner of Patents in reviewing and determining drug patent applications.

My second proposal also deals with patents, but is further reaching in its impact. This recommendation focuses on the duration and scope of drug patents, especially pertinent in view of the monopolizing effect of such patents. It is my view that in duration as well as scope, drug patents provide excessive protection from competition, to the detriment of consumers. Accordingly, I offer two alternative plans for making

drug patent protection relate more closely to the realities of this industry. These two plans are alternative policies for the compulsory licensing of drug patents.

The first alternative is to require compulsory licensing of all drug patents after some specified period, such as 3 years.

Three years of exclusive patent protection is a reasonable period in an industry characterized by rapid product turnover and a high rate of obsolescence. Numerous studies have shown that the greatest portion of sales of any product is likely to occur in the first few years after its introduction. Company price policies explicitly take into account these considerations, and most companies, if not all, estimate very conservatively the anticipated market life of their products, usually taking 3 years as the period to recoup outlays and earn a profit.

If licensing were required after the first 3 years of a product's life, that is, after its estimated life expectancy for pricing purposes were ended, there could occur entry by other firms into that product market and, hopefully, competition in price among the rivals. Of course, beneficial results to consumers would be possible only for those products with a therapeutic or commercial life longer than 3 years, but despite the swift product turnover in this industry, data on product sales indicate that the majority of sales in any recent year represents those of products on the market longer than 3 years.

For them, the patent holder would continue earning entrepreneurial profits, though perhaps at a lower rate than before, on his own finished-product sales and those of licensees, and consumers possibly could now purchase their prescriptions at lower prices.

The impact of such a policy on research and development does not seem unfavorable; it provides a time long enough, from the companies own viewpoint, to earn profits justifying the innovational effort. It might even promote greater research and development by inducing even more rapid product turnover. In many cases, a realistic period of exclusive use and compulsory licensing at a fair royalty rate afterward seem unlikely to deter research and innovation.

My second alternative patent-licensing policy focuses on scope, as contrasted with the first alternative and its focus on duration.

This view of drug patents raises the question as to the justification for any period of exclusive patent use. The contention that none is necessary is based on the fact that a drug patent gives its owner a monopolistic position in either of two markets, that of bulk sales, that is, of drug substance itself—or that of dosage form products.

To the extent that he takes his profits in the sale of bulk or in royalties from licenses for its manufacture, he must share the market for finished products; if he retains his monopoly in the latter—the finished product market—he cannot reap profits from bulk sales or licensing, but of course, can earn substantial profits as the sole seller of finished products.

Compulsory sales of the bulk drug or licensing of its manufacture merely specifies that the patent holder must reap his gains in the bulk market rather than the final-product market; it does not take away the opportunity to earn a profit jusifying the effort behind the discovery. And entry into the preparations market would occur at the

time when the item is introduced, rather than 3 years later, and competition can possibly come into play that much earlier.

Perhaps in this plan the royalty might have to be higher than in the earlier approach, but not by so much as to prevent licensing from being an effective check against exorbitantly high bulk prices.

Patentees would earn reasonable and adequate profits by charging attractively high bulk prices or by imposing the most favorable royalty rates permitted. But the cost of bulk ingredients is usually only a small fraction of the total cost of production, and high bulk costs or royalties would be more than offset by the economies in resource use, particularly reductions in the vast and largely wasteful advertising effort, and the more reasonable profit margins that price competition would bring about.

Compulsory licensing, because it permits rival firms to enter into the market, thus is a necessary condition if price competition is to be restored to the industry. But it is not a sufficient condition for that competition to arise, it opens the door to the entry of additional firms into markets closed by patents but it does not make them effective competitors of the dominant one or few.

I come then to my last major recommendation—the prohibition of trade name designations. Trade names, as you well know, are those unique company names for its products—simple, catchy, and easily remembered—Syncillin, Achromycin, Tetracyn, Pen Vee, Miltown, Ledercillin, Orinase, and on and on and on throughout the catalogs of the large drug houses. Such names are totally unnecessary in every respect. If differentiation of drug products is necessary, and I am not fully convinced that it is, let it be done not through a proliferation of new names that are intended to displace generic terms for the product, but in the same way as differentiation is made in virtually every industry, by the use of the manufacturer's name. Thus, the names "Carter: meprobromate" and "Wyeth: meprobromate" tell us much more than do the words "Miltown" and "Equanil," while preserving company differentiation.

(These statements of mine parallel very closely the testimony of Dr. Garb on June 20.)

The use of brand names that combine the company and generic comparability becomes clear and unobscured, contrary to the purpose and effect of trade names.

The elimination of trade names will go far in establishing the facts of generic similarity to physicians. Those doctors who want to select the speciality of a particular firm can continue to do so by using the brand name; but those who feel, as many do, that generic equivalents are therapeutic equivalents can thus prescribe by generic name alone, or by the brand name of a reputable seller whose product bears a competitive price tag.

These three proposals of mine—a special drug patent board, some form of compulsory licensing, and the elimination of trade names—can, together, go very far in restoring opportunities for competitive entry into markets, in restoring price competition in the place of wasteful and often harmful promotional competition, and in bringing about reasonable prices to consumers, while preserving the incentives for the research and development effort behind the industry's generally commendable product performance.

The opportunities for extraordinary profits still exist, but only for innovation or discovery of therapeutic merit—not through monopolization of markets and exploitation of consumers who have no alternative but to pay prevailing prices.

All this seems to me to represent a considerably more acceptable situation than now prevails in the ethical drug industry.

Lest the tone of my proposals, or the spirit in which I offer them be misunderstood, I would like to offer a sort of epilog to my prepared statement.

I do not view Government as something necessarily separate from the citizenry of this country, nor do I view it as a monolithic force seeking to create for itself an increasing power over the individual persons or business firms in our economy. I firmly believe that, as a Nation, we have maintained a prima facie case for individualism, for free enterprise, and for the free market economy.

But our economy, as other facets of our society, requires a system of checks and balances to prevent the generation of private economic power and its subsequent abuse. Our general commitment to competition is based on the importance of the checks and balances that competition imposes on the pursuit of economic self-interest, thus channeling the operation of the economy in a direction that serves the interests of society as a whole.

But the absence of effective competition in most sectors of the drug industry must be recognized, and its implications in terms of that industry's operations have been the basis and the main concern of this committee's hearing.

The large firms in this industry have acquired an economic power incompatible with our conception of a free market economy; opportunity is severely limited for the many small firms in the industry, and the purchasers and consumers of ethical drug products are denied the benefits of competition in the manufacture and sale of those products.

Even if we opposed only the abuse of such power, rather than its existence, the ethical drug industry has not restrained itself in any significant way. The profit record of the industry, unjustifiable by any of the accepted standards of economic performance, attests to this lack of restraint. Wastes in promotion and other aspects of development, manufacture, and sale add to the costs imposed on society because of the absence of effective competition.

Thus, in the absence of restraints on individual power through market competition or self-imposed restraints, it falls to Government to induce an improved total performance from this industry. This, as I see it, is a proper and necessary role for Government in the economic field, and a role not at all incompatible with our commitment to a free enterprise economy.

I believe we have come a long way in our understanding of the factors contributing to both the positive and negative aspects of this industry's operation and performance—and that we can devise appropriate changes in the context of its operation that will greatly enhance its total performance, while preserving the incentives necessary for its existence and growth.

At this point, Mr. Chairman, I would like to request that a recent article of mine, "The Ethical Drug Industry: The Case for Com-

pulsory Licensing," the Antitrust Bulletin, fall 1967, be included in the record of these hearings in the appropriate place, for its relevance to the proposals I have made.

I thank you for honoring me with the opportunity to make these remarks to you and for your kind attention in my presentation of them to you.

Senator NELSON. The article on the "Case for Compulsory Licensing" will be printed in the record at this point.

(The material referred to follows:)

[From the Antitrust Bulletin, fall 1967]

THE ETHICAL DRUG INDUSTRY: THE CASE FOR COMPULSORY PATENT LICENSING

(By Leonard G. Schifrin*)

Introduction

On December 7, 1959, the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, then popularly known as the Kefauver Committee, shifted the focus of its investigation of administered prices in the American economy to the ethical drug industry.[1] In the Spring of 1967, the monopoly subcommittee of the Senate Select Committee on Small Business began hearings on ethical drug prices, particularly on the often large price differential between finished products sold under company-assigned brand or trade-names and finished products of the same generic designation sold under the chemical or generic name,[2] an issue originally raised by the Kefauver Committee. In the seven-and-a-half years between the first and the most recent Senate hearings, at least nine other series of hearings dealing with this industry have been conducted, and at least three additional committee reports or studies have been submitted to Congress. Some legislation has resulted from this extensive examination, but the only action of real substance, the Drug Amendments of 1962, deals mainly with questions of drug safety and perhaps owes its passage as much to the Thalidomide tragedies in Germany and other European countries as to the economic and medical issues raised in these many hearings.

Despite the lack of legislative accomplishments, the time and attention spent in scrutinizing this important industry have, for the most part, been productive The industry grew to maturity without drawing attention to its practices and performance, perhaps because of its close relation to the medical industry which traditionally does not publicize its economic activities or perhaps because of its continuing high profitability. The investigations, however, have revealed flaws in its operation, specifically its wasteful use of resources in promotion and research, the dubious contribution of some of its output, and the uneconomic relationship between the costs and prices of its products. In the years in which the industry has been so frequently studied, public concern regarding the health services and products available to consumer-patients has grown: Medicare has become part of our Social Security law; support for the construction of health facilities has multiplied significantly. These activities are, of course, only part of our growing concern for ever more numerous facets of the quality of human life. To the extent

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[1] It is symbolic of the character of the ethical drug industry that the term "ethical drug" itself has become obsolete. Drugs, technically, are the active ingredients which go into dosage-form products or pharmaceutical preparations, rather than the products or preparations themselves. Now, however, the large majority of all preparations are prefabricated, i.e., already in dosage form when sold to pharmacies and doctors. Hence, the modern ethical drug industry includes firms primarily engaged in the fabrication, finishing, or sale of drug products or preparations in finished dosage forms such as pills, capsules, tablets, etc. Although the industry would be more accurately described as the ethical-drug-products or preparations industry, common usage still retains its now-dated designation.

[2] All ethical drugs have generic, i.e., common or chemical, names. In order to distinguish their items from rival products with the same generic designation, some firms (mainly large, prominent ones) employ trade-name or brand-name designations as well. A trade name is an original, trademarked, name assigned by a firm to its own item, such as Lederle's use of the trade name Achromycin and Pfizer's use of the trade name Tetracyn for the tetracycline capsules each produces. Brand names, which combine the product generic name and the name of the producer or seller, are used less often than trade names. Examples of brand names are "Cortisone: McKesson and Robbins" and "Armour Thyroid."

that Congressional attention has fostered and promoted this central goal of public policy, the examination of the ethical drug industry has been a worthwhile endeavor on its part.

To the economist concerned with the relationships among market structure, industry behavior, and economic performance, important findings have been added by these hearings and reports to his catalogue of knowledge. This knowledge serves him well, for it strengthens his understanding of the forces contributing to the desirable and undesirable aspects of market performance. Conclusions already suggested by other industry studies have gained additional substantiation; other tentative conclusions have been amended, qualified, or rejected in the face of new knowledge gained from these investigations. Most important, we have come closer to an understanding of the determinants of market performance and the manifestations of their influence in this industry.

This paper has as its frame of reference this economic approach. Its goals are two-fold: first, to evaluate the performance of the ethical drug industry on the basis of the material presented in the various hearings and other sources, and, second, to suggest how substantial improvement in this performance can be achieved through amendment of the patent laws applying to drugs.[3] The thesis presented is that compulsory patent-licensing is essential for the needed improvement in the "market" performance of the industry (where market performance refers to those aspects of the industry's activities that determine the cost and profit elements covered by the prices consumers pay for finished products). It will also be argued that such a patent policy will not impair, and may even improve, the industry's product performance (where product performance refers to those aspects of the industry's activities that contribute to better health through the flow of new products to consumers as a result of research and development expenditures).

I. THE SALIENT STRUCTURAL AND BEHAVIOR FEATURES OF THE INDUSTRY

The ethical drug industry can trace its lineage back many decades and even centuries to the fields of chemistry, pharmacy, and medicine. Nonetheless, in its present form it is a young industry, arising out of our break in World War I with Germany, on whose sophisticated and knowledgeable chemicals industry we were then dependent for our drugs. Building on the foundation afforded by wartime successes in drug synthesis and manufacture, medical science and drug therapy began a co-operative effort that soon led to the discovery of insulin in 1921 and its commercial manufacture the next year. There followed discoveries and development of sex hormones; vitamins, first from natural sources and later by synthetic processes; barbiturates; germicides; intravenous anesthetics; improved forms of sulphanilamide; the commercial manufacture of penicillin; and then advances in the whole area of antibiotics. In the post World War II period, successes came more and more quickly: steroid hormones; tranquilizers, antidepressants, and other mental drugs; oral antidiabetic drugs; polio and measles vaccines; oral contraceptives; and a host of other new types of drugs.

The development of new products has been the main source of the industry's growth. The rapid expansion of the industry's output, to a current domestic level of $3 billion per year at the manufacturers' level, is one measure of the increasing success that the industry has had in its research and development activities and the applicability of its discoveries to an expanding range of illnesses and injuries. But of equal significance to its rate of growth of output are the characteristics which the industry has acquired as it has matured.

A. The emphasis on "specialties"

In the late 1940's and early 1950's the ethical drug industry faced serious problems. The discoveries of penicillin and streptomycin caught the attention of many firms. Penicillin, a so-called "product of nature," was unpatentable; the streptomycin patents were held by Rutgers University and freely licensed. As a result, markets for these products were easy to enter. The government encouraged the expansion of facilities, and new production methods greatly increased yields. The combined result of these factors was a large overcapacity in the pro-

[3] It is important to note that drugs, which, technically, are the active chemical substances in drug products, are patentable, as are the processes in drug and drug-preparation manufacture. The finished products are notpatentable per se, although the brand or tradenames under which they are sold are copyrighted.

duction of products containing these drugs, drastic price competition in their sale, and, frequently, sizeable losses.

The situation was chaotic from the producers' point of view. With many firms manufacturing items of generic equivalence and selling them under generic labels, the only form which competition could take was in price. The major firms soon realized that shifting the basis of competition to some form other than price and reducing the extent of competitive rivalry were the keys to increased profitability. Thus each of the large firms turned its attention to the production of "specialties," i.e., differentiated and hopefully, exclusive items. The emphasis on specialties had two manifestations: the increased reliance on obtaining patents covering new drug discoveries, and a shift to the use of trade-names for the items, both old and new, in company catalogues. Both of these pursuits have been impressively successful. Few of the many drugs discovered and developed since 1950 have not been protected by patents awarded to private firms; and reliance on trade-names in prescribing drug products has become the rule rather than exception, particularly in the dominant private-prescription market, in which private physicians prescribe medicines for patients, to be purchased at drug stores.

As a consequence of the shift to specialties, the three dozen largest firms in the industry, which represent about five percent of the total number of firms but account for over 95 percent of all research activity and selling outlays, have come to dominate the industry. These few firms account for virtually all the significant research advances coming from within the industry; have acquired patents on the large majority of new drugs; and have successfully induced physicians to make product choices in trade-name terms. The growth of patents and of trade-name use have effectively changed the nature of competition in most of the industry's markets from frequent and substantial price competition to competition in product development and promotion and advertising. Price competition is quite a rare phenomenon in all but a few limited instances. Presently, only institutional purchasers—mainly hospitals and government agencies—employ generic designations to any substantial extent. "Specialties" have accomplished their primary purpose.

B. The industry's research effort

The high rates of new-product introduction and rapid obsolescence that characterize most drug markets give testimony to the size and effectiveness of the industry's research effort. Even in those cases where discoveries were made in universities (e.g., Salk vaccine) or government-sponsored research (e.g., penicillin), it usually has been the developmental work done by drug firms which made the product commercially available. This is not surprising. The drug industry is the most research-conscious of all non-defense industries, with more company-financed research and development in relation to sales than any other industry. In 1964, the all-industry totals for research and development expenditures as a percent of sales was 4.4 percent; for drugs and medicines, 4.7 percent. For company-financed research and development, moreover, the all-industry total was 1.9 percent, as compared to 4.5 percent for drugs and medicine.[4] For the period 1956 to 1964, the average annual increase in research and development expenditures for the drugs and medicines industry was 13 percent, compared to an economy-wide increase of slightly less than 10 percent in total industry expenditures and between six and seven percent in total company-financed expenditures.[5]

Furthermore, while it is true that most research and development expenditures in the drug industry are for applied research and product development, the drug industry devotes a greater proportion of its research budget to basic research than does the economy as a whole or the industrial sector.

For the drug industry, then, research and development expenditures have shown marked increases in recent years, compare quite favorably with expenditures in other industries in relation to sales, and are devoted to basic research, not just product development. The research and development record of the drug industry is commendable.

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[4] National Science Foundation, Basic Research, Applied Research, and Development in Industry, 1964, Washington, D.C.: U.S. Government Printing Office, 1966, p. 62. There are several industries that have greater research and development expenditures relative to sales than the drug industry. These industries, however, are in scientific, military, and engineering fields and receive the bulk of their funds from the government.

[5] Ibid., p. 62.

C. Product introduction

One prominent result of the extensive research effort of the industry is the market impact of the large volume of new items introduced annually. In any given year, most drug sales are likely to be accounted for by items introduced in the preceding five or six years. However, many products have a longer commercial life, and any decline in their share of total sales may be due as much to the acceleration of total sales through the introduction of new products as it is to their actual displacement by newer items. Nonetheless, market success is not an inevitable result of research and discovery or of new product development, and no more than a short life is assured to those products that are well received initially.

D. Promotion and advertising

Just as a large part of the industry's research effort reflects its efforts to develop patentable specialties, much of its outlay for promotion and advertising [6] reflects its efforts to establish trade-names as a basis for prescription writing. In the case of research, no doubt the conquering of illness and legitimate profit considerations are complementary factors. In the case of promotion and advertising, the important need for conveying technical information to physicians so that they may employ drug products with maximum effectiveness is a reason which complements profit considerations.

A number of factors in medical practice have rendered physicians increasingly dependent on producers as their major source of information. Among these factors are the proliferation of products containing new and older drugs; increasing specialization; increasing demands on doctors' time; the time-lag in the publication of journal articles; and the fact that most of the pre-introduction testing of new products and the continued testing of older products is done by or under the supervision of the drug firms themselves. All of these factors have contributed to the growth of the promotional element of selling costs.

The responsiveness of physicians to the use of trade-names is both result and cause of a large-scale advertising effort. As a consequence, advertising outlays have grown at a pace at least equal to promotion. Expenditures for advertising and promotion now account for roughly 25 percent of the sales dollar and one-third of total costs of production of large firms. Selling outlay ranks second only to the rather inclusive category "cost-of-goods-sold" as a cost component and is about four times greater than the research effort of which the industry is so proud. The advertising element alone is approximately twice that of research and development for the typical large firm. Few other industries compare closely with this in advertising effort relative to sales.

E. Market concentration

Of the 700 firms in the industry, the twenty largest account for more than 90 percent of total sales, and another dozen or 15 account for half of the remainder. The high costs of research and development and of effective promotion of trade-names have set the large firms off from their many smaller rivals. The new products come almost entirely from these few large firms; in the markets for older products, the popularization of trade names has rendered the firms selling generically-designated items ineffective as competitors. Only in the production of products containing freely-available bulk drug ingredients (which are diminishing in relative economic importance) and in sales to those institutional buyers who purchase by generic designation can the many small firms participate. In all other market situations, the large firms dominate the picture.

This uneven division of shares of total industry sales between large and small firms is but one dimension of concentration. Concentration is an even more meaningful concept in individual product areas than it is for the industry as a whole, for it is this aspect of structure that conditions price policies and the nature and extent of market competition. Among the large firms there has emerged a pattern of specialization that tends to break them into smaller, rather exclusive groups, each group sharing a product area such as antibiotics, or steroid hormones with little fear of entry even by other large firms.

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[6] Promotion and advertising are interrelated activities, but separable in concept, function, and perhaps also in magnitude. Promotion, in essence, is the conveying of technical information about drug products that makes possible their use in therapy. Advertising is mainly directed at establishing and reminding physicians of the trade-names of company specialties. Estimates within the industry indicate that total selling outlays are divided roughly evenly between the two categories.

Thus, as patented specialties occupied a growing prominence in drug markets, and as the high costs and cumulative nature of research effort induced specialization by drug firms, drug markets increasingly became oligopolized by the few large firms specializing in each of the different areas of research and production. While the exact order of firms in a market may change, the positions of leadership are effectively preserved for the large firms specializing in that area. Concentration thus tends to be both high in degree and stability. Even in the case of those older (and a small number of newer) products not protected by exclusive patents, large firms, with their trade-named specialties and their successful promotion campaigns, have come to dominate sales.

As an example, in antibiotics—the largest of the various ethical drug classes—there are but ten prominent sellers and even they are unevenly participative within the area. Only six of them are important manufacturers of broad-spectrum antibiotics, and only five (including three of the broad-spectrum oligopolists) engage in the manufacture of the leading medium-spectrum products. There are many firms producing products which contain the older, unpatented penicillins, but an estimated 70 percent of all such sales are accounted for by Lilly, Wyeth, Abbott, and Squibb, four of the ten major firms. Comparable concentration is to be found for other antibiotics, including streptomycin and dihydrostreptomycin, penicillin-dihydrostreptomycin combinations, and penicillin-sulfa combinations. A similar pattern of high concentration can be found in the manufacture of hormone-drug products, mainly the cortical steroids, where seven firms dominate the market.

The same high degree of concentration is to be found in virtually every other product area in the industry. In the most recent study of market concentration in the drug industry, the four largest firms in each of 13 major product areas accounted for between 60 and 80 percent of sales, sometimes substantially more and rarely less.

The main characteristics of the ethical drug industry—its emphasis on specialties, its large research and selling effort, the growing patent protection afforded its developments—have changed the structure and nature of rivalry very much since the penicillin era. But high concentration and a changing nature of competition are one thing, and undesirable market performance and the need for corrective policy changes are another. Judgments based only on industry structure and the over-all nature of rivalry may be unwise; thus, it is to an examination of the various dimensions of the performance that is conditioned by these factors that we must now turn.

II. INDUSTRY PERFORMANCE

There are many dimensions and facets to the performance of industries and the markets in which they function. Perhaps it is best to consider those of the ethical drug industry and its markets as being of two main types. These groupings, as noted earlier, may be called product and market performance criteria, respectively.

A. Product performance

On the product side, the main concerns are the efforts to develop new and better drugs, the increasing availability of these drugs, and their impact on life and health.

The large outlays by the industry for research and development have already been discussed. In both absolute and relative terms the industry is justly proud of its emphasis on basic and applied research. While certain qualifications concerning both the magnitude and quality of this effort may be in order, on the whole the industry's research input is impressive.

The results of this activity have been substantial. In the sixteen year period 1948–63, the total new products introduced amounted to 5,386.[7] Most of these new products were duplicate items of products already on the market, new dosage forms of previously known drugs, or new compounds. 618, however, contained chemical entities not previously known (as did an indeterminate number of the new compounds).[8] All of these, including the duplicate single products, may

[7] Study of Drug Purchase Problems and Policies, U.S. Department of Health, Education, and Welfare; Washington, D.C., U.S. Government Printing Office, 1966, p. 11.
[8] Ibid.

represent contributions to improved therapy. All increase the range of choice for physicians; many represent new alternatives and some represent breakthrough discoveries into areas where no effective products had been available previously.

The benefits of the new drugs cannot easily be measured, since most drugs provide symptomatic relief rather than cures. While the reduced hospitalization and shortened durations of incapacity may be quantifiable, within limits, the great reductions in suffering can only be recognized in general. We do know the preventive and curative drugs have greatly reduced the incidence of certain illnesses. Influenza, tuberculosis, pneumonia, and syphilis no longer are the severe killers they once were. The childhood diseases of measles, meningococcal infections, whooping cough, gastritis, duodenitics, colitis, and enteritis have been brought under control. Poliomyelitis is no longer the great crippler it had been. Steroid hormones have greatly reduced the pain and crippling effects of inflammatory diseases, particularly arthritis. Tranquilizers and other drugs have done much to reduce the seriousness and the hopelessness of mental illness.

Indeed success over illness has become an expectation by the public, and this expectation has been considerably met by the industry. These contributions by the drug firms in the form of new products warrant the industry's pride in its accomplishments and its recognition by society. Added to this record is the rapid expansion in the industry's productive capacity and output, which has made both new and older products available in increasing quantity.

Yet, while the achievements in research and development effort, new product introduction, and expansion in output have been impressive, certain criticisms of both the magnitude and quality of these activities must be noted.

It is apparent that the industry exaggerates its research and development effort, perhaps to convey an impression of extreme risk, or competitiveness, or exceptional enterprise, with the purpose of justifying high profits. The industry, when speaking of its research and development activities to stockholders or to the public, defines them very broadly, being far more inclusive than the Internal Revenue Service or National Science Foundation. For example, industry spokesmen appearing before the Kefauver Committee put the 1959 research and development outlay at $198 million; the NSF figure for that year was $154 million, or 22 percent lower.[9]

Not only does the industry over-estimate the quantity of this activity, but many critics, including a large number within the medical profession, have questioned its nature and direction. There are serious allegations that much research activity is not related to product improvement but is imitative in nature, so as to generate specialties that are not really needed, or is directed toward the acquisition of patent protection. Furthermore, it is contended that the great profit potential awaiting new products induces their introduction before there is sufficient knowledge of their limitations and dangers.

These allegations have been at least partially substantiated. It has been shown above that duplicates, new dosage forms, and mixtures represent the large majority of the products being introduced, and the therapeutic advances they represent may not be very great. Many of the new single chemicals, it has been claimed, represent no significant progress in drug therapy. It would seem, then, that only a few "new products" represent real progress. Further, if research outlays in certain ways are excessive, in others they may be inadequate. When the Food and Drug Administration raised the standards for testing of new drugs as a response to the Thalidomide experience, the number of new drug applications and of approved new products declined sharply.

Certainly the behavioral patterns and motives that are alleged to lie behind these criticisms of the industry are compatible with the structural and other features of the industry noted earlier. These are important criticisms of the industry's product performance and must be taken seriously.

It thus seems likely that the industry's product performance is not as great as claimed, nor is it as great as it might be with a re-direction of its research and development effort. Despite these qualifications, the available data support the conclusion that the industry has contributed greatly to people's lives and indirectly to the economy. For these contributions the industry deserves great credit, whatever the flaws that exist in its structure and operation.

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[9] *Research and Development in American Industry, 1962*, Washington, D.C.: U.S. Government Printing Office, 1963, p. 9.

B. Market performance

The other side of performance is what we have called market performance. Though it is related in varying degrees and manner to product performance, such a distinction is a useful one for this study. Market performance concerns primarily the efficiency with which the industry uses the economic resources available to it in the development, production, and marketing of its output, and the relationship between prices charged and costs incurred in making goods available to consumers. The criteria of good market performance are quite traditional in economic analysis:—that (1) the costs incurred by sellers be closely related to activities from which consumers derive benefit, be they expenditures needed to develop new and better products, direct and indirect cost of manufacture, or marketing outlays that lead to better product selection or expansions in demand that justify larger-scale, but lower-cost methods of production; and that (2) the prices consumers pay bear a reasonable relation to these costs; that is, prices provide profit margins that are sufficient to reward enterprising firms for activities that serve consumers, but not so large as to represent gains from behavior not in the consumers' or society's interest.

These criteria are now used to evaluate the drug industry's performance. First, in regard to the cost elements it has been indicated above that research and development and selling outlays are large, although quite unequal. Further, criticism that the research outlay is, at least in part, wasteful has been noted. While the extent of such waste from misdirection of outlay may not be closely determinable, there appears to be logical support for the contention that the goal of obtaining patentable specialties may conflict with that of achieving maximum therapeutic gain from research effort, particularly since the commercial rewards for "new" products are sizeable. Protection of an oligopolistic position by imposing patent barriers around existing key products and processes also seems to influence the direction of research effort to some extent. Again, the question as to frequency and extent of wasteful research effort is incapable of precise answer; yet the large financial rewards awaiting new products, coupled with the large promotional outlays preceding, accompanying, and following their appearance, means that significant therapeutic progress need not be a necessary condition for large profitability.

Second, as noted above, selling expenses in the industry are about four times as large a cost factor as is R & D. The promotion part of selling and the advertising element are roughly equal and each is twice the R & D component. Promotion and advertising, both of which may be important marketing functions, nonetheless include very costly outlays for activities that may provide the consumer no benefit, directly or indirectly, or may actually do him a disservice. There is considerable opinion that promotional excesses are closely related to the appearance of new products that are of limited merit but which might become profitable through large-scale promotions.

The costs of promotion are, perhaps to a large extent, necessary under present institutional arrangements. Physicians have, for reasons already noted, become dependent on drug firms for their information on new products. Thus much promotional effort, particularly that providing information on new and old products, on the incidence and nature of side effects, and on other technical matters, is necessary. But advertising, whose function is to popularize and remind physicians of trade-named specialties, serves merely to raise the costs that ultimately become part of prices while not improving the drug selection process. Also, the quality of information conveyed has been questioned, largely by the physicians at whom it is directed. Incomplete information, excessive claims, and non-reporting of side-effects are frequent among their criticisms. Thus, advertising may even be detrimental to sound drug therapy.

That there is excessive, wasteful, and mis-directed expenditure for research and promotion in the industry, and that such waste is of sizeable proportions has been reported numerous times in the hearings involving the industry. Prices conditioned in large part by these costs are, therefore, necessarily higher than they otherwise would be.

Drug prices are uneconomically high for another reason. They provide drug firms with profits that are consistently well above those of most other industries. There is little justification of the profit levels that prevail. With rapid turnover of products and successful research results uncertain, the industry has been described as one of high risk, in which fortunate firms can be expected to earn

substantial returns. Yet the evidence that high risk exists would require low profits for the unfortunate firms, and such evidence is not apparent.

Table 1 shows data for profits in the drug or pharmaceutical industry [10] compared to broader aggregative groupings for the past decade. The data show quite clearly the continuing and substantial above-average profitability of drug manufacture and sale.

TABLE 1.—ANNUAL RATES OF RETURN AFTER TAXES ON STOCKHOLDERS' EQUITY, DRUG INDUSTRY AND ALL MANUFACTURING CORPORATIONS (EXCEPT NEWSPAPERS), 1957–61; PHARMACEUTICALS AND ALL INDUSTRY, 1962–66

[In percent]

	Drug industry	All manufacturing corporations (except newspapers)
1957	18.6	10.9
1958	17.7	8.6
1959	17.8	10.4
1960	16.8	9.2
1961	16.7	8.8
	Pharmaceuticals	**All industry**
1962	14.4	8.9
1963	14.7	9.1
1964	16.3	10.5
1965	18.0	11.8
1966	20.3	(1)

[1] Not available.

Sources: 1957–61 Federal Trade Commission—Securities Exchange Commission Quarterly Financial Report; 1962–65 Fortune Annual Directory of 500 Largest Industrial Corporations; 1966, Federal Trade Commission, cf. New York Times, June 4, 1967, p. 14F.

Within the drug industry, company profits for the recent past not only are high on the whole, but fairly stable. For example, in the decade 1952–61, for 18 of the largest drug firms for which data have been obtained, the average after-tax rate of return to net worth was 18.5 percent: Only four firms earned below 10 percent, a reasonable estimate of the all-industry average, as based on Table 1, at any time in this period. Of these four, Mead-Johnson fared below 10 percent (9.3 percent) only in 1952; Merck had annual profits of 9.6, 8.9, and 9.6 percent in the first three years and averaged 15 percent in the last seven; Bristol-Myers had annual profits of 7.1, 6.8, and 9.3 percent in each of the first three years and averaged 16 percent in the last seven. Olin-Mathieson is the fourth. It entered the industry with its acquisition of Squibb in 1955, and, in the seven years within this period in which it participated in drug manufacture, had profits below 10 percent in four. But Olin-Mathieson is a large conglomerate firm, and its drug operations are a small part of its total activities. Merck, Mead-Johnson, and Bristol-Myers are also conglomerates, though in lesser degree, owing to their sizeable activities in bulk chemicals, dietary products, and proprietary drugs, respectively, and in each case the drug-operations of these conglomerates have been substantially more profitable than other operations.[11]

These and other data show that profits in the drug industry as a whole, and for the large majority of its leading firms, rank substantially and consistently above those of industry in general. Examples of unstable or occasionally below-average company profits are difficult to find. Thus evidence in support of the existence of a high risk element facing the large firm is lacking.

Another defense of the industry's high profits is that these profits are needed to finance the industry's large research effort. But, as we have seen, the research

[10] The data for the "drug industry" and "pharmaceuticals" include both ethical and proprietary (non-prescription) products. Since ethicals account for 70 percent or more of total pharmaceutical sales, however, the inclusion of proprietaries does not seriously distort the accuracy of the data.

[11] Subcommittee on Antitrust and Monopoly, Senate Committee on the Judiciary, *Administered Prices, Drugs, Report,* Washington, D.C.: U.S. Government Printing Office, 1961, p. 63.

effort is not as large as is often suggested. Nor is the argument a logically valid one. Profits represent the difference between revenues and full costs, including research. To add to costs an additional element for future research (which, of course, will also be paid for by future sales) is to charge consumers twice for the research component.

Another point suggested in regard to profits is that the profit record of the industry may reflect the continuing success in new product development by all major firms. But many of these new products, including a few that have had the greatest impact on profits, are produced under license and do not reflect the firm's own research. American Home Products and Smith Kline and French consistently have been among the most profitable firms not only in the drug industry but in all industry as a whole. For each, one or two ethical items dominates the product mix. American Home Products' (Wyeth) leading ethical specialty is Equanil, manufactured and sold on license from Carter. SKF's leading specialties are Thorazine and Compazine, made and sold on license from Rhone-Poulenc of France. Most major firms sell a number of specialty items containing bulk drugs purchased from patent holders or manufactured on license from them. Furthermore, superior profitability is not limited to new product success. A number of firms, e.g., Abbott, Parke, Davis, and Richardson-Merrell, have contributed few significant developments in recent years, yet their profit rates have consistently been well above that of most firms in the economy. It is noteworthy that Parke, Davis' profit rate was substantially above the all-industry average in those years when its one major development and leading sales item, Chloromycetin, was temporarily but almost virtually off the market because of the appearance of drastic side effects.

Certainly an alternative thesis that is equally plausible is that high profits are due to meager competition in most of the industry's markets, including the entire private-prescription market and most product areas of the institutional market. The weakness of competition is largely attributable to the fewness of competitors which results from the patents on most new discoveries, from limited licensing, and from financial and technical obstacles to entry. Patents and limited licensing are, of course, in accord with public policy. And many of the criticisms regarding wasteful cost elements, excessive and inaccurate promotion, and unjustified profitability have been directed toward many industries. But the operation of the ethical drug markets warrants special concern and special public policy measures for a number of reasons.

First, there is the fact that health is at stake. New products which confuse drug selection, and "information" and claims that mislead, may impair drug therapy and harm the public.

Second, the peculiarly exploitable nature of the patient-consumer, which is conditioned by his need for drug products and the fact that physicians rather than consumers make product selection, renders the reasonableness of drug prices particularly important. The greatest harm befalls those who are unable, because of prices higher than necessary, to afford all the medication they need.

III. PUBLIC POLICY

The essential question is how to reduce the wasteful outlays by firms and the excessive profit margins and pass these reductions to consumers without impairing new product development. The answer lies in inducing those changes in the structure and operation of drug markets that will generate price competition, while retaining the availability of rewards sufficient to promote the discovery and development of new and better products. A number of co-ordinate policy changes are necessary.

First, free entry into finished-product markets must be encouraged for entrants who can become effective competitors of the established oligopolists. A substantial increase in sellers is likely to lead to more vigorous competition, particularly in price, and the elimination of wasteful and uneconomic practices. For entrants to become effective competitors, the barriers posed by patents on drug ingredients must be lowered and the use of trade-names in prescription writing must be prohibited. Stricter quality controls by the FDA and its requirement of more prominent mention of generic names in labelling and advertising have perhaps already laid the groundwork for an increased use of generic terminology in prescription-writing; recent publicity regarding the large differentials usually found between generically labelled items and trade-named special-

ties hopefully will spur further efforts in that direction. Better and more accessible information from professional rather than industry sources may reduce the impact of advertising on physicians, thus reducing the magnitude of its use. Higher FDA standards for new drugs will reduce the appearance of new items of little need, thus eliminating mis-directed research and development expenditures and the promotional outlays and abuses that sometimes accompany them. These and other changes need to be effected for an improved industry performance. The net result of these changes can be the selection of items by physicians on the basis of price rather than company identification.

The pertinent question remaining is how to reduce the patent barriers to entry without dangerously weakening the incentives for research and development. The economic philosophy behind our patent system is that monopoly grants of a temporary nature and of limited scope, while perhaps creating imperfections that temporarily mitigate price competition, serve as inducements for rivalry in research and development which provide long run benefits to consumers that more than offset the temporary mitigation of market price competition.

Antitrust decisions have defined the limits of patent protection by condemning tying restrictions and other devices which owners of patents valid in one market have used to reduce competition in other markets. Flagrant abuses of patent rights, such as practiced by the United Shoe Machinery Company, have led to imposition of compulsory licensing on the offending firm. While compulsory licensing has been imposed to date only as a punitive measure on flagrant violators of the antitrust laws, the special importance of the drug industry to society's well-being and the critical flaws in its structure and behavior warrant the adoption of special drug-patent policies that include compulsory licensing as a general condition. This policy is a necessary condition for improved industry performance in terms of costs, profits, and also in the critical matter of prices. Together with other policy changes already adopted or proposed, that induce physicians to prescribe generically, complsory licensing may also be a sufficient condition for improving substantially the market performance of the industry.

It is doubtful that the continuation and advancement of drug research would be impaired by such modification of drug patents. The industry is characterized by rapid product turnover and obsolescence; studies have shown that the greatest portion of sales of any product is likely to occur in the first few years after its introduction. Company price policies explicitly include these considerations, and most, if not all companies, estimate quite conservatively the market life of their products, taking three years as the average period to recoup outlays and earn a profit. If licensing were required after the first three years of a product's life, the period taken as the estimated life expectancy, entry into the market and the price competition it would create could contribute to lower prices and profitability after the patent holder has earned a profit justifying his innovation. Of course, the beneficial results would be confined to those products with a commercial life greater than three years. Although product turnover is swift, data on product sales indicate that the majority of sales in any recent year represents those of products that had been on the market longer than three years. For them, the patent holder would continue earning profits, though at a lower rate, on his own finished-product sales and those of licensees, and consumers would be able to buy at lower prices. In regard to the impact of the proposed policy on research and development activity, it might generate even greater effort by inducing swifter turnover. In any case, a realistic period of exclusive patent use and a fair royalty rate afterward seem unlikely to deter research and innovation.

Another view of the role of drug patents raises a question as to the need for any exclusive use period. The contention that none is necessary is based on the fact that a drug patent gives its owner a monopolistic position in either of two markets, that of bulk sales or that of dosage-form products. To the extent that he sells a drug in bulk or licenses is manufacture, he shares the market for finished products; if he retains his monopoly in the latter, he cannot reap profits from bulk sales or licensing. Compelling bulk sales or licensing would require the patent holder to rely on the bulk market for his innovational profits, and would promote price-competition in the finished product market at the time when the item is introduced, rather than after a few years as in the above scheme. In this plan, the royalty rate would have to be higher than in the previous scheme,

but not by so much as to prevent licensing from being an effective check against exorbitantly high bulk prices. Patentees would earn sufficient profits by charging high bulk prices or imposing the most favorable royalty rates permitted. But the cost of bulk ingredients is only a small fraction in total cost of production, and high bulk costs or royalties would be more than offset by the economies in resource use and by the smaller profit and selling elements in drug prices that price competition would bring about.

Either of these proposals would lead to lower prices for consumers while maintaining the profit incentive for drug discovery and development. Of the two, perhaps the first is more feasible politically, but that is another consideration, for examination at another time.

Senator NELSON. I want to thank you very much for a most thoughtful and valuable contribution to these hearings.

We appreciate this very much.

Do you have any questions, Mr. Gordon?

Mr. GORDON. I have just one.

The drug industry very frequently states that high profits are necessary to finance its large research expenditures.

What do you think of that argument?

Dr. SCHIFRIN. Well, I think it is entirely fallacious, deliberately so. Profits, of course, are the residual between revenues and costs. Thus you have profits only when all your costs are met. Research is part of your cost. Thus, the high profit exists after the research outlay has already been accounted for.

A twist of this is to say tht high profits are necessary to finance future research. But, of course, in future prices, there is an element that covers the research going on. To justify a high price because it is necessary for future research is in fact to charge the consumer twice for the research. He is paying for the present research and future research. The future consumer will also pay for present and future research, and on and on.

It is an argument that does not justify the consumer paying double in the cost.

Mr. GROSSMAN. We talked about proliferation of products before.

You stated—that at least that brought in competition. But I think the point you discused with Senator Nelson before was very important and I wonder if your solutions really cover it. That is the failure of the small firms really to be able to compete due to the promotional problem.

Dr. SCHIFRIN. Sir, do you want me to comment on how my proposals——

Mr. GROSSMAN. Yes; can we ever meet this?

Dr. SCHIFRIN. Yes. You see what keeps the small firm from being effective in the market now are two barriers. The patent may keep him out of the market. If there is no patent barrier, the emphasis on trade names keeps him out because he can't promote his trade name. As I say, compulsory licensing is necessary, but not sufficient. They cannot be an effective competitor as long as prescribing is done by trade names. Thus I think trade names have no basis for existence.

If brand names are used, they will clarify the matter as to generic equivalency. Once that is established, the small firm with a generic product will have a better chance of getting its items selected, certainly once its low prices become recognized.

Mr. GROSSMAN. Do you think it will also help if the larger firms will cut down on its advertising?

Dr. SCHIFRIN. Definitely, because you will not be advertising a trade name trying to make it seem something different from other products with generic equivalency.

Mr. GROSSMAN. So a lot of wasted effort is cut down?

Dr. SCHIFRIN. Right.

If you could eliminate the waste, it would reflect on the consumers in two ways: They would either pay less for what they get or get more for what they pay.

Senator NELSON. I thank you very much.

We will take a 5-minute recess and then hear Dr. Steele.

(Recess.)

Senator NELSON. Our next witness is Dr. Henry Steele, professor of economics at the University of Houston, Houston, Tex., and an economist with very distinguished credentials.

We appreciate very much your coming to testify today, Dr. Steele. You have presented to the committee a very detailed and well-prepared analysis of testimony given by the economists representing the Pharmaceutical Manufacturers Association before this committee as well as additional material. You may present this material in anyway you see fit. All of your statement, as well as your critique of the presentations of the economists for the PMA will be printed in full in the record.

You may present your material in any way you see fit.

STATEMENT OF HENRY B. STEELE, PH. D., ASSOCIATE PROFESSOR OF ECONOMICS, UNIVERSITY OF HOUSTON, HOUSTON, TEX.

Dr. STEELE. Thank you, Senator Nelson.

I would like to read the first half dozen pages or so from my major statement and then turn to the supplemental statement commenting on the PMA presentations, if I may.

I greatly appreciate the privilege of being invited to make this statement before this subcommittee, and it is my hope that the information which I am able to present will be of some use to you in your deliberations regarding the vitally important economic problems arising out of the market context within which the drug industry operates.

I am an academic economist with major research interests in industrial organization and the regulation of industry, and have done much work in the area of medical economics and drug industry regulation.

I received my Ph. D. degree in industrial economics from MIT in 1957, and since then have been engaged in teaching and research, as well as in consulting for private firms, U.S. Government agencies, and foreign governments. At present I am an associate professor of economic at the University of Houston. My research in the drug industry has continued over the last 7 years, and I have written three articles on drug industry economics and regulation and coauthored two articles on the supply and distribution of physicians' services, all of which have appeared in professional economics journals.

In March 1965, I presented a paper on drug industry regulation before the University of Illinois Medical School at the invitation of

Dr. Harry Dowling, the chairman of the Council of Drugs of the American Medical Association; and in February 1967, I presented a comprehensive program for the reform of Canadian drug laws and regulations before the Special Committee on Drug Costs and Prices of the Canadian House of Commons.

Senator NELSON. May I interrupt just a moment?

Do you have with you the three articles on drug industry economics and regulation and the two articles on the supply and distribution of physicians' services?

Dr. STEELE. I have the three articles on drug industry regulation with me.

Senator NELSON. Would you submit them for the record?

Dr. STEELE. Yes; and I can submit the other two articles as well.

Senator NELSON. Would you also submit the other two articles, and they will be printed at the conclusion of your testimony.[1]

Dr. STEELE. Thank you. I continue.

In making the Canadian presentation, I represented the government of the Province of Alberta, and of the 14 recommendations which I submitted, 11 were incorporated in the final report of the committee to the Canadian House of Commons. All of my research on the drug industry in the United States has been entirely self-financed, and in presenting this statement to the Subcommittee on Monopoly I wish to make it clear that I represent no one but myself.

I. INTRODUCTION

What can an economist contribute to hearings on drug industry problems?

It is curious that in all the hearings held in the United States, as well as those in England and in Canada, the original demand for the hearings has come about because of the conviction that prices are "too high," but very much of the hearings have been occupied by investigations into the safety and efficacy of drugs, and medical and pharmacological considerations have quite generally been predominant over economic issues.

Yet, for every person who is moved to voice a complaint over poor drug quality, there must be a hundred who complain about high prices. But the emphasis on drug safety and efficacy inevitably redounds to the advantage of the major firms, who would much rather fight on the battleground of relative quality than of relative prices. Their argument has two parts:

First, drug prices are related to costs, particularly quality control costs. Second, drug quality and hence safety and efficacy is related to these same costs. Hence it is asserted that one cannot divorce questions of cost and price from questions of safety and efficacy; therefore, since problems of drug quality, being matters of life or death, are obviously more crucial than drug price problems of mere dollars and cents, steps to assure high quality should take precedence over economic reforms. Economic reforms are correspondingly delayed. (This was the net effect of the otherwise admirable Kefauver-Harris Act of 1962.)

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[1] The five articles submitted by Dr. Steele begin at p. 1950, infra.

This argument is faulty in several respects:

First, drug prices are not related to drug costs, but instead to demand and ability to pay.

Second, while drug quality obviously depends upon care exercised in manufacture, the cost of quality control has been shown to be a very small part of the total costs, and the difference in cost between a minimal satisfactory program and a deluxe program would not begin to account for the difference in prices between the generic drug and its brand name equivalent.

But to return to the question: What can an economist contribute to drug law reform hearings?

If the data were made available, he could analyze cost-price conditions within the individual drug firms, and the pattern of interfirm price and product competition, and arrive at an informed judgment regarding the status of competition in the industry. But such data have not been made available, even to economists retained to defend the industry.[1]

In view of the absence of the data in the analysis of which the economist has a comparative advantage, what constructive role can he play? Primarily that of coordinating and synthesizing the economic aspects of the data which is in the record, and evaluating the economic relevance or credibility of certain of the arguments advanced by the drug interests.

It is noteworthy that drug spokesmen produce arguments in their defense which either stress or ignore similarities or differences between drugs and other industries to suit their convenience. Thus, in the PMA studies presented last month, one study treated the drug industry just like any other industry in relating the variance of the earnings of member firms in an industry (rather arbitrarily called "riskiness") to the average rate of earnings in that industry, while the other analyzed product competition in drugs in a vacuum as it were, without introducing comparative data from any other industry. But both the similarities and the differences of the drug industry should be analyzed and allowed for before making any comparative study of drug prices, costs, and profits in relation to those of other industries.

[1] As Professor Markham stated before this Subcommittee on December 19, 1967, in response to just such a question, "you are just not going to get those data, and I do not think—I would be less than honest if I said I would try to get them, implying that I could get them for you." (Transcript, volume 23, p. 2805.) Markham apparently referred not only to the confidential status given the information, but also questioned whether or not drug firms bothered to make all the cost allocations involved. Although it is to be admitted that many of the calculations can be made only on the basis of arbitrary assumptions, one would expect that well-managed firms would find it prudent to undertake such analyses for their own information. In fact, Dr. M. A. Phillips, in his Sainsbury Committee memorandum to the British Ministry of Health stated that the drug industry was no different from other organic chemicals industries in observing the customary precautions of making detailed cost studies prior to engaging in producing projects. These studies include the costs of research and development and of promotion. Dr. Phillips' statement is unusually authoritative in that he is a drug industry conslutant who has made many economic evaluation studies for drug firms. Phillips complains that "It has been found very difficult to obtain figures for the cost of research and development and of promotion and advertising, although this must be known to those who have to spend this money in these ways . . ." and explains that even with the approximations his organization has to use in estimating these costs, he is satisfied that the accuracy of the estimates for these items is within 25 percent. *See Competitive Problems in the Drug Industry,* Part I, pp. 54–55, of the *Hearings* before this Subcommittee on the present matter. (It might be observed that only if there is a very large gap between cash flow and expenditures is a company actually likely to indulge in some carelessness or negligence in the relating of total costs to individual items sold.)

The major similarity between drugs and other industries is that the firms are privately owned and are managed in the interests of maximizing profits and the value of the shareholder's investment.

Provided that there is effective competition among firms, the profit-maximization goal is an excellent coordinating mechanism since it motivates managements to produce a given output at minimum total cost and hence stimulates efficiency.

At the same time, price competition among firms will keep price levels from exceeding for any great period of time the equilibrium levels necessary to elicit from producers that level of production which consumers demand at that price. This is basic to the classical economic doctrine of Adam Smith (who was mentioned more than once with approval by PMA witnesses last month) that the force of price competition taking effect through the market, acts as the famous "invisible hand" which by allocating resources efficiently makes each economic agent serve the general welfare even though he is only interested in furthering his own private fortunes.

But unless effective competition prevails, private and public welfare in the market are not consonant. In the drug industry, the invisible hand is invisible chiefly because it is so deeply buried in the consumer's pocket. And it is the extreme vulnerability of the drug buyer to economic exploitation which makes the drug industry (both in economic and public policy terms) a unique market which cannot be compared directly with any other. This peculiar vulnerability of the drug buyer to exploitation is related to several major characteristics of the drug market which prevent price competition from acting as a safeguard and which also tends to make an economically unregulated drug industry productive of much misallocation of resources in its attempt to maximize the profits of the individual firms.

I do not intend to advocate punitive regulation of the drug industry. But the industry at present enjoys the benefits of what amounts to public regulation in its favor, through the availability of the patent privilege, trademark and copyright protection, and the laws supporting prescribing by brand name, to name only the major advantages. This stacks the cards heavily in favor of the industry and against the drug buyer. I am in favor of corrective legislation to redress the balance and increase the chances of the patient's getting fair value for his prescription dollar.

At the same time, it must be stressed that to be critical of the drug industry is by no means to be critical of private enterprise as such. Most industries are routinely accorded exemption from special economic regulation because they naturally tend to function tolerably competitively in a free market environment.

But if the drug industry is permitted to retain its present special position of institutionalized protection in the economy, it will continue to display elements of both monopoly and rivalry. Spokesmen for the industry habitually refer to the intense degree of competition among firms. Unfortunately, however, the "competition" referred to is of the type which raises costs instead of reducing prices. This category of activity is generally referred to by economists as "rivalry" rather than "competition" since the latter term is usually reserved for the economically beneficial activity specifically of price competition. Ob-

viously, the industry which is subject to intense price competition at all times is the exception rather than the rule in today's economy.

Nevertheless, the perennial threat, and occasional outbreak, of price competition does much to keep the price policies of the typical industry on the side of moderation. My research and consulting experience in the field of industrial organization during the last 10 or 12 years has been such as to convince me that the great majority of product markets in the United States are more or less workably competitive, but the specific legal and marketing arrangements which the drug industry enjoys are such as to make it virtually a foreign body in an otherwise workably competitive economy.

Then if I may I would like to turn to my supplemental statement, which focuses on the presentations of the PMA witnesses last month.

Senator NELSON. We will print in full the statement that you just read from in the record at this point and we will then start your supplementary statement.

Dr. STEELE. Thank you.

(The complete prepared statement of Dr. Steele follows:)

STATEMENT OF HENRY B. STEELE, PH. D., ASSOCIATE PROFESSOR OF ECONOMICS, UNIVERSITY OF HOUSTON

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I. INTRODUCTION

What can an economist contribute to hearings on drug industry problems? It is curious that in all the hearings held in the United States, as well as those in England and in Canada, the original demand for the hearings has come about because of the conviction that prices are "too high", but very much of the hearings have been occupied by investigations into the safety and efficacy of drugs, and medical and pharmacological considerations have quite generally been predominant over economic issues. Yet, for every person who is moved to voice a complaint over poor drug quality, there must be a hundred who

complain about high prices. But emphasis on drug safety and efficacy inevitably redounds to the advantage of the major firms, who would much rather fight on the battleground of relative quality than of relative prices. Their argument has two parts: First, drug prices are related to costs, particularly quality control costs. Second, drug quality and hence safety and efficacy is related to these same costs. Hence it is asserted that one cannot divorce questions of cost and price from questions of safety and efficacy; therefore, since problems of drug quality, being matters of life or death, are obviously more crucial than drug price problems of mere dollars and cents, steps to assure high quality should take precedence over economic reforms. Economic reforms are correspondingly delayed. (This was the net effect of the otherwise admirable Kefauver-Harris Act of 1962). The argument is faulty in several respects. First, drug prices are not related to drug costs, but instead to demand and ability to pay. Second, while drug quality obviously depends upon care exercised in manufacture, the cost of quality control has been shown to be a very small part of total costs, and the difference in cost between a minimal satisfactory program and a "de luxe" program would not begin to account for the difference in prices between the generic drug and its brand name equivalent.

But to return to the question: what can an economist contribute to drug law reform hearings? If the data were made available, he could analyze cost-price conditions within the individual drug firms, and the pattern of inter-firm price and product competition, and arrive at an informed judgment regarding the status of competition in the industry. But such data have not been made available, even to economists retained to defend the industry.[1]

In view of the absence of the data in the analysis of which the economist has a comparative advantage, what constructive role can he play? Primarily that of coordinating and synthesizing the economic aspects of the data which is in the record, and evaluating the economic relevance or credibility of certain of the arguments advanced by the drug interests. But since much of the evidence and many of the arguments transcend the realm of economic analysis as such, an economist is vulnerable to objections that he is exceeding the limits of his professional competence.

Certainly the economist is not alone in this. During the drug industry investigations in the English-speaking countries, testifying physicians have been criticized for not being economists, economists have been challenged for not being physicians or pharmacologists, medical educators have been chided for not being doctors in full-time private practice, etc. But until the ideal witness appears,[2] someone who is less than fully qualified has to stick his neck out and attempt to put the entire picture together. There are reasons why an economist who specializes in the area of industrial organization and regulation is not the least qualified of all specialists to make such a presumptuous attempt. First and foremost,

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[1] As Professor Markham stated before this Subcommittee on December 19, 1967, in response to just such a question, "you are just not going to get those data, and I do not think—I would be less than honest if I said I would try to get them, implying that I could get them for you." (transcript, volume 23, p. 2805). Markham apparently referred not only to the confidential status given the information, but also questioned whether or not drug firms bothered to make all the cost allocations involved. Although it is to be admitted that many of the calculations can be made only on the basis of arbitrary assumptions, one would expect that well-managed firms would find it prudent to undertake such analyses for their own information. In fact, Dr. M. A. Phillips, in his Sainsbury Committee memorandum to the British Ministry of Health stated that the drug industry was no different from other organic chemicals industries in observing the customary precautions of making detailed cost studies prior to engaging in producing projects. These studies include the costs of research and development and of promotion. Dr. Phillips' statement is unusually authoritative in that he is a drug industry consultant who has made many economic evaluation studies for drug firms. Phillips complains that "It has been found very difficult to obtain figures for the cost of research and development and of promotion and advertising, although this must be known to those who have to spend this money in these ways . . ." and explains that even with the approximations his organization has to use in estimating these costs, he is satisfied that the accuracy of the estimates for these items is within 25 per cent. *See Competitive Problems in the Drug Industry*, Part I, pp. 54–55, of the *Hearings* before this Subcommittee on the present matter. (It might be observed that only if there is a very large gap between cash flow and expenditures is a company actually likely to indulge in some carelessness or negligence in the relating of total costs to individual items sold.)

[2] The ideal witness would probably be a practicing family physician who has also in the past been a pharmacist, a pharmacologist, a medical educator, a hospital administrator, a drug industry executive, a compiler of official therapeutic compendia, a medical public welfare program administrator, a high official variously with the AMA, the PMA, and the FDA, a patent attorney, a research scientist, an economist, and a member of Congress.

firms in the drug industry are economic enterprises. The economist George Stigler has defined business as a collection of devices for surmounting barriers to profits, and the splendid profitability records of the drug firms indicate that their business-oriented managements have very efficiently achieved this goal. Secondly, the anomalous price structures and price-cost relationships in the drug industry are so striking as to be obvious to the layman,[3] while other evidences of delinquent performance in the discharge of the drug industry's responsibilities are not exactly so subtle or equivocable as to be apparent only to those with highly specialized backgrounds in professional disciplines.[4]

It is noteworthy that drug spokesmen produce arguments in their defense which either stress or ignore similarities or differences between drugs and other industries to suit their convenience. Thus, in the PMA studies presented last month, one study treated the drug industry just like any other industry in relating the variance of the earnings of member firms in an industry (rather arbitrarily called "riskiness") to the average rate of earnings in that industry, while the other analyzed product competition in drugs in a vacuum as it were, without introducing comparative data from any other industry. But both the similarities and the differences of the drug industry should be analyzed and allowed for before making any comparative study of drug prices, costs, and profits in relation to those of other industries.

The major similarity between drugs and other industries is that the firms are privately owned and are managed in the interests of maximizing profits and the value of the shareholder's investment. Provided that there is effective competition among firms, the profit-maximization goal is an excellent coordinating mechanism since it motivates managements to produce a given output at minimum total cost and hence stimulates efficiency. At the same time, price competition among firms will keep price levels from exceeding for any great period of time the equilibrium levels necessary to elicit from producers that level of production which consumers demand at that price. This is basic to the classical economic doctrine of Adam Smith (who was mentioned more than once with approval by PMA witnesses last month) that the force of price competition taking effect through the market, acts as the famous "invisible hand" which by allocating resources efficiently makes each economic agent serve the general welfare even though he is only interested in furthering his own private fortunes. But unless effective competition prevails, private and public welfare in the market are not consonant. In the drug industry, the invisible hand is invisible chiefly because it is so deeply buried in the consumer's pocket. And it is the extreme vulnerability of the drug buyer to economic exploitation which makes the drug industry (both in economic and public policy terms) a unique market which cannot be compared directly with any other. This peculiar vulnerability of the drug buyer to exploitation is related to several major characteristics of the drug market which prevent price competition from acting as a safeguard and which also tends to make an economically unregulated drug industry productive of much misallocation of resources in its attempt to maximize the profits of individual firms. I do not intend to advocate punitive regulation of the drug industry. But the industry at present enjoys the benefits of what amounts to public regulation in its favor, through the availability of the patent privilege, trademark and copyright protection, and the laws supporting prescribing by brand name, to name only the major advantages. This stacks the cards heavily in favor of the industry and against the drug buyer. I am in favor of corrective legislation to redress the balance and increase the chances of the patient's getting fair value for his prescription dollar.

At the same time, it must be stressed that to be critical of the drug industry is by no means to be critical of private enterprise as such. Most industries are routinely accorded exemption from special economic regulation because they naturally tend to function tolerably competitively in a free market environment.

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[3] As Senator Nelson observed, in inquiring of Professor Cootner how a price differential of $32.62 versus $2.60 might be justified between the United States and Canada, "I didn't think I was asking a question that required expertise." (Transcript of these hearings, volume 23, p. 2706.)

[4] Drug industry spokesmen have patronized Morton Mintz, author of *The Therapeutic Nightmare,* referring slightingly to his having become an expert on the drug industry during the Kefauver hearings. He did not become an expert on the industry, but upon the abuses practiced by the industry—as did anyone else who read the entirety of the Kefauver Hearings carefully.

But if the drug industry is permitted to retain its present special position of institutionalized protection in the economy, it will continue to display elements of both monopoly and rivalry. Spokesmen for the industry habitually refer to the intense degree of competition among firms. Unfortunately, however, the "competition" referred to is of the type which raises costs instead of reducing prices. This category of activity is generally referred to by economists as "rivalry" rather than "competition" since the latter term is usually reserved for the economically beneficial activity specifically of *price* competition. Obviously, the industry which is subject to intense price competition at all times is the exception rather than the rule in today's economy. Nevertheless, the perennial threat, and occasional outbreak, of price competition does much to keep the price policies of the typical industry on the side of moderation. My research and consulting experience in the field of industrial organization during the last ten or twelve years has been such as to convince me that the great majority of product markets in the United States are more or less workably competitive, but the special legal and marketing arrangements which the drug industry enjoys are such as to make it virtually a foreign body in an otherwise workable competitive economy.

As I have elsewhere stated, the market characteristics of the drug industry bias it in the direction of inefficient and non-competitive performance in five major respects.[5]

(1) Essential to the effective operation of a free market is the ability of the buyer to choose among suppliers on the basis of an adequate knowledge of the price and quality of the alternative products which they may provide him. But in ethical drugs, the buyer has no practical means of gaining access to knowledge of the range of price and quality alternatives in the market; indeed, his purchasing agent, the prescribing physician, is constantly oversupplied with biased information and even misinformation which facilitates confusion and ignorance of prices.

(2) The price-conscious buyer should be able to identify the lowest-priced seller and purchase from him without artificial impediments. Instead, the possessor of a newly-written prescription is unable to buy any but the specified drug, regardless of price. The willingness of the price-conscious physician to prescribe lower-priced drugs may be compromised if he has been exposed to repeated attempts to disparage low priced drugs on the part of representatives of brand name drugs who contend that low price means low quality. And even if a generic prescription is written, the buyer has no power to compel the dispenser to sell him a reasonably priced generic drug instead of substituting a less reasonably priced brand name equivalent.

(3) There must be freedom of entry into the industry by new firms, such that high profits being made by existing firms will attract new competitors who will, by engaging in price competition, drive profits down to competitive levels. But freedom of entry in drugs is greatly lessened by the existence of the patent privilege, the trademark device, and the necessity for newcomers to match the enormous advertising outlays of existing rivals.

(4) There should be an adequately large number of competitive sellers offering buyers genuine alternatives in terms of product price and quality; none of the sellers should be so large that he overshadows the magnitude of his competitors and poses a potential threat should they incur his displeasure. In drugs, restricted entry limits the number of sellers, and while there are few if any genuine product monopolies, the size of the major firms is certainly appreciably greater than that of their smaller generic-name competitors.

(5) A market is not workably competitive unless all firms act independently—there must be no overt or tacit collusion, no passive acquiescence in prior decisions arrived at by others and established by mutual consent . . . (in the drug industry there are) two circumstances which act to hamper independence of action. First, there is the practice of price leadership and the pricing of new medications at exactly the same levels charged for existing substitute drugs. Second, there is the fertile field of patents. While an individual patent confers a monpoly, the scope of the monopoly privilege is limited. But in an industry with complex technology, the efficient production of a drug may require the use of processes controlled by rival patent-holders. The negotiation of the resulting

[5] Submission of the Government of the Province of Alberta to the Special Committee on Drug Costs, and Prices of the Canadian House of Commons, Minutes of Proceedings and Evidence, No. 33, pp. 2427–2429, Feb. 14, 1967.

cross-licensing agreements requires the mutual compromise of patent monopoly positions, and may well stimulate such meetings of the minds as will lead to the development of a greater sense of community of interest in policies regarding prices, production, and participation in world markets.

In connection with this last point, it should be emphasized that the United States drug industry is not unacquainted with outright collusion. In December 1967, Pfizer, Lederle, and Bristol Myers were convicted by the Federal District Court of New York City of conspiracy in restraint of trade, conspiracy to monopolize, and monopolization in the tetracycline market. (Squibb and Upjohn were named co-conspirators but not defendants.)

A further respect in which the drug market can be distinguished from other markets is in the involuntary nature of the purchase. While an individual ordinarily ought to pay no more than the competitively determined full supply price for a product, he should also pay no less than this price since in order to supply his wants, the economy has had to allocate scarce resources which could have been used alternatively in the production of other products. But there is a difference between paying the full cost of financing an activity deliberately engaged in, in contrast to one forced by accident or misfortune upon the buyer through no fault of his own. This is to suggest that the financing of drug purchases, like other aspects of health care, has an element of insurance against risk in it. Such insurance arrangements could conceivably be either public or private. A prudent man of sufficient income might participate in a voluntary health insurance program including drug costs. But the required income to make participation attractive does not depend upon the "full competitive cost" of drug supply, but instead upon actual prices charged in highly non-competitive markets. Unless drug prices can be made reasonable, the possible expenses of drug therapy under a comprehensive private health insurance program might be so great that enormous premiums would be required. Under these circumstances, the expenses of drug therapy would not constitute an insurable risk for practical purposes. This is all the more applicable to public health insurance and welfare programs, of the medicare variety or otherwise. Truly comprehensive drug coverage under such plans might allow sellers of patented high-price drugs to levy a publicly-underwritten tribute on the sick and afflicted and divert a not-negligible portion of tax revenues and the national income into the hands of the pharmaceuticals industry. The only difference, fortunately, is that public authorities are in a position to exert more effective efforts to discipline high drug prices than are private insurance companies.

The above consideraions should be kept in mind when assessing the effects of the great variety of drug industry activities and expenditures on the price of drugs, when such costs are generally borne in full by persons involuntarily afflicted, whose earning power and ability to pay may be greatly reduced by the very circumstances which make medication imperative.

The absence of workable competition among sellers is compounded by the barriers which consumers face in obtaining information regarding drug prices and quality. If neither a seller's customers nor his rivals can force him to compete, what limits are placed on his ability to exploit his customers? Essentially only two—self-restraint and public constraint.

Self-restraint is ordinarily an impediment in the management of a business enterprise, and under competitive market conditions would detract from efficiency. During the Kefauver hearings several witnesses referred to their impressions that there had been within memory some decrease in the degree of self-restraint in marketing among drug firms. Actually, it is to be doubted that self-restraint in itself ever posed much of a barrier to high profits. Upjohn, for example, made over 30 per cent after taxes on its net worth in each of the deep depression wears 1930–1935.[6] But this does not necessarily contradict the observations that self-restraint was still more prevalent among drug firms prior to the second world war. In the post-war era, however, it became obvious to all that the profit possibilities inherent in the "Miracle Drugs" era of the industry's history were simply too vast not to be fully and intensively exploited. Although it did not prove possible for new small firms to enter the market and become genuine factors to be reckoned with in the industry, larger firms found it possible to diversify by merging with existing drug houses, and producers of bulk chemicals and fine chemicals found it profitable to integrate forward into drug making and market-

[6] *Hearings on Administered Prices,* Part 20, p. 11082.

ing. Some firms which had previously specialized in patent medicines began to produce prescription or "ethical" drugs. For this reason and others, the change in the composition of the industry was accompanied by an increased emphasis on sales promotion. Several physicans and medical educators testified during the Kefauver hearings that as the quantity of promotional matter increased greatly, there was a concomitant decrease in its average quality. It was argued by some that the industry should be saved from itself, it being alleged that if only one or two indifferently scrupulous firms saturated the physicians with marketing appeals of dubious merit, all the others had to imitate their tactics in self-defense. These observers tempered criticism with courtesy by omitting to single out the firms involved, but I have been amused by a phrase which I keep running across in my own contacts with people in the medical community who are interested in drug reform: "Where there's smoke, there's Pfizer."

It seems safe to conclude, in any event, that the intensified rivalry which transformed drug industry marketing practices in the 1950's in all likelihood eliminated the factor of industry self-restraint from the category of feasible solutions to drug industry problems.

Public constraint has so far been somewhat asymmetrical with regard to safeguarding the drug buyer. While the acts of 1906, 1938, and 1962 have progressively improved the quality of drugs in terms of increased assurance of their safety and efficacy, legislative concern for the economic health of the patient has not been nearly as marked. This is unfortunate since a sick man's economic health may often be more delicate than his physical condition. Economic convalescence can be much more prolonged than physical recuperation. And two or three acute illnesses in succession, requiring drugs and hospitalization, may put a person of limited means into the ranks of the chronically medically indigent. Even the legislation regarding drug quality was obtained only with great difficulty. There seems to be two reasons for this. First, the lobbying and other governmental relations activities of the drug industry, made effective not only through the individual firms and their trade associations, but also through their allies in organized medicine and some areas of pharmacy, and probably through the "army" of some 15,000 detailmen. Second, public apathy tempered with the widespread uncritical attitude that the makers of miracle drugs must be miracle workers who are without fault. Even so, these obstacles to legislation have not rendered the industry completely reform-proof.

The Elixir Sulfanilamide tragedy of 1937 prompted the passage of the reforms embodied in the Food, Drug, and Cosmetic Act of 1938. And although the industry has not been backward in its efforts to cultivate the public image of the private drug firm laboratory as having a complete monopoly over the creation of "miracle drugs," it has been more neglectful in publicizing the fact that, by the same token, miracle drugs can produce "miracle diseases." Dr. Walter Modell of Cornell University Medical School has observed that some 40 or more new diseases have been recognized and attributed to the employment of modern drug therapy.[7] But in 1961 the point was made more dramatically through the creation of a sizeable "miracle generation" under the auspices of thalidomide. Again, the reaction of the public to another tragic blunder by the drug industry was to pass a reform law, the drug amendments act of 1962, to reduce the possibility of the recurrence of such a calamity and to further safeguard the public by insuring more adequately the safety and efficacy of drugs. But the danger is that public interest rapidly subsides after each calamity, while the industry itself is continuously in search of expedients which may be employed to minimize the impact of regulatory reforms.[8]

The net result is that while the drug buyer who obtains a drug of substandard quality (such that his health is impaired for this reason alone) is probably a very rare individual, the drug buyer who obtains his purchase for a genuinely reasonable price is probably a still rarer individual. Reform laws are now needed to institute price competition in the drug industry. One certainly hopes that such a law can be passed without the necessity for a fresh tragedy to mobilize public opinion. Still, it is hard to imagine a sufficiently striking tragedy in purely economic terms, short of some revelation that a large number of low-income individuals with no access to welfare case status had died of malnutrition during

[7] Drug Industry Antitrust Act Hearings, Part 1, p. 318.
[8] See, for example, Morton Mintz, *The Therapeutic Nightmare,* pp. 222–229.

some period of time because purchase of medications at inflated prices had usurped the entirety of their budgets.[9]

But one must first inquire into what sort of reforms might most appropriately be embodied in legislation to enhance the likelihood of price competition and lower prices in the drug industry. To do this requires a study of supply and demand in the drug industry—of drug costs in relationship to prices. What functions does the industry perform? Of what benefit are these functions? How efficiently does it perform them? Could any of these functions be more effectively performed under other auspices? An attempt is made to answer these and other questions in the next section.

II. AN ECONOMIC ANALYSIS OF SUPPLY AND DEMAND FOR PRESCRIPTION DRUGS

No economic analysis of the operations of a privately-owned industry is properly oriented unless primary attention is given to the operation of the profit motive in influencing the allocation of economic resources within the market. On this point, drug firm managements, investors, trade associations, and industry critics should find themselves in agreement. But while price competition presupposes mutually opposed interests on the part of separate competing firms striving to increase their share of the market, it also requires a pervading fundamental understanding that the institutons of the market—the price mechanism, for example, and the contractual arrangements of purchase and sale—shall be adhered to in a cooperative manner, such that the "rules of the game" exclude so-called "unfair" competitive tactics like the disparagement of a competitor's goods, outright dishonesty in financial dealings, and the like.

One has not said much when he simply states that the relationship of supply and demand in a particular market determines the price charged, and the quantity bought and sold. One must also investigate the factors determining the supply and demand functions. Unfortunately, many of the determinants of these relationships are rather subtle and tend to elude quantification. Generally, speaking, supply is influenced by the costs of production, promotion, and distribution; by the arrangements in the terms of which production costs are allowed to influence pricing and production; by the channels of distribution employed; and by the legal provisions affecting the cost and availability of imports, the techniques of promotion, the ability of new products and new firms to enter the market, and the strategies available to sellers to temper competitive pressures. Demand is influenced by the severity of the patient's need for the drug, his ability to pay (either privately or through eligibility for public aid or reimbursement), and the degree to which sales promotion efforts succeed in capturing the attention of the physician in such a way as to influence him to prescribe a certain brand of drug.

A. An analysis of the factors influencing the supply of prescription drugs

1. Costs incurred by drug manufacturers

The major costs incurred by drug manufacturers may be categorized as follows: (1) basic research; (2) applied research; (3) product development; (4) manufacturing the active ingredient; (5) preparation of finished dosage forms; (6) sales promotion outlays. Each cost category may be best discussed by contrasting activities actually undertaken with those which would be appropriately in an effectively competitive drug industry.

Basic research.—The drug industry has a distinct weakness for arguments to the effect that high drug prices are due chiefly to high research costs, that most of the research is basic in nature, and that high profits are necessary to finance these large research budgets. The argument is beginning to seem a bit anachronistic in view of the repeated demonstrations that the research budget is only a very small part of the sales dollar, being in the vicinity of 6 per cent. But there are further weaknesses in the argument. It is obvious that while high prices might be necessary to finance large research outlays, high profits are not. As has often been pointed out, profits are a residual after deducting all costs, including research costs. High profits indicate simply that a large part of the sales dollar was *not* accounted for by research costs—or any other costs. Furthermore, the majority of what is included under the category of "research" is something

[9] E. D. Bransome of the Arthritis and Rheumatism Foundation, while fortunately having no mortalities to report, did state that some individuals with severe inflammatory diseases would go without food in order to be able to afford to buy drugs. Hearings on Administered Prices, Part 14, pp. 7992–7993.

quite different than fundamental research. (It appears that within the last few years, some drug industry spokesmen are becoming more willing to admit that the share of their research budget devoted to truly basic research is a minor one; but there is no sign of any retreat from the position that the type of research which they do engage in is of immense benefit.)

It is not surprising that drug firms devote relatively little time to strictly fundamental research since this sort of activity is inherently risky in that the firm incurring the costs may not be in a position to capture all the benefits. Basic research, in the sense of activities which extend the frontier of knowledge, is potentially the most productive form of research, but also the riskiest. Risky to whom? Here in a narrow sense the answer is clear—to the firm which invests in this activity, since failure to obtain results will mean the loss of investment. But to whom is basic research productive? It depends upon the ultimate implications of what you find, which are quite unpredictable. It may help the firm doing the research, but it may help its competitors even more. Or it may help firms in different industries. Or it may simply accrue to the benefit of humanity generally.

To engage in basic research, a drug firm must satisfy itself that this use of the company's funds is more productive than an alternative use in applied research, marketing, or the like. Such a decision is contingent upon obtaining satisfactory answers to the following questions:[10]

(1) What is the risk of failure of a given project? (Fundamental research is always highly risky; this is its very nature.)

(2) If the project is successful, will the findings ever be commercially applicable? (Many findings are too generalized to be immediately applicable, although they may lead to subsidiary findings which will have commercial applications.)

(3) Will the resulting findings ever lead to patentable discoveries? (Often the findings are not patentable in the form in which they are obtained, and unless they can be embodied in some sort of marketable item, may never be profitable even though patentable.)

(4) Will the time horizon between initiating the research project and its fruition in the sales of commercially marketable products be sufficiently short that the discounted rate of return on the investment will justify the outlay? (If initial risk is high and the research and development period is long, the net return over time may be lower than can be earned through such alternative uses of the funds as marketing, even though the project is eventually successful.)

(5) Will the "gestation period" of product development for patentable discoveries be short enough that patent protection will be commercially profitable?

(6) Will the discoveries prove to be of equal or greater benefit to the rivals of the firm? (With the well-developed state of the art of molecular manipulation, this is a great risk and may discourage basic research to some extent.)

(7) Will the discoveries prove to be of greater application in industries outside the pharmaceuticals field? (This is a distinct possibility since pharmaceuticals is a very specialized field. It might be more likely that a major firm in the chemical industry could undertake basic research that might lead to either a chemical or pharmaceutical discovery, and in the latter event it might be possible to diversify into drugs. The reverse is less likely.)

(8) Will the discoveries pose the threat of obsolescene to presently profitable products?

These constitute a large number of difficult hurdles to clear, and so it is not surprising that drug firms should do little truly basic research. Actually, fundamental research is ultimately a philanthropic activity in the sense that it always has some potential for benefiting society generally. Hence it is appropriate that most basic research be carried out by endowed foundations and universities as well as publicly financed agencies specialized for this purpose.

It may be concluded that under efficiently competitive conditions, private drug firms would not do much basic research because greater profits would be more likely if the money were invested in other functions. Instead, the industry would rely upon the results of basic research made publicly available by more broadly-

[10] See Submission of the Government of the Province of Alberta, *op. cit.*, p. 2435.

financed agencies. And it appears that in fact the drug firms do not engage extensively in truly basic research. But this does not necessarily imply that drug industry research activities give rise to no distortion in the spectrum of basic research efforts. It has been said that too little basic research in areas relating to health and therapy is done by non-industry organizations, at least partly because the ability of the industry to pay high salaries (in turn dependent upon the high profitability of drugs under present market conditions) diverts too large a portion of the very small pool of qualified investigators and technicians away from public employment in basic research and toward private employment in applied research and product development, testing, and application—all of which are lower-priority uses for their very scarce skills. The remedy would seem to lie not in increasing the amount of basic research done by private firms, but in taking steps to reduce their ability to drain off the best scientific personnel for work in less productive employments than they are capable of pursuing.

Applied Research.—The economic rationale of applied research is quite straightforward in any industry: to serve as one means of implementing a profitable marketing operation. The direction and emphasis of this research in the field of drug therapy is influenced by (1) the nature of the patent system: (2) the impact of the patent system on the organization of the industry; and (3) the effect of industry activities on research outside the industry. The mere existence of the patent privilege for drugs biases research toward patentable inventions and away from areas where no patents can be obtained. This discriminates against basic research and stimulates applied research. It also discriminates among different channels of applied research. From the medical point of view, research is unbalanced due to an unduly intense emphasis on chemotherapy, while the complementary fields of nutrition, public health, biochemistry, and preventive medicine are underemphasized. Antibiotics provide the most sharply focussed example. Concern has been widely expressed that antibiotic therapy may ultimately prove to be a blind alley due to overuse and the development of resistant strains of micro-organisms. It would seem wiser to spend less effort on activities which tend to make micro-organisms increasingly resistant to control, and more effort on attempts to make man naturally more resistant to micro-organisms.

Furthermore, by biasing efforts toward applied research, the patent system will reduce the scope of basic research findings which can be applied, and ultimately will depress the productivity of applied research. There has been much discussion in recent years of the "increasing cost" of drug research per new discovery. (This was true even before the FDA began to implement more stringent controls over new drugs.) But to speak of increasing costs is simply to refer indirectly to the decreasing productivity of efforts. Again, antibiotics offers a good case in point. Applied research here was productive for a good many years, in large measure because fundamental research in this field had already elucidated much of the mechanism of infection by micro-organisms. Bacteriology was already an established field of study. But the same is not true in the other major areas of drug research, such as tranquilizers and oral antidiabetic agents. Here there has been a less prolific output of various useful drugs and less enthusiasm among independent authorities regarding the extent to which the later drugs are advances over the earlier drugs, and perhaps even over related drugs which antedated the "miracle drug" era.

Another bias of some interest is related to the fact by protecting new products, either as such or through exclusive process privileges, the patent law biases applied research in the direction of concocting new products rather than fully investigating the properties of known compounds. As Prof. George Wright of the University of Toronto has contended, it seems to indicate rather overly one-sided emphasis that new drugs coming from drug houses are almost invariably novel concoctions and therefore patentable, while the reservoir of some two million already known compounds has only been pharmacologically investigated to a very modest degree.[11]

To the extent that patent reforms can reduce biases of this type, resources will be allocated more efficiently throughout the drug research sector of the

[11] Professor Wright advocates more screening of known compounds rather than an exclusive emphasis on the concocting of new ones, on the assumption that "much is yet unknown about the association between chemical structure and pharmacological action," observing that the screening approach originally brought the sulfa drugs into existence. Canadian Hearings, *op. cit.*, no. 8, p. 540.

economy. Basic research will increase relative to applied research, so that there will be a greater variety of fundamental research findings on the basis of which applied research can be conducted. The potential which resides in the areas of nutrition, biochemistry, public health, preventive medicine, and other areas will be more nearly capable of full achievement. The bias in favor of contriving new compounds instead of systematically conducting an empirical study of existing compounds will be reduced. And the amount of exclusively imitative research, and of other types of research of secondary importance aimed at finding a patentable vehicle for a "blitz" sales promotion campaign, will be reduced or even eliminated.

This latter phenomenon of duplicative activities is a major element in drug research today, as conditioned by its patent orientation. Basically, there is an over-intensive exploitation of those approaches known in the past to have yielded profitable drugs. Since the number of known approaches is limited, it is within the capacities of major firms to explore several of them, and since all firms are conscious of the commercial advantage of being able rapidly to duplicate the successful new drugs which their rivals may find, the research programs of large drug firms tend to duplicate, at least in part, the programs of their major rivals. (This was attested to not only by many witnesses at drug industry hearings, but also by the near-simultaneous discovery of several drugs by two or more firms.) This constitutes a compounded misallocation of resources: not only are scarce talents diverted from basic to applied research, but wasteful duplication of effort on precisely the same applied research projects seems to be common.

Much of the criticism of the "molecular manipulation" approach can be most appropriately directed at this phase of the industry's operations. The ideal manipulated molecule is one which is pharmacologically identical with the profitable product of a rival, but is legally distinct in the sense that a patent may be obtained. However, it is the latter criterion which is crucial, not the former, and the typical me-too version of an existing drug is of dubious superiority, if not absolutely inferior, to the original drug which it is intended to supplant. The most impressive testimony regarding the prevalence of misdirected research in the major drug houses came during the Kefauver hearings from two physicians who formerly served as medical directors for major firms. Dr. A. Dale Console, formerly with Squibb, when asked whether there was much drug research which produces nothing worthwhile and is not intended to, replied:

"I think the majority of it is in that category . . . and I should point out that with many of these products, it is clear while they are on the drawing board that they promise no utility; they promise sales. It is not a question of pursuing them because something may come of it . . . it is pursued simply because there is profit in it." [12]

He also reported that imitative research could crowd out productive work:

"When a 'crash program' comes along in which some product is being pushed in order to get it out before a competitor gets it out, it is not unusual for a worthwhile research program to be postponed so that the people can be taken off it to be put on the 'crash program'. Very frequenty some of these programs are never picked up again. So I think that good research is actually hampered by this type of thing." [12]

Dr. Haskell J. Weinstein, formerly with the Roering division of Pfizer, denounced industry managements for wasting the time of their research personnel:

"Their talents should not be expended on patent-bypassing chemical manipulations, on ridiculous mixtures of drugs, or inconsequential additives to established drugs. Since the number of well-trained capable scientists is severely limited, their potential should not be wasted. The long-term benefits of the appropriate utilization of the abilities of these skilled individuals would be immeasurably greater." [13]

This illustrates some of the subsidiary distortions in applied research resulting from the patent incentive: not only modified molecules, but the development of often irrational combinations of existing drugs which lack flexibility and compound the problems of dosage and toxicity, and the devising of additives which

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[12] Hearings on Administered Prices, *op. cit.*, part 18, p. 10379.
[13] *Ibid.*, part 18, p. 10254.

may constitute questionable and/or necessary flourishes in the interest of increasing a drug's absorption rate, guarding against side effects, etc.[14]

Product development.—The category of product development includes many activities, such as experimental and clinical testing, determination of appropriate dosages and dosage forms, obtaining FDA approval for marketing new drugs, constructing pilot plant facilities, etc. Subsequent to initial marketing there would be product application work relating to long-run evaluation of the total effects of a drug, improvements in dosages, revisions of brochures, and related activities.

In an efficiently competitive drug industry, profit prospects from marketing new drugs would be moderate, and the temptation for extreme haste in product development would be correspondingly slight. It is very important that this temptation be minor, since proper testing and evaluation of new drugs is an important and time-consuming task. And, as Dr. C. D. Leake of Ohio State Univeriity has observed, "There is no shortcut from chemical laboratory to clinic, except one that passes too close to the Morgue."[15] But before certain needed reforms were legislated in 1962, many firms yielded to the temptation to rush new drugs thru the development phase and on to the market as soon as possible, limiting experimental and clinical work to the minimum acceptable levels under the old legislation, harassing FDA staff members into approving inadequate applications,[16] and even skipping such seemingly essential product development stages as pilot plant operation.[17] Furthermore, with an inflated number of drugs being clinically investigated in the expectation of reasonably rapid FDA approval, the available time of the most highly qualified investigators was soon completely employed, and recourse to less trained, less capable, and in some instances less scrupulous individuals was necessary. But drug evaluation by unqualified investigators can be worse than useless.[18]

Since the passage of the 1962 legislation, there has been much improvement in this area. More stringent requirements for approval of new drug applications have been imposed; the number of new drugs being evaluated has apparently declined, making possible an increase in the average quality of evaluations, and the morale and effectiveness of the FDA has greatly improved. This is apparently one area in which drug safety reforms may have been successful in eliminating certain economic wastes as well as improving drug quality. But it should be noted that any reduction in total drug development outlays would be likely to result from a reduction in the number of new drugs under investigation; the average cost of investigation per drug is likely to increase, and this increase is certainly in the best interest of public health.

Manufacturing of the active ingredient.—In an efficiently competitive drug industry, each stage in the production process would be carried out at minimum

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[14] Dr. Harry F. Dowling of the University of Illinois Medical School cited an excellent example involving both molecular manipulation and the use of inconsequential additives. Lilly discovered erythromycin in 1952, and in 1953 Pfizer retaliated with a molecular shadow, carbomycin, which proved less effective in human disease than in the test tube, and was finally withdrawn from the market in 1960. Pfizer tried again in 1956 with another chemical echo of the erythromycin, eleandomycin, and in 1957 modified its own modification, called it triacetyloleandomycin, and advertised it widely as a major breakthrough in that the same oral dose as eleandomycin produced somewhat higher concentrations of the drug in the bloodstream. Lilly responded in 1958 by modifying its original erythromycin and marketing it in the form of its propronyl salt, claiming a higher blood concentration rate than could be achieved with triacetyloleandomycin. None of the four later drugs had any real advantage over the original discovery, since slightly higher doses of the original drug would have been as effective as the later variants. *Ibid.,* part 24, pp. 14167–14168.

[15] *Ibid.,* part 18, p. 10418.

[16] See testimony of Dr. Barbara Moulton, *Ibid.,* part 22, pp. 12025–12032.

[17] Lederle bypassed the Pilot-Plant Stage with its Triamcinolone. See *Fortune,* May 1960, p. 276.

[18] Dr. Maxwell Finland, Harvard University Medical School, cited an instance where a clinical investigator had reported successful treatment of 100 cases of staphylococcal pneumonia without a mortality. Since the usual mortality rate among the patients concerned is 50 percent, the drug would appear to be miraculous. But upon investigation, Dr. Finland concluded that not a single case of staphylococcal pneumonia had been present, and inferred that the investigator was incompetent to diagnose the presence of the true disease from the laboratory cultures. He concluded pointedly: "This is the sort of thing that I say is dangerous because another doctor who knows how to make a diagnosis of staphylococcal pneumonia will use that drug to the peril of his patient." Hearings on Administered Prices, op. cit., part 24, pp. 450–451.

cost, and without incurring the cost burdens of excess capacity, which one suspects are characteristic of industries like drugs which shun price competition and rely on product differentiation.[19] Although very large investments in plant and equipment are common in the heavy chemicals industry, in the pharmaceuticals field this is not the rule. The investment in facilities required for the production of the active ingredients varies considerably from drug to drug. For those active ingredients which can most efficiently be produced by truly mass-production techniques, production by makers of fine chemicals or even bulk chemicals would be indicated. But for many drugs, the required investment is relatively modest in comparison with the supply of funds avalilable in capital markets. Relatively small firms can efficiently produce the active ingredients for such drugs. Mass production methods are not appropriate for many drugs since the physically minute quantities used in dosage forms require only a small total annual volume of output. But it still might be more efficient for a small firm to buy the basic ingredient under contract from a larger firm. If the market were competitive, the relative economies of scale in produnction versus those in dosage form preparation and in distribution should govern the extent of the functions assumed by different producers at different stages in the industry. If patents posed no real barrier to entry into drug selling, chemical raw materials and intermediates could be made by bulk chemical companies, the active ingredient could be made by fine chemicals producers, and the finished dosage forms could be tableted and packaged by drug makers to be distributed through various channels. Without barriers to entry, the comparative costs of each stage in the industry would determine the allocation of functions among different firms. As far as financial requirements are concerned, there is no reason why a large number of relatively small firms might not compete effectively in the drug market.

But under present market conditions there are a number of factors which distort the division of labor among firms and introduce other criteria than comparative costs as determinants of The Degree of Specialization within and Among Firms. A relatively small drug maker might find a new drug, patent it, and undertake production of the active ingredient on his own premises, despite the circumstance that his costs might be high due to his inexperience, inappropriate facilities, and overall lack of adaption of his operation to the requirements of fine chemicals manufacture. Production would still be undertaken at higher costs, however, if the patent holder wished to prevent the "know-how" which is ordinarily not disclosed in the patent, from being acquired by another firm. The inefficiencies inherent in this arrangement could be partially overcome by the merger of the small firm with a larger producer of bulk or fine chemicals, but this would increase the market power of the formerly small firm relative to its rivals.

Forward integration by merger is also stimulated by marketing practices. The intense sales promotion of drugs under brand names particularly thru nationwide advertising and detailing, is a practice which creates economies of large scale marketing even though none may exist in production. This is unusual; ordinarily it is economies of large-scale production which prevent the successful operation of a large number of small firms, but in drugs it appears that while efficient production might occur at a very small level of output, the exploitation of modern marketing techniques in the drug market context can be taken full advantage of only by a very large firm.

Where the factor of "know-how" is not important, drug firms may contract out the production of the active ingredient to specialists. In such cases, the ratio of the price of the bulk drug to the market value of the substance when embodied in final dosage forms and sold to distributors is well worth noting. Ratios of the order of magnitude of one hundred to one are not unknown.[20] This is very simply explained. There is price competition among the firms which make the active ingredient, but none in the sale of the finished product. If competition were to be

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[19] By way of example, when Bristol was producing about one-third of national tetracycline output, it still had 80% excess capacity in this drug. Drug Industry Antitrust Act Hearings, part 4, p. 2056.

[20] During the recent Canadian Hearings, Empire, a small generic firm, estimated that it could manufacture the drug diazepam for $68 per kilogram and a kilogram of diazepam embodied in dosage forms is worth about $20,000—a ratio of 125 to 1. (This makes diazepam worth about 16 times as much as gold.) See Alberta Government Submission, *op. cit.*, p. 34.

introduced at the finished product level, drug prices would decline until they were more in line with production costs for the active ingredient.

Preparation of finished dosage forms.—The simple technology of the preparation of most finished dosage forms, the low operating costs of these processes, and the modest capital requirement for such facilities, renders this stage of the industry ideally suited for workably competitive market performance. The processes involved for most dosage forms are technologically routine and elementary, tabletting and bottling being particularly trivial operations technically. (After all, every pharmacist is taught—and taught well—to do such compounding operations on his own premises. It is both amusing and dismaying to observe industry attempts to convince the general public that there is some magic in the preparation of even the simplest dosage forms, which is by implication a secret known only to the major brand name firms.) It has been shown by evidence presented at drug hearings both in the United States and Canada that for the typical drug, "factory costs" (producing the active ingredient and making and packaging the dosage forms) are a minor part of the wholesale price. There is no purely economic reason why numerous small firms could not contract out the manufacture of the active ingredient and then tablet and package the finished dosage forms on the basis of a quite moderate total investment. Brisk price competition between many small sellers of drugs might develop if production costs were the only barrier to entry. And this in fact is the prevailing mode of market behavior for those small firms which produce generic name drugs for which tight patent control could not be achieved over their manufacture and/or the sale of their bulk powder. These firms can either produce or buy the bulk powder at the low prices which result from competition among bulk suppliers. These firms then tablet, package and sell the drugs at low prices representing their low costs of production. But in most markets these generic drugs compete with their presumed brand name equivalents, and it is likely that the true production costs of the brand name sellers are even lower than those of the generic firms. But does this mean that the large firms choose to undersell the small generic houses? By no means, they charge prices up to ten or more times as high. But does this not mean that they are not able to make any sales at these high prices? Again, by no means. They outsell the lower-priced drugs ten or twenty to one. To an economist who has been trained to expect that quantity sold is inversely related to prices charged, this is a dumbfounding situation. The answer of course, as is well known, is related to sales promotion tactics.

Sales promotion outlays.—Any spokesman for the domestic drug industry will tell you that its outstanding accomplishments have been in the area of research. But any well-informed expert on marketing is much more likely to tell you that the drug industry's real expertise lies in the area of sales promotion. And indeed the relationship of the marketing budget to the research budget suggests as much. But the myth seems to persist in the general mind that research budgets exceed advertising budgets, despite repeated demonstrations that the latter is several times as high, as can be verified by even a superficial examination of the financial statements of any large drug firm. It seems to me that public education can sometimes be furthered more effectively, therefore, by witty ancedotes or epigrams than by mere statistics. For example, in my experience, Dr. A. D. Console seems to have done more than anyone else to expose to salutary ridicule the dubious nature of much drug industry "research" in his memorable statement during the Kefauver hearings; "They stress that there are many failures for each successful drug. This is true since it is the very essence of research. The problem arises out of the fact that they market so many of their failures." [21] The same device can be used to put drug prices, research costs, and sales promotion outlays in perspective. During the recent Canadian drug hearings, one participant observed: "for every dollar the drug industry spends on research, they spend four dollars telling you about it, and charge you ten dollars more for listening." If anything, this witty statement errs on the side of moderation. Research costs apparently amount to something less than one-fifteenth of sales price, and somewhat less than one-fourth of sales promotion outlays.

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[21] Hearings on Administered Prices, *op. cit.*, part 18, pp. 10372–10373.

In an efficiently competitive drug industry, sales promotion activities would be adapted so as to reflect the structure of information needs and to take advantage of the ability of the relevant individuals to absorb information, in order to minimize the cost of providing the necessary data. Since ethical drugs are ethical in that they cannot be bought over the counter, advertising to final consumers would seem unnecessary. Instead, advertising need be directed only to prescribing physicians. But doctors would seem to constitute a specialized market for several reasons. First, they are highly trained professional men. Second, they are extremely busy. Third, they are unquestionably prosperous. A rational advertiser would adapt his sales strategies accordingly. Since the physician is quite intelligent and well-trained, he can respond adequately to modicum of purely informative advertising material and need not be bombarded with masses of insistently persuasive promotional appeals. (If a word to the wise is sufficient, the drug firms are guilty of a colossal insult to the physician's intelligence.) Since doctors are busy, the time they can devote to the study of drug information of all sorts is limited. And since doctors are men of some financial means, and profit from the availability of good drugs, they should be expected to pay the costs of being supplied with adequate drug information. The sales promotion outlays of the drug industry, like all their other expenditures, are paid for entirely by the patient. Even if doctors find that detail men are convenient sources of information, the patient is still subsidizing the doctor by providing him with a number of tutors, and biased tutors at that. It is debatable whether this sort of subsidy is justified. However, the amount of the subsidy, rather than the nature of it, is the chief point. If the doctor were to be required to bear the costs of obtaining his own drug information, he could still pass the costs on to his patients through higher fees. But the costs of alternative means of being supplied with information—subscriptions to official compendia and their periodical supplements, or to independent newsletters such as *The Medical Letter*, would be a very small fraction of the amount spent at present on sales promotion by drug firms.

Obviously, the necessary information on drugs must somehow be supplied. It may be supplied by the companies, by independent evaluating organizations, or by government. If supplied by government it can either be made available upon subscription or can be distributed free of charge. By whatever medium it is communicated, it should achieve four objectives: (1) insure adequate flow of accurate and unbiased information; (2) minimize the volume of redundant communication; (3) make informative communications more concise; (4) eliminate all misinformation.

The provision of this information by the companies themselves has been sharply criticized, chiefly by the recipients of these promotional attentions, on numberless occasions. This is not the place to deal in detail with these criticisms, but the chief complaints may be recapitulated in terms of failure to achieve the goals of a satisfactory communication system: (1) constant interference of commercial bias; (2) excessive communication, such that the volume of indifferent information and just plain "noise" minimizes the likelihood of the detection of the occasional communication of genuine value; (3) emphasis on persuasion and suggestion rather than upon providing genuine information; (4) redundancy of communication as a result of the mutually offsetting nature of sales promotion rivalry among firms not competing on a price basis; (5) the presence of a certain amount of outright misinformation, chiefly in regard to inadequate disclosure of side-effects or contraindications.

Evaluation by independent sources, or by public bodies, should eliminate commercial bias and minimize the temptations to indulge in excessive or overly persuasive communication. Intentional misinformation should also be eliminated, although the fallibility of human agency will render any drug information system less than perfect. It is, however, doubtful that the first goal of an information system—insuring an *adequate* flow of information—will be achieved by any system which leaves the aquisition of the information source up to the discretion of the physician. Proof of this is supplied by the small fraction of the medical profession subscribing to the *Medical Letter*: only about 15 percent, which is to be deplored. (It is of course possible that if the institution of price competition in the drug industry lowered profit margins and eliminated the detail-man, more physicians would subscribe.) In England the *Prescriber's Journal* is distributed free to all doctors, and a similar step is being considered in Canada. We in the United States should be hesitant to extend such a subsidy

to the members of a well-paid profession, but this may still be the least costly way of insuring at least the availability to all doctors of adequate and unbiased drug information. And while an element of subsidy to the doctor would remain, the subsidy would now be financed by the public as a whole, rather than that smaller and to some extent disadvantaged segment of it which in a given period of time finds it necessary to purchase drugs in varying amounts.

If adequate drug information were to be made available from unbiased sources, by how much might drug industry sales promotion costs decline? Unless steps were also taken to institute price competition in drugs, expenditures would probably not drop at all, and might even increase, each firm trying not only to offset advertising efforts of other firms, but also the now more widely-distributed data from unbiased sources. To explain why this outcome is likely, the crucial role of sales promotion in the drug industry must be further explored at this point.

The key role of sales promotion lies in its ability to substitute for productive research on the one hand, and for genuine price competition on the other. If a firm's research department discovers a highly effective new drug of unmistakable value, the drug tends to advertise itself. Physicians themselves rapidly spread the news. On the other hand, as Dr. Walter Modell of Cornell University Medical School has stated, "The more a drug has to be peddled, the more one begins to wonder why."[22] Dr. Console, formerly of Squibb, was more explicit—about the relationship between unproductive research and the advertising budget: "Advertising is called upon to make successes of research failures."[23] Since it appears that almost any drug will sell, at least for a while, if promoted intensely enough, it does appear that the good offices of the sales promotion department may compensate greatly for the indifferent fortunes of the researchers—but at quite a cost, in terms of premature and usually unnecessary obsolescence of existing products. Even these costs, however, are converted by drug spokesmen into rhetorical capital: they are construed as measuring the risks of product obsolescence, allegedly due to the rapid development of superior medications, and these "risks" are supposed to constitute a justification for the high profit rates characteristic of the industry. The "risks" involved are not wholly illusory, but are not, as claimed, inherent in the research process. Instead, they arise from the way in which drugs are developed and promoted. The high profits cannot be justified by the high risks because the height of the profits induces expensive and disruptive product competition which manifests itself in such "risks". But if one were to create price competition and reduce profits, this mode of product competition would be too expensive to support, and the "risks" of product obsolescence would be diminished in proportion to the decline in profits.

Even more important is the degree to which sales promotion can substitute for price competition. This is true in most industries, but drugs are unique in that such efforts can almost completely suppress price competition and furthermore can seriously discredit the price competitor. Again, the sheltered institutional circumstances of drug marketing should take the credit. If a company can monopolize the eye and ear of the prescribing physician, it monopolizes the most important drug market, given the existence of laws supporting brand-name prescribing. But monopolizing the physician's attention becomes increasingly expensive when more than one firm tries this strategy. It soon becomes so expensive that only a limited number of firms have the resources to continue—hence, as mentioned before, economies of large scale marketing act as barriers to entry where production costs in themselves would not be prohibitive. Smaller firms cannot ordinarily bring their products to the attention of the physician, even though they may be selling at perhaps 90% less than the brand name drugs.

And there is yet another way in which the sales promotion techniques of the industry put the small firm at a prohibitive disadvantage. Although the small low-price firm cannot ordinarily make its presence in the market directly known to the physician, the doctor may eventually become aware of its existence and perhaps wonder how the midget firm can undersell the giant by a ten-to-one ratio. The detailman is ready to supply the answers. It appears likely, on the basis of the testimony of many doctors at public hearings, that a major reason

[22] Drug Industry Antitrust Act Hearings, Part I, p. 325.
[23] Hearings on Administered Prices, *op. cit.*, part 18, p. 10372.

why drug firms spend so much on detailmen is because of their peculiar ability to disparage, with relative impunity, quality of the products of the low-priced generic firms. The conscientious physician is naturally vulnerable to having his confidence in low-priced drugs undermined by such disparagement since he is personally not in a position to evaluate the relative quality of drugs. Whenever a buyer lacks full information on the nature of the product at the time of purchase selling efforts take on some of the coloration of a "confidence game" where the buyer is induced to take the seller's word for it that his product is better than his rivals'. It is suggested that to be unknown is to be suspect in the drug industry, and that it is common knowledge that most generic drugs are subpotent, adulterated, etc., and may even be made by counterfeiters. Thus the physician may be induced to equate low price with low quality and hence shun generic prescribing. Hence drugs priced 90% below the market may account for less than 10% of all sales. For these reasons there is no other industry in existence where the disparagement of the quality of lower priced products can so completely substitute for price competition.

Is there any substance to this disparagement? There should be very little reason to suppose that low price need be associated with low quality. If anything, doctors should be more hesitant to prescribe by brand name, since counterfeiters (who make more on $100 bills than on nickels and dimes) naturally specialize in the high-priced brand name drugs. As far as economic motivations to save costs by cutting corners are concerned, these should be minimal in drugs. The strength of the positive motivation—cost reductions—is relatively small, since neither the costs of quality control nor of the active ingredient itself are particularly large components of total cost. For a major firm, quality control costs seem to range from about one to three percent of the sales dollar, and although the figure would probably be higher for a small firm, it should still not be a controlling factor in costs. And while official compendia specify a certain range of allowable variation for drug potency, the typical range is only about 90 to 110 percent. But since the cost of the active ingredient in a given drug is usually only a minor part of total cost, the cost saved by orienting the production process to produce an average content of 90 percent of stated label potency would save at most only 10 percent of this cost. Furthermore, it would inevitably mean the production of a number of substandard drugs and would expose the firm to punitive actions by the FDA. This brings up the negative aspect the deterrents to substandard performance. Both generic drugs and their brand-name equivalents must meet official standards specified in drug compendia. Experts have testified that there is no therapy gain to be achieved by producing to purity standards "exceeding official" "minimum" standards. The products of all producers are held to the same inspection standards, and a small firm will be even more strongly motivated than a large firm to conform to the regulations since the impact of a given fine will be much more disruptive to its finances.

Brand name firms have alleged that there is no therapeutic equivalency even among drugs which satisfy the requirements of official compendia. I sympathize with such witnesses as Dr. Solomon Garb, who professes to find this sort of argument both elusive and baffling.[24] I respect Dr. Garb's opinion and share his suspicion that the differences are trivial and that they cannot be meaningfully specified. It is very hard to follow drug industry arguments which suggest that because no two drugs, or capsules, are absolutely identical, that one should buy brand names and shun generic names. The emphasis on the unique nature of each pill is reminiscent of the philosophical doctrine of nomanilism, which implies that no generalizations are possible since everything is in a unique category by itself. I submit that drug firms are more pragmatic than nominalistic in their serious moments.

The most authoritative testimony of this point would appear to have been given by Dr. Lloyd Miller, Director of Revision of the United States Pharmacopeial Convention, before this Subcommittee, in stating that "there are not

[24] Dr. Garb expressed himself as follows: "It seems to me that if any group of drug manufacturers wish to use the argument that their brand name drugs are better because of certain differences, and that the doctor knows what these differences are, they should show how the doctor finds out these differences . . . I think the differences are trivial, but my point is I do not know that they are trivial, because I cannot find out why they are. I have never been able to find out what the difference is between one brand of the drug and another brand of the drug." *Competitive Problems in the Drug Industry, op. cit*, Part 2, p. 545.

more than a dozen examples where the difficulty (questionable clinical equivalency of drugs meeting USP standards) has been discovered, and it is not generally true even for all of them."[25] My own evaluation of the "generic equivalency" or more precisely therapeutic equivalency dispute is that the brand name firms have greatly overstated the significance of any valid or partially valid elements in their position, and that the argument on the whole is without merit. The verdict of lack of merit seems inescapable since there should be no reason to assume that the therapeutic equivalency of two brand name preparations is any greater than that of a brand and a generic name preparation. As Dr. Martin Cherkasky recently testified before this Subcommittee, "I must tell you that I feel quite insecure at the same time about the performance of some of the major drug companies in this country."[26] The intensity of the dispute is all the more puzzling since it appears to take for granted that pharmacology is much more of an exact science in practice than in fact it is.[27]

It would seem that the best argument which the major drug firms have in support of their charges that unsafe drugs are on the market is the contention that FDA inspection is not adequate. This is a perennial charge, and one which in recent years has become much less plausible because of long-needed increases in FDA staffs and budgets. But if any doubt remains as to the adequacy of FDA inspection, it should be resolved by providing FDA with still more funds to the full extent which may prove necessary. Perhaps. Still, it is the direct responsibility of the FDA to safeguard the public from poor drugs, in a much more immediate sense than this responsibility is shared by USP. Batch certification of all drugs might be one solution. Dr. Solomon Garb's proposal that all drug manufacture be subject to continuous federal inspection is another solution. Dr. Miller charges that the former proposal would be unnecessarily costly; Dr. Garb reports that drug makers contend that the costs of his plan would be astronomical (although, as he points out, there is private inspection today at less than astronomical cost, and it would seem quite feasible simply to substitute public for private inspection with avoidance of excessive duplication of efforts.) An economist would wish to make one point. Regardless of the methods adopted, the physician must be made confident that all drugs on the market are safe to use. Relative costs of the methods employed to bring about this confidence are important, but it is very unlikely that the costs involved would fail to justify the resulting benefits: complete elimination of substandard drugs and the opening up of much of the prescription market to price competition between low-priced generic drugs and currently high-priced brand-name equivalents. The cost of the industry's current system of "insuring" drug quality by advertising intensively to promote brand-name drugs and discourage generic prescribing does tend to increase the sales of the former drugs and reduce the sales of the latter. But beyond that, it perpetuates a great barrier to price competition and places an

[25] *Ibid.*, Part 2, p. 514.
[26] *Ibid.*, Part 2, p. 668.
[27] A layman can perhaps be forgiven for introducing into the record the idea that with few exceptions (but among them some admittedly very important ones) in the present state of our knowledge, drugs tend to be relatively blunt instruments when employed in human therapy, so that the question of "therapeutic equivalence" when generalized to include all drugs frequently becomes subsidiary to the question as to whether or not the drug can be depended upon, in a particular circumstance, to do its job at all. Placing some emphasis upon this may put the issue of therapeutic equivalence in a more adequate perspective. The significance of this issue would become much greater if one could always assume that if each drug is optimally manufactured and administered, it will accomplish a predictable, effective, and exclusively beneficial therapeutic result upon each administration. But where the effect of the drug is unpredictable, imperfect, and tempered by side-effects, therapeutic equivalence as such is a much less paramount consideration, and the importance of other factors, such as biological variations among human recipients, incidence of side effects, and the inherent uncertainty regarding the mechanism of action of the active ingredient itself, become more significant. The notion that many drugs are blunt instruments is not propagated by the industry, but it is hard to avoid drawing such a conclusion, if for no other reason than the inability, to date, of molecular engineers, to eliminate side effects. Candid doctors have submitted that these effects should not be regarded as incidental disadvantages, but are an integral part of the total action of the drug, and should rather be referred to as "concomitant effects." Just as burning down the house would be a "broad spectrum" recipe for roasting a pig, so also must one regard antibiotics which indiscriminately kill both harmful and beneficial organisms within their range of activity as being relatively blunt instruments. One is reminded of Buckingham's characterization of his parody of the dramatic hero, Drawcansir, in the play *The Rehearsal.* Drawcansir's battle cry was:

> Let petty kings the names of factions know;
> When e'er I fight, I slay both friend and foe.

unjustifiable price premium on the brand name drug. This system amounts to insuring drug quality by what is tantamount to private taxation, and levied through the charging of prices far above production costs. But this does not eliminate the production of substandard drugs, since FDA studies show that a disturbingly high percentage of both brand and generic name drugs do not meet requirements. It should be cheaper to institute universal FDA inspection, of plants *and* products. While the cost to the government might increase (unless as in the case of meat inspection, the companies were to pay the salaries of the inspectors) the resulting increase in price competition which should be expected, once arguments that low price means low quality become manifestly specious to all, should reduce the expenditures of drug buyers greatly.[28]

2. Influence of Economic Aspects of Drug Distribution on the Supply of Drugs

There is one complaint voiced by the drug manufacturers with which I have some sympathy. While about 50 per cent of the retail price of drugs is accounted for by distribution costs and markups, rather more than 50 per cent of the criticism of high drug prices has been centered upon the manufacturers. The proximate cause of the seeming disproportion in attention given the drug makers would appear to be the great visibility of their profit achievements—outstandingly high average profit levels over the last 15 or 20 years—in contrast not only with the absence of any data to show that the druggists have been similarly successful in feathering their nests, but even a general impression to the contrary. The number of retail pharmacies seems to have declined during the period of greatest drug firm success, and many pharmacists who have failed to make what seemed to them a reasonable living in their own profession have reportedly been hired by the drug industry, where they can obtain more remunerative—if perhaps less productive—employment.

But low profit margins in themselves do not necessarily attest to effective competition, since not even a complete monopolist is assured of high profits unless he can operate efficiently. On the other hand, not all inefficiencies are necessarily traceable to the mismanagement of the individual firm. Some inefficiencies may be thrust upon the distribution level from without; others may be unintended consequences of policies fostered within group itself. But before looking into these questions, it is first useful to distinguish between wholesale and retail distribution.

The wholesaling function seems to be the most efficiently performed stage in the industry, chiefly because the wholesaler operates in the most competitive market. Drug manufacturers have their markets protected by patents, trademarks, sales promotion outlays, and the relatively small number and large average size of the major firm. Druggists also enjoy rather protected markets because of the practice of brand-name prescribing, antisubstitution laws, and other regulations which put the consumer at a disadvantage, plus the advantages associated with being a closed profession regulated by semi-autonomous professional associations which have at least the potential for limiting the number of qualified practitioners and hence influencing the rate of entry into pharmacy. The wholesaler, however, has no comparably strong bargaining position. There are many wholesalers, mostly very small, and no appreciable barriers to new entry. Furthermore, if drug makers can perform their own wholesaling functions more efficiently than the independent distributor, they will integrate forward and sell directly to retailers. And if retailers can do better for themselves

[28] I am aware of no recent estimates of the cost of making FDA inspection fully adequate. However, an order of magnitude approximation of the relation of probable costs to required cost reductions can be made from data presented at the Kefauver Hearings. In 1959, FDA Commissioner Larrick stated that it would take a budget increase of $3,418,000 to permit adequate drug inspection. Profits of the 22 major drug firms were $562 million in 1958. A decline in drug prices sufficient to cut drug firm revenues by $7,121,000 would of course cut before-tax profits by the same $7,121,000. With a tax rate of 52% in effect at that time, this reduction in pre-tax profits would have cut tax receipts by $3,705,000. The net gain can be roughly measured as the $7,121,000 saved by drug buyers, minus the $3,705,000 in reduced tax receipts, or the required $3,418,000. Thus if adequate drug inspection could create confidence in lower-priced drugs to the extent that the resulting competition would lower major drug firm prices by enough to cut total profits by as little as 1.27 percent before taxes, the savings realized would pay for the expanded enforcement budgets. If total profits are about 20% of gross revenues, the necessary percentage price cut would be as little as 1/5 of the 1.27 percent, or ¼%. See Hearings of Administered Price, *op. cit.*, Part 22, p. 12132.

by forming their own wholesale supply agency, on a cooperative or other basis, they can integrate backward and buy directly from the factory. Hence the independent wholesaler must meet the test of a competitive market, and provide efficient, reasonably-priced services, or find himself by-passed. If all stages of the drug industry were similarly competitive, there would probably be considerably fewer complaints about drug prices.

But at the retail level the pressures of competition do not work as beneficially, and more inefficiencies and impediments to the proper allocation of resources are present. Some inefficiencies are probably traceable, at least in part, to certain of the tactics of drug makers designed to maximize profits at the manufacturer's level: the proliferation of branded products, combinations, dosage forms, etc. which increase the druggists inventory costs; the liberal distribution of free samples to physicians, which probably reduces average retailer drug turnover rates; the economically more complex question of the "discriminatorily" low prices made to large-volume non-profit buyers, which again probably reduces drug turnover rates; and possibly certain aspects of policy on returns of unsold or outdated drugs. But certain of these marketing policies are not without costs to the drug companies as well as the druggists, and it is probably unwarranted to impute any primary hostility on the part of the drug makers toward their retailers. But certain inefficiencies have also been forced upon druggists by the actions of their own spokesmen and trade associations. The National Association of Retail Druggists, for example, was certainly the prime mover in facilitating adoption of the so-called "fair-trade" laws by state after state in the 1930's.[29] And yet although these laws prevented or greatly limited price competition for trademarked drugs, by enhancing the unit profit margins on these items, more dealers were induced to sell them, and the resulting increase in the number of sellers reduced turnover and earnings on these products. And druggists supported the passage of the Robinson-Patman Act, which prevents them from taking advantage of any possible cost savings available through obtaining supplies on competitive bid, and in other ways prevents the lower-cost distributor from benefitting commensurately from the potential economies in his operations.

From this, one might conclude that not all drug price problems originate at the manufacturer's level. The druggist's markup on the average prescription item is no doubt higher than it might be, but then his unit costs are also higher than they might be for many reasons, including those outlined above.

Clearly, the druggist has his problems. But the drug buyer has his problems, too. These include: (1) inability to purchase a low-price generic drug if he has been given a prescription for its brand name equivalent; (2) inability to shop around for the lowest available price on a prescription, regardless of its manner of specification, if the medication is needed quickly for treatment of an acute condition, or if the prescription holder is otherwise suffering marked distress pending the securing of his medication; (3) ignorance of the content of the prescription, in many cases, which can simply mean inability to decipher the prescriber's jargon, or lack of knowledge of the brand and/or generic name of the drug—either of which may give rise to collateral inabilities, such as (a) inability to determine whether or not a generic prescription was actually filled with a brand name equivalent, and (b) inability to determine whether a generic prescription actually filled as written was dispensed at the lowest generic price; (4) buyer ignorance or docility such that he does not even realize that the prescription form is his own property and does not have to be surrendered to the first pharmacist to whom it is presented—who may be the one whose name is on the prescription pad; (5) the frequently poor prospects for reasonable prices present even for the unusual buyer who does shop around for a low price, due to the tradition of hostility among most druggists toward price competition, and the way in which this tradition is fostered and buttressed by the inhospitable attitudes of pharmacy agencies toward price competition and the advertising of prescription prices, by the state "fair trade" laws, by the Robinson-Patman Act, and by still other influences.

How can greater efficiency be obtained in the retail distribution of drugs? The characteristics of an efficiently competitive retail drug market can be broadly outlined in a few sentences. All sellers should act quite independently with respect to pricing policies; no formal or informal arrangements which would facil-

[29] See, the example, Clair Wilcox, *Public Policies Toward Business*, Third Edition, 1966, pp. 707–710.

itate uniformity of action on prices should exist. Prescriptions should be written so as to facilitate the ability of drug buyers to stimulate price competition among pharmacists. There should be no barriers to the dissemination among buyers of information on the prescription drug prices of individual pharmacies. Buyers should be free to seek out the lowest-price seller, both for the original dispensing of a prescription and for refills. Entry into the retailing of drugs should be free from any artificial barriers, legal or otherwise.

Under present market arrangements, there is no real incentive for the druggist to stock low-priced generic drugs. First, there is little demand for them, physicians' prescribing habits having been influenced as they have by industry efforts. Second, if the usual two-third markup is added to invoice cost, the unit profit to the pharmacist is proportionately smaller for the lower priced drug. Third, the same logic applies to the wholesaler, so that even if a druggist wishes to stock generic drugs, he may find it hard to obtain them.

It is obvious that the substitution of the "professional fee" approach in the place of the uniform percentage markup would make the dispensing of generic drugs relatively more attractive to druggists. But the application of compensatorily higher percentage markups to the lower-invoice-cost drugs would accomplish the same purpose. Optimal economic efficiency in the dispensing of drugs would require that relative markups on individual items be determined by price competition among sellers. The markup should be at the minimum rate above cost which is consistent with the retailer's cost of distribution, including a competitively-determined rate of return on an appropriate level of investment. If genuine competition exists, the *method* by which the markup is arrived at will be less important than the *amount* of the markup, since competition will require that this amount be substantially equal among competing sellers. The notion of adopting a uniform professional fee for any and all prescriptions has drawbacks. It lacks the necessary flexibility in the pricing of services which must exist if price competition is to prevail. And the level of the fee is very important. While I doubt if the size of the fee will be set at too low a level, setting it too high will not insure druggist prosperity. Instead, the high unit profit margin on each prescription will induce new entry into the industry. Many pharmacists now among the ranks of the detailmen will be encouraged to return to pharmacy. As the number of sellers increases, average turnover declines to the point where a balance is achieved between high unit profits and low turnover, and further entry is finally discouraged because of low total profits. In comparing this situation with the low prices and high turnover which would prevail under price competition, it is apparent that competition is to be preferred since prices are lower and excess capacity and investment in underutilized resources is minimized, while the profits on investment should be about the same in either case.

A few words should be devoted to contrasting druggist retailing of drugs with other drug dispensing media. One can readily understand the unhappiness of retail druggists who pay the full dealer list price when they read about the much lower prices obtained by hospitals and government agencies in response to competitive bids. Drug firms have tried to account for such price differences by references to economies of large scale selling, and to promotionally low prices for the sake of introducing their products to hospital physicians. But the price differences are clearly too great to be accounted for merely as the equivalent of quantity discounts. And the "promotionally low prices" argument can be dismissed as a rationalization since it is not characteristic of major drug firms to be so negligent of sales promotion possibilities that the doctor would be likely to overlook a drug if he did not have it on hand in a hospital. The basic reason for the price differences is simply the fact that price competition can often be kindled between brand and generic name drugs and even among major producers of brand name drugs by means of the competitive bid approach. It has been contended that sales to druggists at high prices "subsidize" the lower price sales to hospitals and public agencies. If this is construed to imply that the latter sales are actually made at a loss, it is no doubt an error. From all evidences, drug production costs are very low. And a firm can always add to its total profits by selling goods at special low prices, provided these prices are above the out-of-pocket costs incurred on the sale, and further provided that these transactions do not affect the prices received on other sales. To the extent that firms have excess capacity, they will be more intensely motivated thus to increase their rate of output and spread the overhead costs of total productive

capacity over a larger volume of production. Differently considered, the seller is simply charging as high a price as he can in two markets which can be separated from each other. Separation exists since hospitals do not resell to druggists at higher prices. By doing so, the seller is engaging in price discrimination (in an economic if not legal sense) since he can get much higher prices in one market than in the other because of the different type of demand and supply situations in the two markets. The supply situation differs not because the cost of production differs, but because sellers can be induced to compete in price in one market and not in the other. The difference in the demand situations deserves more attention.

The druggists' demand for drugs is derived from the demand of the individual patient, which is of course very insensitive with regard to price because of the reasons outlined above. Retail druggists can afford to pay high prices for drugs since they can charge even higher prices to their customers without discouraging sales. The demand on the part of hospitals and other public agencies is differently constituted. These are non-profit agencies which operate within a general budget, and while they do not concern themselves directly with selling individual items in accordance with a market-oriented schedule of charges, they are concerned with lowering total operating costs and staying within budgets. Their purchasing agents may also take pride in the successful exercise of professional skills through economical buying. But although an interest in economical purchasing is a necessary condition for obtaining low prices, it is not sufficient unless rival sellers can actually be compelled to compete in terms of price. Other things being equal, retail druggists might have less interest in economical purchasing because they could more readily pass on their high costs to their paying customers. But hospitals with charity patients and a whole host of other exotic financial problems may be less able to forego possible savings from economy in purchasing. Furthermore, hospitals may manufacture some of their own drug needs if they cannot obtain reasonable bids, and this is another factor which makes their demand for drugs less insensitive to price. With demand more responsive to price, hospitals and public agencies can obtain lower prices for many of their requirements, particularly where absence of patent monopoly makes it possible for generic firms to compete. But where patent monopoly obtrudes, there may be no avenue through which prices may be lowered for any buyer.

B. Factors influencing the demand for prescription drugs

It is chiefly the nature of demand for prescription drugs which makes the drug industry an inappropriate vehicle for the unregulated exercise of market power by sellers. Demand is so insensitive to prices charged that there is little exaggeration in stating that prices have no relation whatsoever to costs. This is contrary to the economics of almost all other industries, where price is broadly determined by the relationship of demand and supply, and where supply is at least directly conditioned or influenced by costs of production. In a purely competitive industry the relationship is conceptually precise: market price is determined by the relationship between the supply price of a good, defined as the cost of production of a given rate of output (including in costs the competitive rate of return on necessary investment) and the demand price which the market is willing to pay in order to buy a given volume of output. While supply price depends upon production costs, demand price depends upon the consumer's need for the product and on his income level. Wealthy and needy buyers will constitute the highest-price or most price-insensitive segment of demand, while buyers with low incomes and/or slight interest in the product will be potential buyers only at very low prices. But since those who are willing to pay a very high price for the product will also buy it at all lower prices, a reduction in price will increase sales, and while it attracts new buyers into the market, it also benefits buyers by cutting their costs of purchasing so that in a very real sense they obtain a "free" increment of "use value" over and above the price which they pay. Since price discrimination is impossible in pure competition, all buyers pay the same price, regardless of their incomes or their relative need for the good.

Under monopolistic market circumstances, even assuming that the structure of demand and the costs of production are the same as in competition, the sellers are in a better position to restrict output, limit sales only to those who are most willing and most able to pay high prices, and in this sense charge "what the

traffic will bear." Now as long as the act of purchase is voluntary, no one will literally pay more than what the product is worth to him. In both monopolistic and competitive markets, the market price is equal to the evaluation placed on the good by the least interested buyer who actually does make a purchase. But in pure competition, with no way of mutually restricting output, total production will generally be large and prices low, while under monopolistic circumstances, output will be reduced in the interest of enhancing prices. This means that the chances of the typical buyer obtaining a substantial free increment of "use value" above price paid is much less under monopoly. But the major difference between monopoly and competition is in the relationship between price and cost of production. In pure competition the two are identical. But if monopoly power is present, price is also a function of the elasticity of demand and will exceed production cost in direct proportion to the insensitivity of demand to price.

Therefore when spokesmen for the drug interests argue that the consumer is paying no more than the drug is worth to him, the obvious answer is: of course not!! Unless force is used, no one can be induced to pay more for anything than it is worth to him, no matter what sort of fleecing or price-gouging scheme, may be employed. It is not surprising that a drug may be worth more to a sick person than its cost of production, but this does not justify charging more, and in a reasonably competitive market, prices would be much closer to cost than to need-value.[30]

The above is a general treatment of the contrast between the relationship of demand to prices in monopoly and in competition. In drugs, the argument applies with even more force because of the extreme insensitivity of demand to price, and the way in which this final consumer demand is mediated through the physician. How should the needs of the sick be reflected in the market demand for drugs? Ideally, the total potential market for a drug or group of related drugs is measured by the total need for medication on the part of the individuals afflicted by all the various disorders which are capable of being treated best by the drug or group of drugs. Economically, the total effective amounts demanded at the level of market price may fall short of total physical need in the case of those with low incomes and no access to public care. But effective market demand may also exceed ideal total physical need to the extent that individuals not suffering from those conditions for which the drug or drugs are of use may nevertheless be treated with them. For any given drug it then follows that the actual market is comprised by the total effective demand for medication on the part of all individuals who can be induced to consult physicians, and who are afflicted, or can make it seem convincing that they are afflicted, by those disorders for which doctors may be inclined or persuaded to prescribe the particular drug. The challenge to drug marketers then consists primarily in persuading physicians, but also to some extent in spreading the good word to the general public that Brand X can cure symptom Y.

And drug marketers doubtless earn their salaries. Changes in the effective demand (i.e., prescriptions written and purchased as written) for individual drugs are brought about by the familiar techniques of direct mail advertising, journal advertising, the dividend of free samples, the financing of symposia, the rental of exhibit space at conventions, and above all the insistence of the ever-present detailman. Although advertising cannot yet manipulate the total incidence of genuine disease, it can readily shift effective demand from one drug to another. And advertising can in a sense actually create demand, even for drugs. Articles planted in newspapers or magazines may mention the name of a drug alleged to be useful in treating certain conditions, and may thus bring to the attention of more people who suffer (or imagine they suffer) from such

[30] Examples where representatives of drug firm interests have defended high drug prices as being no more than what the drug is "worth" to the buyer are legion. The most recent exposure of this Subcommittee to this argument is embodied in page 7 of Professor Simon Whitney's written statement in behalf of PMA, where he states: "If a $5 prescription, or 6 of them, will keep a patient from losing a couple of days pay or spending a night in a hospital, the price is reasonable." This can scarcely be taken seriously by an economist unless the price is also commensurate with the competitive supply cost of the drugs. But no one who has presented this argument has so far been able to outdo Austin Smith, who mused publicly during the Kefauver Hearings: "I wonder if any member of this Subcommittee knows how much it costs to die? . . . death costs about $900 . . ." Hence Smith has proved conclusively that any price less than $900 for a handful of pills (32 in this case) is a bargain since it must be worth at least $900 to the patient to avoid the expense of demise. Hearings on Administered Prices, Part 19, p. 10615.

conditions the fact that specific drug therapy might be purchased. Two of the greatest drawbacks of sales promotion in drugs stem from these characteristics of demand. First, doctors may be oversold on a drug which is then overprescribed, often for minor conditions where it can do no good and may cause mischief. Although antibiotics are usually cited in this context, other drugs may also be overused and abuse is compounded when it is administered for chronic, rather than acute, conditions.[31] A second drawback, associated with the first, is that patients themselves often insist on unnecessary drug medication.

III. APPROPRIATE DIRECTIONS FOR PUBLIC POLICY

The difficulties involved in reducing prescription drug prices to reasonable levels can scarcely be exaggerated. There are four major parties to the typical prescription drug transaction: the drug maker, the physician, the druggist, and the patient. The only party with any direct interest in reducing drug prices is the patient, and he has by far the least bargaining power. In fact, at the time the transaction is made, his interest in low prices may usually be quite subordinate to his concern over his health. The major interests of the other parties in drug prices lies in different directions.

The drug corporation, whether large or small, has to maximize profits to keep the stockholders happy. The doctor's chief professional interest is in healing, and if he can be made to believe that quality of one drug is superior to that of another, he will be inclined to prescribe it regardless of price. His insensitivity to price is naturally increased by the fact that he does not pay for the medication he prescribes. But the doctor himself is also a business man and may not be entirely unconcerned with maximizing his own net income. It may help his reputation if he is always among the first to prescribe all the new drugs, and it may increase his prestige if he prescribes the higher priced drugs. And as an independent businessman in an age of "organization men," he may even admire the buccaneering tactics of the more flamboyant drug firms. Beyond that, he may well own stocks in one or more drug firms.[32] But whether he likes this or not, he is vitally affected as a practicing physician by the policies of the AMA, which since has in recent years received over half its revenues from the drug companies. Hence under present institutional circumstances, the average doctor has little direct interest in prescribin gthe lower price drugs and is contained within a professional environment which may discourage such tendencies as he may develop in that direction.

At the drug retailing level, druggists, like other dealers, resent price competition because although it is a good servant to the consumer, it is a harsh master to the producer. Druggists, however, are somewhat unusual among retailers in that they have been more active and more successful than the others in securing the passage of laws aimed at limiting price competition and protecting the interests of the existing group of competitors at the expense of the vigor of competition. This fact, in conjunction with the closed profession aspect of pharmacy suggests a relatively poor prognosis for the rapid development of price competition at the druggist level. Even so, the awareness that it is desirable to restrict competition, and even the presence of institutional arrangements which might be used to implement this awareness, do not necessarily combine to produce the hoped-for prosperity of the profession. As long as entry is reasonably possible, and unit profit margins high, low turnover and excess capacity are likely to develop and cancel out the advantages of high price levels.

A satisfactory solution to the problem of high drug prices must await the adoption of a series of related reforms which will alter marketing and prescribing

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[31] Professor Mark Nickerson of the University of Manitoba Medical School reported that the sales of adrenal steroids in the United States and Canada in 1960 was about $250,000,000, and commented: ". . . personally I feel that I am being very liberal when I say that fifty million of that was needed." *Report Concerning the Manufacture, Distribution, and Sale of Drugs,* Restrictive Trade Practices Commission, Department of Justice, Ottawa, 1963.

[32] Dr. Calvin Kunin of the University of Virginia School of Medicine submitted to this Subcommittee for inclusion in the record an article reporting on a survey among medical students, interns, and residents at the University of Virginia Medical Center. Six out of 73 owned stock in one or more drug firms, and 58 of the 67 non-stockholders stated their belief that such stocks were good investments. As these students and residents continue to pursue their careers and increase their affluence, it is likely that many of the favorably disposed non-stockholders will buy stocks. *Competitive Problems in the Drug Industry,* Part 2, p. 734.

practices and bring about price competition at both the manufacturing and retail levels. The elements of such a solution would include:

(1) Abolition of drug product patents and compulsory licensing of drug process patents at reasonable royalty rates.

(2) Outlawing of brand names for drugs, with the requirement that drugs be identified and hence advertised and sold only by use of the generic name(s) of the active ingredient(s) in conjunction with the company name of the seller.

(3) Provision of FDA with sufficient authority, staff, and funds to permit it to carry out a drug inspection program adequate not only to prevent the sale of substandard drugs but also the plausible insinuation of the possibility that substandard drugs might be on the market.

(4) Elimination of unnecessary barriers to entry of new drug firms into the industry. If a drug has been cleared for marketing as the result of adequate data compiled by one applicant, the same drug should be approved for marketing by any firm capable of producing the identical drug. Unnecessarily burdensome requirements by way of conducting studies which merely duplicate existing studies should not be imposed. In this regard, the suggestion of FDA Commissioner Goddard before this Subcommittee that such drug data submitted to FDA be made a part of the public record is an excellent one.

(5) Provision of the medical profession with more accurate, systematic, and objective drug data. If the price competition injected into the industry as a result of reforms succeeds in reducing profit margins and eliminating the detailman and if the medical profession does not then respond by subscribing adequately to independent newsletters, the provision of a publicly sponsored newsletter, similar to the *Prescribers Journal* in England may become necessary.

(6) Exertion of every feasible effort to infuse more price competition into drug retailing. Serious consideration should be given, at all relevant levels of government, to the liberalizing of the requirements for operating drugstores and dispensing prescriptions, so that the further development of lower-priced outlets such as discount pharmacies and drug mail order houses can be stimulated.

(7) Recognition of the possibility that even the above reforms may not be sufficient to reduce drug prices. If after a reasonable period of time, prices have not declined sufficiently, consideration should be given to such additional reforms as (a) compulsory licensing of imports of patented drugs: (b) complete abolition of drug patents; and (c) price control or public utility regulation. The interrelationships of these recommendations may briefly be summarized.

As has been ephasized by other witnesses, the absolute nature of the drug patent privilege in this country is paralleled only in Panama and Belgium. All other countries with drug patent laws provide either for the denial of drug product patents, for compulsory licensing under certain circumstances, or for both. The abolition of product patents and the making available of compulsory licenses on patented drug production processes will increase the number of firms, both large and small, making and selling each type of drug. This will stimulate price competition, particularly since the small firms will naturally be selling at low prices in order to counter the initial advantage of the highly advertised brands. But the limitation of promotion to generic name plus drug company name will reduce the relative appeal of the major firm's drugs in the market, and this, coupled with the cancellation of disparagment efforts by adequate FDA inspection, will make sales promotion efforts less differentially profitable. And since production costs are low, price competition between large and small firms will greatly reduce unit profit margins and in time will reduce the ability of major firms to engage in sales promotion contests among themselves.

By such means, drug prices might in time be very substantially reduced. Drug firm spokesmen claim that even if all profits were eliminated, prices would not be cut by more than 15 or 20 per cent.[33] But this overlooks the amounts spent on

[33] Dr. Harold Burrows, for example, testified before this Committee to this effect: "If Parke, Davis, for our 1966 year, had reduced our prices by 20.5 percent, we would not have made any money . . . This is the maximum margin that we are talking about . . ." *Competitive Problems in the Drug Industry, op. cit.*, Part 2, p. 612.

promotion, the costs of excess capacity, and the like. In an efficiently competitive drug industry, sales outlays could probably be cut by something like 90 per cent, and excess capacity costs would be substantially eliminated. It is premature to speculate in regard to the possible magnitude of price reductions, but bringing prices more in line with production costs would reduce them by more than half.

The major firms would have a certain amount of time in which to adjust to changed circumstances, owing chiefly to the backlog of "goodwill" built up in their behalf by intensive selling efforts. Although it has been argued many times that the physician must be free to write brand name prescriptions because he only trusts one particular company's product, the use of the brand name rather obscures the identification of both the company and the drug. The use of generic name plus the company name will still allow the doctor to specify the maker of the drug. It is likely that much of the appeal of brand name prescribing lies in its convenience; if it is made less convenient to the doctor by requiring that he specify the company as well as the drug, it is probable that more purely generic prescribing will result. If these factors are operative, plus an increased reliance on purely generic drugs due to confidence in the adequacy of FDA inspection, then in time the great initial advantage of the major firms in terms of their "ethical" image will be dissipated and they will tend to lose their favored position. It is not certain that the major firms' physical sales volume will decline, although the unit profit on such sales will certainly fall. But the impact should be sufficiently gradual to allow major firms to diversify out of drugs and into other areas, such as luxury goods, where the marketing methods which the managements have perfected at such cost can be applied in ways less mischievous to society. As to the impact on research, there will always be a place in the industry for the firm which engaged in basic, and in the long run, truly productive research. Unfortunately, there seem to be fewer of these firms in the industry than one has been led to believe. It is hard to attribute credit properly because to do so requires the judicious deflation of the barrage of outrageous assertion surrounding each firm's own public estimation of its research accomplishments, rather like trying to find out which Hollywood spectacular really *is* the most Super-Colossal. One firm, Merck, does rather stand out, if only because of the credentials of the Nobel Prize winning "character witnesses" (the phrase is Dr. Louis Lasagna's) it has been able to summon in its defense.

While a firm which is interested in truly fundamental research may not earn extremely high returns on the funds it invests in such research, in the long run it is probably more likely to survive. Without doubt, the greatest single obstacle to the securing of drug patent reforms has been the argument that drug research would suffer. The issue should be faced head on. Would a reduction in the expenditures which the firms classify under the heading of research necessarily be detrimental to public health? This depends upon the types of research outlays which are reduced, and whether or not any possible decline in productive private firm drug research might be offset by increases in productive drug research undertaken under other auspices. After drug law reforms, the level of drug firm research expenditures may be reduced except in those firms where research is permitted to be pursued in large part for its own sake. But it is in the environment created within such firms that research is likely to be most beneficial in the long run. On the other hand, research of the "copyshop" type is likely to dwindle, but this is a gain to the extent that such research typically produced less of genuine social value than it consumes in terms of the alternative uses of the human resources employed, even—or perhaps a particularly—in such an operation as Pfizer, where molecular manipulation reportedly attained the status of a true art.[34]

Even if total drug industry research spending does decline, professional personnel resources will probably be shifted into non-profit channels. It can be argued that a major diversion of pharmaceutical research endeavor from private firms to public, university and foundation channels will in due time result in equally major gains. Private firms appear to carry on relatively little fundamental research, and more of this is needed at present to make applied research eventually more productive. Non-profit research will also mean less waste of very scarce human resources in imitative and duplicative programs, and in marketing-oriented activities masguerading as research.

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[34] C. E. Silberman, "Drugs: The Pace Is Getting Gurious," *Fortune*, May 1960, pp. 275–277.

The possibility remains, however, that drug manufacturers' prices might be reduced by competition and yet these reductions might not be passed on very efficiently by retailers. To increase the likelihood of competitive performance on the part of druggists, the appropriate levels of government should review the requirements for entry into drug retailing and compare them with the requirements for satisfactory performance of drug merchandising services under current conditions. Clearly, the pharmacist's function has changed from that of actively compounding prescriptions to those of passive merchandising; many of his skills have become obsolete as the result of the revolution in the drug industry. Those interested in drug industry reform should join in urging the maximum practicable liberalization of the traditional restrictions limiting entry into drug retailing. This liberalization should be such as to constitute recognition that the traditional pharmacists' distinctive functions are being altered away from professional competence in compounding and toward skillfulness in merchandising. Such recognition would be likely to stimulate new entry by those not traditionally opposed to price competition. In many lines of retail trade, dealers were inertia-bound and distribution methods unprogressive until price competition developed from such sources as chain stores, supermarkets, and mail order houses.

In my own state of Texas, where we have never been burdened by resale price maintenance laws, discount pharmacies and the drug departments of large discount houses are doing a thriving business, and have not only given the price-conscious drug buyer an alternative source of supply of both brand and generic drugs, but have exerted downward pressure on the margins of traditional druggists. Similar competition is rendered much more difficult in those states in which fair trade laws are enforceable, but one of the advantages which drug nomenclature reform should possess is in eliminating trademark names for drugs and thus making them ineligible for the protection against price competition which the fair-trade laws now allow. Some modifications of the other laws limiting price competition, such as certain provisions of the Robinson-Patman Act, should be also accomplished so as to allow druggists at least the possibility of soliciting competitive bids from suppliers.

All of these reforms represent movements in the direction of creating a market framework within which a freely competitive privately-owned industry can efficiently operate. If these reforms do not prove sufficient to bring about the desired result, two further measures would then become relevant. First, the patent privilege for drugs might be further modified by allowing the importation of patented drugs from abroad if the dealer could more cheaply purchase them abroad than produce them domestically. This would fall short of patent abolition in the sense that the U.S. patent holder would still be able to collect a reasonable *ad valorem* royalty on sales by the importer. (Naturally, the quality of the imported drugs would have to be acceptable, and the importer might perhaps be required to pay for the costs of FDA inspection at the port of entry.) If this did not prove sufficient drug patents could be completely abolished. And only if drug price levels still prove impervious to reduction after all these reforms should such measures as price control or comprehensive public utility regulation of the drug industry be imposed. These latter remedies are likely to be less efficient in operation because of the absence of a competitive market criterion for prices of drugs under price control, and the general unsuitability of the drug industry as the subject of regulation of the conventional public utility variety. Hence these expedients should be regarded as last resorts, to be used only after every effort to inject price competition has been exerted.

Dr. STEELE. Prof. Paul Cootner, professor of finance at MIT, made a statement in which he discussed risk and rate of return in very general terms and made little reference to the particular economic situation of the drug industry.

I. STATEMENT OF PROF. PAUL COOTNER

(A) In his presentation, Professor Cootner makes each of these statements:

1. First, he admitted quite candidly, and I quote:

Now, I do not appear here as an expert on the drug industry, either with regard to its pricing policy or the riskiness of its investments (p. 1).

2. And again I quote:

* * * Neither Schumpeter nor I, nor indeed any responsible economist, will argue that industrial abuses should not be corrected, when found (p. 4).

3. Finally, what I think is a very significant statement on page 9:

* * * If one were to decide, by administrative action, to reduce the average rate of return in a risky, competitive industry without at the same time reducing the risks, we would find an immediate impact on that industry's investment policy (p. 9).

(B) In general, I think that Professor Cootner's paper is a sound pedagogical exercise which in commonsense terms conveys some of the major subjective factors which influence an investor's frame of mind in appraising investment prospects.

In fact, I find myself in agreement with virtually every statement he makes. But I particularly agree with the three statements quoted above. Statement No. 3 is sound economic theory. Statement No. 2 is also true, in fact a truism if one defines responsibility in an economist in terms of sensitivity to industrial abuses. And if one agrees with statement No. 2, surely one must agree with statement No. 1, since Professor Cootner neither suggests that he is aware of drug industry abuses nor proposes corrections for them.

(C) The consequences of Professor Cootner's admitted lack of expertise on drug industry economics is that his paper, although educational in a general sense, is misleading because it suggests that the industry is like any other industry in that high returns are likely to be associated with high risk, that the drug industry's aggressiveness in anticipating demand and "promptness in accepting innovation and change" (p. 10) is socially beneficial, and that if industry risks are reduced it will lead to a reduction in the net social productivity presumably due to these risky investments.

But things don't seem to work this way in the drug industry. Consequently, the net effect of Cootner's paper is misleading because he says all the favorable things about the productivity of risk-taking in industry generally, without elucidating any of the drawbacks of the policies which result in high profits and hence in allegedly high risks in drugs.

I would like to emphasize that: 1. Statement No. 3 does not really refer to drugs since it specifies "a risky, competitive industry" while drugs are a profitable and rivalrous industry, not too much troubled by true price competition. Among price-competitive industries, one can expect the average profit levels of firms showing positive profits in risky industries to exceed those shown by similar firms in safer industries. But once we drop the assumption of price competition, there is no such clear-cut relationship.

A pure monopolist of an absolute necessity could make enormous profits in perpetuity and face no risks. But in the drug market there are elements of both monopoly and rivalry. Patents confer monopoly power with respect to a certain product and extremely inelastic demand allows enormous unit profit margins. But these generous margins will attract new entrants who will find it profitable to spend vast sums in imitating the patented product legally. Once a rival compound is concocted, how can the new drug take sales from the old?

Price competition is one route but a very costly one, and unless there are a large number of rivals, it is not likely to break out. Instead,

sales promotion outlays will be the vehicle of the rivalry, and the originally enormous profit margins are whittled down progressively by the necessity of engaging in increasingly extravagant sales promotion campaigns to counter those of one's rivals.

Senator NELSON. Is the ordinary consumer of drugs benefited in any way by this rivalry?

Dr. STEELE. No, I would say the benefit is essentially negative in that rivalry functions in the drug market as a substitute for price competition on the one hand and genuine research advances on the other. When Dr. Console, former medical director of the Squibb Co., testified before the Kefauver hearings, he said the drug industry is an unusually safe industry. Risks are low because if the research department fails to make an advance, the advertising department can substitute its expertise and make the drug appear to be an advance. So in this sense, this rivalry prevents price competition by the ways which Professor Schifrin has just described. And it also confuses the issue regarding drug information and the substantive advantages, if any, made by new drugs.

Senator NELSON. Thank you.

Dr. STEELE. In order to make the greatest profits per drug it is usually necessary to be first in the market, otherwise the advertising cost of wresting the market away from the first (and also heavily advertised) drug is disproportionately great. Hence the motivation to devise new drugs. But at the same time, the new drugs found by others must be rapidly copied, so that the costs of research, both primary and imitative, come to mount up. And the fact that everyone is trying to copy and/or improve everyone else's drugs leads to an overly rapid rate of product obsolescence and an artificially induced "risk" of short commercial life for the average product.

Since many doctors have testified that there is generally no net surplus of advantages over disadvantages for the manipulated molecules, rapid changes in market shares betray motion but not progress. Thus sales promotion and product competition substitute for price competition, and unit profit margins decline not through price reductions but through cost increases. It might even be contended that this route to profit erosion roughly equates risks and rates of return, such that even though the risks are self-created by the seller's own choice of rivalry tactics, they are real risks and only enough will be invested in sales promotion and patent bypassing research to keep the rate of return on investment from dropping below the minimum satisfactory rate relative to the artificial risks built into the market.

One might agree with this analysis and still contend that it would be socially beneficial to alter the market structure so that price competition would be forced upon the sellers and lowered profit margins would become insufficient to support constant devising of new drugs and their rapid copying. Hence the "risks" would decline in direct proportion to the decline in rate of return.

But it is also possible to dissent from this analysis. First, inherent commercial risks in the drug industry are probably lower than in most industries because of the depression-proof character of the industry. Drugs are needed in fair times and foul, and a sick man will buy as many drugs as he needs regardless of his income, right up to the limit of his ability to finance current purchases. Second, drug firms may have come to realize in recent years that the market is practically satu-

rated with advertising appeals, such that although it is necessary for each firm to maintain current sales promotion levels in order to offset the efforts of others, incremental advertising expenditures will have no real impact; therefore, profit rates remain above risk-determined levels because additional spending on sales promotion, and possibly even on production competition, simply doesn't lead to even the prospect of further differential gains. In such a case, the only remaining tactic to bring profit rates down to equilibrium levels consistent with risk (regardless of the nature of the risk, whether inherent or artificial) is price competition, and drug industry repugnance to this force, plus the fact that the number of sellers in each market; that is, effective competitors is still too small to compel price competition, generally results in a sort of high-profits truce between companies which refuse to engage in the price competition which would effectively reduce profit levels to equilibrium relationships in comparison with true risk. (However, Mr. George Squibb's testimony with regard to the frequency of special deals to distributors indicates that although list price competition may be unknown, there may be a substantial amount of hidden competition in terms of such special inducements to dealers. And I suspect that excess capacity in production processes is probably a major reason for this.)

Mr. GORDON. Are you aware that one of the risks attributed to the drug industry is the possibility that the industry may become competitive?

Dr. STEELE. I think this is true. I think Mr. Squibb also alluded to this risk in his statement.

Senator NELSON. Well, in economic terms, is competition considered a risk?

Dr. STEELE. Well, I think it is really a pleasant risk. Competition would not be a risk in itself. In comparing two equally competitive industries, one would expect that the rate of return would be greater in the inherently more risky industry. But if an industry, let us say, had been monopolized, and there is a likelihood that for one reason or another, competition will break out, then investors will see this as a risk in the sense of the institutional frame of risk or something like that, but it won't be something that is inherently in the market structure of ordinarily competing sellers.

(2) Professor Cootner does formally recognize the possibility that the firms might react to profit reduction measures by reducing the riskiness of the ventures in which they engage. But the relevance to the drug industry is limited since the example mentioned assumes that the risk taking activities hypothetically curtailed are socially productive, and do not consider the possibility that these risk taking activities are also creating.

(3) Cootner makes two statements which are not quite compatible. On page 8 he states: "This basic conclusion is that as risk rises so does the required rate of return." But the "required" rate is a subjective expectation; it is basically an ex ante phenomenon. However, on page 4, Cootner states that "one should not be surprised to find large average profits in risky enterprises * * *" which is not quite the same thing. One would expect to find large average profits for companies making profits, but if true risk is significant, also large average

losses for companies failing to break even. I would say petroleum exploration would be a good example of this. If you take the companies which only show profits and average their returns, the industry looks better than if you take companies which incur losses. In such an industry, if you take their returns and add them in, it is not clear that the average ex post rate of return on all investment in a risky industry should always necessarily be higher than in a safe industry where losses are very rare. This is, of course, one of the major weaknesses of statistical measurement of the risk rate of return hypothesis: the data are usually available only for the largest firms in an industry, which because of their very size face relatively less risk than small firms (since riskiness is basically a property of individual investment projects, and not of the firm itself, which is collection of many projects) the small ventures which fail, or do not get included in the blue ribbon listing of firms, may so regularly make losses that total industry rate of return is significantly depressed.

II. STATEMENT OF PROF. SIMON WHITNEY

(A) While I am in general agreement with almost all of Professor Cootner's statements, I find myself in strong disagreement with the majority of Professor Whitney's. Time does not permit the criticism of more than a limited number of these statements.

(1) Whitney's statement as a whole is based on the implicit assumption that if private drug firms don't do drug research, it just won't be done. But great sums of public money are now spent on research in health and medicine. Even if drug industry reforms do reduce private drug research, there is reason to believe that the researchers could be more productively employed by universities, foundations, and government agencies in doing much the same type of research.

I would like to comment now on the statement of Prof. Simon Whitney and preface my comment by saying that I am in general agreement with almost all of Professor Cootner's statements. The only thing wrong with them is they are rather irrelevant. But I find myself in strong disagreement——

Mr. GORDON. You say you are in general agreement. Yesterday, Dr. Mueller of the FTC, stated:

> Thus Conrad and Plotkin unwittingly have made a case for the inference that a substantial part of the high profits earned by drug companies are really due to advertising-and-promotion-created barriers to entry, rather than risk. This, of course, coincides with the conclusion of nearly every economist who has studied the drug industry.

Dr. STEELE. I would agree with that. I would regard myself as one of those who agree with the statement.

But the Cootner statement is different from the Conrad and Plotkin statement. The Cootner statement says, really, very little about the drug industry, just discusses the problems of risk and so on.

Mr. GORDON. I see. He doesn't discuss the drug industry at all.

Dr. STEELE. Not really.

Whitney's statement as a whole——

Senator NELSON. Doctor, has anyone done a study to find out how much research has been done by Government in the health field—by

NIH and other agencies—that is really directly related to the drug field?

We know what the total research budgets are. We have received some material from time to time indicating expenditures by Federal agencies of hundreds of thousands or millions of dollars, part of which was spent in research on a particular drug or testing of a drug, but the amount spent on the drug alone was not clearly isolated so you could specifically identify it.

Are you aware of any studies, reports, by anyone who has attempted to identify the amount of money that goes into research that you would say is related rather directly to the drug industry?

Or to put it another way, research of the kind that the drug industry does?

I am not talking about molecular manipulation or anything like that.

Are there any studies of that kind?

Dr. STEELE. Unfortunately, I do not know of any. All the ones I know of share the defect you have just described. They refer to project research. Only a small proportion of the project may be devoted to evaluating the particular drug.

Senator NELSON. We intend at some stage to have testimony from the various Government agencies on this but I though perhaps somebody had done a study and made some breakout of the funds spent in this area. You are not aware or any such study?

Dr. STEELE. No, I am afraid I am not.

On page 3, Professor Whitney states that:

"* * * $3 of additional stockholders money per dollar of net worth in 1950 went into drug manufacturing for every $1 in all manufacturing * * *."

Stated in this manner, it sounds as if new stock issues were sold to raise the three additional dollars.

Actually, as Whitney explains in a footnote (without appearing to appreciate the significance of this factor), most of the increase came about from reinvestment of earnings. Professor Whitney is trying to have the best of two worlds: the Adam Smith world of atomistic competition, and the modern corporate finance world of noncompetitively high prices and profits, and discretionary plowbacks of retained earnings by management. On pages 2 and 3 Whitney implies that the first function of profit is the allocation of investment, which is true in the classical sense. But the classical theory of consumer sovereignty applied also to investors; in principle, all profits in a corporation, under this theory, should be paid out to shareholders, and the decision as to whether to reinvest in the same enterprise or in others should be made anew upon the receipt of each dividend. This would insure a more impartial appraisal of alternative uses of dividends; whether for reinvestment or for consumption spending, than does the modern system of having managements, rather than owners, decide upon the reinvestment of about half of total earnings. (The obvious tax disadvantages of higher dividends to high-income stockholders and underwriting costs for new securities have been instrumental in transferring discretion over total profits from stockholders to managers, but this does not alter the basic principle involved.)

And with price competition, relative profit margins in different industries would reflect the scarcity of supply relative to demand and hence indicate the relative need for expansion of investment and productive capacity.

But if monopoly power exists, output may be restricted and prices and profits can be at high levels although the monopolist may actually have excess capacity and no need to expand his facilities.

Furthermore, discretion over prices may result in prices which are too high relative to costs and in resource misallocation relative to the outcome which would have prevailed in a purely competitive market.

If excessive profits, made by overcharging buyers, are plowed back into the industry by bypassing the investor's discretionary power over all profits, the investor benefits from what is tantamount to a capital levy on the consumer. The drug buyer thus contributes much of the capital—the great majority of additions to capital investment—on the basis of which the drug stockholders now expect high earnings because of the "risk" to which "their" capital is subjected. Furthermore, Whitney takes it for granted that this increase in capital value resulted in at least commensurate social gains; on page 4 he identifies these gains with increases in drug sales and with research and development expenditures.

But in neither instance is it necessarily the case that the true value of drugs or drug research is measured by dollars spent. The individuals most qualified to judge these matters are physicians and medical educators, and their judgments as recorded in public hearings on drugs have not been such as to encourage those who wish to equate dollars spent and value received in drugs.

(3) "Many hundreds of new drugs, as documented by earlier PMA witnesses, resulted from this profit-motivated research" (p. 4). This is misleading if the reader naively interprets this to mean genuinely new chemical entities. Non-PMA witnesses supply different "documentation." Dr. Martin Cherkasky has previously stated before this committee that the industry's claim in the early 1960's to have produced over 400 new drugs required more than 90 percent deflation. He said:

> On examination, only 29 of those were really new contributions. The rest of them were gimmicks, new dosages, new combinations that really hadn't much value ("Competitive Problems in the Drug Industry," pt. 2, p. 676).

And during fiscal 1967, FDA Commissioner Goddard stated that of the 83 New Drug Applications approved, 62 were for "what have been called 'me too's' or molecular manipulation." (Ibid., pt. 2, pp. 757–758.)

(4) On page 6, Whitney suggests that the lower prices charged by generic name firms reflect the absence of research, quality control, and original distribution costs on their part. This sort of approach is a favorite with pharmaceutical manufacturers associations. The Canadian PMAC made similar charges against Canadian generic name firms during their drug hearings for 1966–67, and, not unsurprisingly, it developed that small generic firms also incurred costs for quality control and research.

The chief cost savings of the generic firm is in the area of sales promotion, which was somehow overlooked by Whitney—unless

original distribution" is taken to be a very inclusive euphemism indeed.

In any event, the major firms are simply voicing their indignation about having to be faced with price competition even if it is only effective in the minute interstices of their total market.

I would refer again to Professor Schifrin's diagram, the roughly 5 percent of total sales by dollar volume, which would be a relatively higher percentage of the physical volume of drugs sold because of lower average cost.

What these firms do not realize is that any argument against price competition is an argument for price control. It is a long-established principle of public policy that where competition will not work, regulation must be substituted. "Do the lower prices charged by generic name manufacturers reflect willingness to operate on lower profit margins?" (p. 6). By no means. Price competition, such as prevails among generic firms, compels producers to be efficient and to accept the low-profit margins determined by competition. But the major companies would ordinarily have little direct experience with this.

(5) "What does it mean, after all, to say that a price is 'too high'?" (p. 7). Any trained economist would answer that it is too high relative to production cost, since this is the standard of efficient pricing in a competitive market. But Whitney invokes a sort of value-of-service standard in connection with prescription drug prices, implying that if the price does not exceed what it is worth to the buyer, then it is reasonable. But this is just the monopolistic practice of charging what the traffic will bear; the full value to the consumer is the absolute minimum price which can be exacted from him, and the major benefit of price competition to the consumer is that it allows him to obtain the goods at a price related to production cost as well as to demand, such that the typical buyer pays less for the goods than its actual maximum value to him, and thus enjoys some measure of what economists call "consumer surplus."

Under monopoly pricing, the average value of this surplus will be reduced, and under systematic price discrimination—the exercise of which requires considerable monopoly power—it may disappear entirely.

(6) "You have heard of large economies made by hospitals through purchases of drugs by generic name. Were all purchasers to do the same, many research-based companies would be put into serious straits" (p. 8). The implication here is that these companies would cease to do research. But since they spend only about 6 percent of their sales dollar on research and 25 percent on sales promotion, it would seem that much greater scope for economies lie in the marketing budget.

But even if research outlays were cut, much of this research could probably be more efficiently accomplished under nonprofit auspices, as mentioned under point 1. And a more equitable distribution of the cost of drug research might also be accomplished if more of it were publicly financed. Although drug spokesmen have defended the price of drugs by reference to research costs on innumerable occasions, I have never once heard of them raising the question of the propriety

of having these costs financed entirely by the sick. And this is a question which deserves much consideration.

Senator NELSON. You suggest that the more equitable distribution of the cost of drug research might also be accomplished if more were cofinanced. Would you elaborate on that? How and in what way?

Dr. STEELE. Well, the argument is that drug research, particularly fundamental research in drugs is ultimately a philanthropic activity which benefits everybody. You might say in a narrow sense, if a person is sick, he benefits and benefits exclusively from taking a drug which he has prescribed for him and which he pays for. However, the narrow view is overly narrow, in that availability of the drug protects the health of everyone. To the extent that individuals who have diseases prevent the disease from continuing and affecting others, the society as a whole will gain. The availability of good medication increases the health standards, the health potential, of the economy as a whole whether or not the medication has to be used.

It is a potential benefit.

If the sick benefit entirely, then the people who by virtue of the sick's having obtained medication do not themselves become affected. So they benefit in a sense almost unjustifiably at the expense of those who have had to pay for medication and because of their sickness, have been in perhaps a worse position than others to pay for the medication and hence for research.

Senator NELSON. What you are saying is that since it is a benefit to the whole public, the individual and the public who never becomes ill, it is in the nature of an insurance benefit. You may own insurance, never have an accident, never become ill, but it is a protection if you do.

Is that what you are saying?

Dr. STEELE. Yes, this is it.

Senator NELSON. How would you finance more of this research?

In what way? Would you contract with companies to do it?

Dr. STEELE. You could do that provided that the benefits to society were not disproportionately appropriated by the companies involved.

I think that primarily, basic research is an activity which is not done too efficiently or effectively by profit-oriented firms. Obviously, you cannot tell what is going to happen when you start on a basic research program. You want to increase your knowledge. You may end up benefitting your competitor rather than yourself.

Research may be a fruitless activity for years, and the loss a company may incur on this basic research may deter it from doing further research. So I think research either under public foundations, universities and so on, or public financing of private research, with appropriate restrictions on patent monopoly could be carried out more effectively.

Senator NELSON. Thank you.

Mr. GORDON. Is not this the principle of roadbuilding, of building highways? The Government pays for highways throughout the country and in States as well. You do not expect the users of the roads to pay for them. Do we not consider that all of the society benefits by it through the opening of communication and so forth? Is that not the same idea?

Dr. STEELE. There is a very good analogy. But I think that in the case of drugs, the argument is even stronger, because a person who buys a car does so voluntarily. He engages in the use of roads in order to further his own gains. But a person who buys a drug is not doing something voluntarily in the sense that he has told society to use its resources specifically to cure his disease. Instead, he is reacting to a situation which has been forced upon him against his will.

What Senator Nelson said, using the insurance in case of a risk, rather than using a voluntary activity.

The next point is a rather technical one. Professor Whitney is in error when he multiplies profits per dollar of sales in drugs by the ratio of profits per dollar of equity capital in drugs to profits per dollar of equity capital in all manufacturing and claims that this brings profits per dollar of equity capital in drugs down to a level equal to that earned in all manufacturing.

The fallacy is that he is assuming a capital turnover ratio of unity for the drug industry. Profits on equity capital are equal to the product of two terms: Profits per dollor of sales and sales per dollar of capital during some time period such as a year. In manufacturing, the product of these two ratios is said by Whitney to be only 61 percent as high as for drugs. But if this ratio is applied to one of the two terms, rather than the product of both of them, in the drug industry, the implicit assumption is that the value of the other term is unity. But Whitney cites the FTC–SEC survey as showing that the drug industry earned 19.7 percent on sales but 22.2 percent on investment, hence the implicit capital turnover ratio is about 1⅛. Hence prices could be reduced by 8.8 cents in the dollar, instead of 7.7.

(8) "Someone will have to make up the corporate income tax payments lost as a result of declining profits of drug manufacturers" (p. 9). In the first place, the Government would save 8.8 percent on all its drug purchases at the manufacturer's level; this would go a good way toward offsetting the lower income tax receipts from drug firms. And to the extent that the Government indirectly finances other drug purchases, the cost savings would be still greater. But the argument is a peculiar one. There is the suggestion that one should not lower excessive profits because the profit maker is liable for Federal income taxes on the full amount of the profits. But the same is true for incomes from fraud, embezzlement, extortion, and other illegal activities, and yet the possible adverse effect on income tax liabilities does not deter policymakers from trying to eliminate such activities.

The next point I think is certainly important. Whitney states:

> Certain trends are alarming. New chemical entities marketed per $100 million of R. & D. expenditures, for 1959 through 1966, were 32, 22, 21, 11, 6, 6, 7 and 3, respectively, * * *. There may be no real recovery if the profits from research are threatened (pp. 9–10).

This is not alarming if it simply means that tighter FDA regulations have reduced the total flow of new drugs by eliminating the inefficacious ones, which FDA did not have authority to do until 1962.

But the fact that the decline was steady even before 1962 probably indicates, in addition, that diminishing returns to the molecular engineering techniques of applied research are being increasingly felt as that method is more and more intensively and extensively applied to

a fixed universe of discovery possibilities. What is needed is money spent on fundamental research, to make the major breakthroughs for the applied researchers in the drug firm subsequently to exploit. Since profits rose throughout the period of declining discoveries, there is no reason for Whitney to suggest a linkage between recovery in discovery rate and the lifting of the threatening atmosphere regarding profits from research. Actually, profits have little to do with it since the drug firms do not find it attractive to invest enough funds in the fundamental researches which constitute the only path to eventually reestablishing the productivity of applied research.

(10) On page 10, Whitney notes that drugs as a percent of total medical care costs have been declining. This is due not to declining drug costs but chiefly to the phenomenal increase in hospital costs. And most of this increase is owing to the inclusion of hospital charges in health insurance programs without adequately disciplining hospital costs and charges.

Health insurance programs increase effective demand for hospital services without at the same time taking any steps to increase their supply. The natural result is an increase in charges. And if drug coverage increases under health insurance plans, including medicare, the same thing is likely to happen in drugs. So the fact that drug costs have increased less rapidly than hospital costs does not mean that drug pricing has been characterized by self-restraint but simply that the coverage of drug costs under health insurance programs has been less comprehensive than their coverage of hospital costs. As pressures build up to increase drug coverage, steps must be taken to discipline drug prices and increase the supplies available at competitive prices.

Senator NELSON. Have some of the declines in drug prices been due to the expiration of patents?

Dr. STEELE. Undoubtedly, this is true.

Senator NELSON. That is, on a particular drug, as the patent expires, there is a tendency for the price to consumers to go down?

Dr. STEELE. This is true, yes, especially in Professor Schifrin's market "B." Some of the major drug firms may sell at lower prices. The patent holder himself may not reduce his own price, or may reduce it only more slowly.

Next I would like to make some comments on the Arthur D. Little report.[1]

III. COMMENTS ON THE A. D. LITTLE REPORT, "RISK AND RETURN IN AMERICAN INDUSTRY"

A. Criticisms of the basic orientation of the study

(1) The study is designed to test the hypothesis that there is a positive relationship between risk and rate of return. But the definition of risk simply as average intercompany variance within an industry is rather arbitrary, even though this has frequently been used as a measure of risk. "Average Intraindustry Variance and Return in American Industry" would have been a more accurate title for this study.

[1] I am indebted to my colleague Prof. James Willis for suggestions and comments in regard to this presentation.

(2) It is misleading to include the drug industry in a comparative study where a large number of industries are analyzed on the basis of measured average rates of return and variance, and conclusions are drawn as to the relative risks encountered by the groups of industries as a collection of observations. This is because the markets of the drug industry are so protected from price competition by patents, trademarks, extremely inelastic demand, brand name prescribing, the mediation of effective demand through a financially irresponsible purchasing agent, etc., that there is no other industry in which the seller has a comparably great power to rise superior to price competition. The drug industry is truly in a category by itself in this respect. Ideally, one should hold constant the degree of competition among industries in making a study of this sort. The relationship between risk and rate of return should be most clear cut if all industries studied were purely competitive. The value of the study is reduced to the extent that industries far removed from price competition are included. After all, a pure monopolist could conceivably earn enormous returns with no risk.

(3) It is difficult to understand why the investor is conceived of as measuring risk in terms of variance alone, without regard to the average rate of return in the industry. It seems likely that an investor will regard two industries as having different risks, if one has an average rate of return of 25 percent and the other has an average return of 5 percent, even though each has a variance of 50, for example.

B. Specific criticisms

(1) On page 11, the authors state: "It is within the individual corporation that the balance between expected returns and expected risks is struck." This is contrary to the approach taken in ecomonic theory and in financial analysis, where the basic unit is the individual investment project, not the firm as a whole. The firm is a collection of projects, some of which may be very risky while some are not.

(2) On page 14, the authors admit that they were unable to allow for possible biases resulting from the fact that their data source limited them to the larger and more successful firms in each industry. This might be the source of considerable difficulty. It is generally known that larger firms make higher profits than smaller firms, both as a general rule and within the typical industry. Hence if an industry composed of 50 medium sized firms is compared with one made up of 25 large firms and 25 small firms, the variance and hence the riskiness of the latter is likely to be greater, although it is debatable if this is in fact the case. And limitation of data to the larger firms tend to underestimate the risks faced in a given industry. The fact that the firm is a collection of investment projects provides an additional reason why the larger firm may be able to make a higher rate of return than the small firm. Not only is it able to take advantage of economies of large-scale production, transportation, distribution, advertising, and finance, but it can also adopt a broader scale risk diversification program which makes it less vulnerable to the possibly unfavorable outcomes of individual projects. Hence the industries containing the largest firms may actually face the smallest risks, and yet their rate of return on investment will be relatively higher.

(3) Another reason why it is unfortunate that data could not be obtained on the smaller and less successful firms is that which is given as comment C–3 on Professor Cootner's statement.

(4) The industry rate of return is defined simply as the average rate over the entire period. But if there has been a significant upward or downward trend in an industry during the period, investors would react to the trend as well as the average. For example, the average might be 15 percent in two industries, but if one had declined from 20 to 10 percent, while the other had increased from 10 to 20 percent during the period, investors would be likely to regard the former industry as a much riskier investment even if both average rates of return and variances were the same.

(5) On page 16 the author states:

> A company may be receiving monopoly returns (returns higher than justified by risk) on its book assets (i.e., monopoly real returns) while the holder of its equity instruments would receive a "normal" return if the monopoly profits were capitalized when the stock was issued.

In model No. I, we note that the drug industry's rate of return is significantly higher than the value given by the regression line for its variance. The computed value is about 14.75 percent, while the actual value is 17.52 percent, or about 20-percent higher.

Since this is the book value regression, one might conclude that some degree of monopoly returns are present, since the returns made are higher than those which would be justified by the risk versus rate of return relationship embodied in the regression line. (Here, a statement from page 5 of Professor Cootner's statement comes to mind: "If abuses are found, one must take care to eliminate only excessive, not not necessary returns on investment * * *." Hence one might conclude tentatively that about a 20-percent reduction in drug industry returns would still leave returns commensurate with the risks as measured by Conrad and Plotkin.)

In other words, as far as the investor, the stockholder is concerned, the rate of return he is receiving is just about the average on the basis of Conrad's—that is, the A.D. Little study's—regression line.

And at a glance at figure II, shows that the market value basis is slightly lower than the value indicated by the regression line. Hence one might interpret the two regressions as showing the presence of substantial monopoly returns on book value consistent with only competitive returns to stockholders due to the competitive nature of the capital market in distinction to the monopolistic nature of the market in which prescription drugs are bought and sold.

(6) The statement from page 16 quoted just above is not entirely consistent with the listing on page 11 of "the various phenomenon that might contribute to interindustry differences in basic riskiness." On page 16, monopoly returns are defined to consist of those which are higher than justified by risk. But on page 11, certain of the elements contributing to monopoly power—or conversely, to its absence—are listed as factors contributing to basic riskiness. These include, for example, differences in ease of entry, in elasticity of demand, in price flexibility, in exposure to foreign competition, and finally, differences in competition among existing, prospective, or potential new products. It would appear that there is serious confusion between the monopoly

elements which contribute to basic risk and those identical elements which, by resulting in monopoly returns, provide earnings greater than those justified by risk. The confusion can only be resolved by assuming that all industries being studied are purely competitive. If this assumption is contrary to fact, then it is not sufficient simply to speak vaguely about factors influencing risk, and about monopoly returns, as if they were two different things. Instead one must devise a better theory to relate rate of return to risk and monopoly power more explicitly and satisfactorily.

IV. COMMENTS ON THE STATEMENT OF GORDON CONRAD, AND ON THE A. D. LITTLE STUDY, "TRENDS IN MARKET SHARE FOR ETHICAL PHARMACEUTICAL PRODUCTS"

A. General comments

(1) On page 1 of his statement, Conrad states that the Little study shows "a significant degree of interproduct competition." But we do not know how significant the data are for drugs until we have data from other industries with which to compare them. Risk, being subjective, is a relative matter and until it s shown that other industries have less interproduct competition, the Little study will remain inconclusive.

(2) Even more important, this so-called interproduct "competition" cannot be beneficial to the consumer unless it results either in price competition or in genuine improvements in the quality of the products. Otherwise we have change, and perhaps wasteful rivalry, but no progress. Yet on the very first page of the Little report we read: "This report does not explain the reasons for competitive changes over the time period since this would require revealing product names and company strategy." This effectively prevents the study from making any real contribution to answering the real question: is the economic performance of the drug industry beneficial to the economy and the consumer? [1]

(3) Conrad's statement concludes:

> These results illustrate one aspect of the potentially high risks facing pharmaceutical manufacturers, that of the genuine uncertainties as to the length of time any one product can be expected to contribute to the company's profits.

[1] This same point was debated during Kefauver's hearings on the drug industry antitrust bill in 1961. At that time Professor Markham placed great emphasis on the amount of turnover or change in the rank order of market shares by products in a particular therapy category. But to assess the degree of workability of competition evidenced by such turnover, one should determine how it was brought about: by price competition? by product improvement? or by less beneficial means? But Markham seemed to believe that turnover was a good thing for its own sake, and at least at the time of his appearance had not analyzed its causes. When asked just what was the value to the consumer of turnover if there were no price competition, he responded: "* * * I would still prefer, even if the prices are the same, and this I know nothing about, that the firms that are trying to serve my needs as a consumer feel that somehow or other they, through product innovation, or by whatever means—the development of new products, new processes, new drugs—are getting my consumer's outlay in terms of competitive activity" (pp. 2105–2106). During questioning, Markham conceded that he had not examined the facts as to whether or not any drug firm had experienced a change in relative sales rank because of price competition (p. 2096). Markham agreed that price competition is of paramount importance to the consumer, but concluded his contribution to the hearings with this statement: "I have not made any careful study of the workability of competition in the ethical drug industry. I was examining primarily these particular issues that seemed to be important" (p. 2111). This suggests that to Markham the issue of workability of competition was not important—but since he is known as one of the foremost students of the problem of workability of competition, the statement remains an anomaly.

Again, it should be emphasized that this is a risk to which the industry intensively contributes, and in fact fosters, by its policy of imitative research and product development programs, sales promotion strategies, and the like. And very little of this is likely to be socially productive.

B. Specific comments

(1) The summary section of the report bristles with unsupported "plugs" for the drug industry. On page 4 it is stated that "the development of effective products with fewer and less severe side effects" is one of the most outstanding features of the market. This is a more sanguine opinion than was stated by many doctors during the Kefauver hearings, particularly those whose statements are contained in part 18 of those published hearings. L. Meyler's book, "Side Effects of Drugs," is highly educational in regard to the general failure of later modified drugs to have side effects much different from the earlier drugs.

(2) The summary section also contends that combination products are improvements. Again, there is much medical opinion to the contrary. The U.S. Pharmacopeia does not list combination drugs; the National Formulary has only a few. Dr. Maxwell Finland stated during the Kefauver hearings that combination drugs lacked flexibility and compounded the problems of dosage and toxicity.

The summary refers to "combination products in which the ingredients provide synergistic effects." Dr. Finland referred to synergism claims as "incorrect and misleading," observing that such activity "is a highly specialized property related to individual strains of bacteria and is recognizable only after special tests. Thus, so-called synergistic drug combinations can only be tailormade to an individual strain of bacterium after such tests" (p. 13928).

(3) It is also contended that there are "obvious economies" in producing and distributing combination products, but no evidence of this is given. But even if economies are realized, of what value are they to the consumer? If drug prices are based on the "value" of the medication—that is, what the market will bear—then costs are irrelevant, and cost savings simply contribute to larger profit margins.

V. COMMENTS ON THE STATEMENT OF PROFESSOR FIRESTONE

A. General comments

(1) Much of this paper is similar in style and approach to that of Professor Cootner: It is a straightforward pedagogical exercise in which some of the rudiments of index number measurement methods and problems are discussed.

(2) But it differs from Cootner's statement, and resembles the "Trends in Market Share" study in that Firestone has a tendency to compliment the drug industry for alleged advances which have been regarded somewhat more skeptically by medical men. For example, on page 7 and again on page 20, he refers with approval to sustained-release medications despite the fact that Dr. R. W. Burack previously stated before this subcommittee that such a preparation "remains unpredictable at best" (part 1, p. 330). And on page 21 he speaks with approval of combination drugs, the criticism with regard to which

have already been mentioned in connection with the comments on the "Trends in Market Share" study.

(3) On page 23, Firestone develops an argument akin to Whitney's that the price of drugs should be judged in relationship to their "value" to the consumer rather than their production cost. Firestone's presentation, although less provocating phrased, is open to the same criticism that was made of Whitney—that use of the "value" criterion betrays a monopolistic pricing strategy.

B. Specific comments

(1) On page 8 it is argued that because there are 110 drug products in the wholesale price index, this "probably results in the drug category being more representative than most other categories of like weight" since the inclusion of only 21 products would be required to give the drugs category adequate coverage in terms of the relative "importance" of this category in the WPI compared with the total number of products included in the WPI. But it should have been made clear that the number of products included does not necessarily guarantee the representativeness of the data reported unless the reported products are themselves representative of the category in question.

(2) On page 11 it is stated that the PMA wholesale price index is limited to brand-name drugs only, which in itself makes it less than perfectly representative of all drugs. Firestone should have estimated how much bias might be introduced into the PMA index by excluding generics, and should have indicated how much of the industry's sales are in generic form.

(3) On page 16 it is claimed that patented drugs declined in price by 24.8 percent between 1949 and 1966, while nonpatented drugs had increased by 1.1 percent.

While it is not surprising to discover that prices in the competitive segment of the industry's market presumably increased, and while it is not likely that any segment of the industry could have experienced substantial price declines during an inflationary period unless initially uncompetitively high prices prevailed, the contrast between the price movements would seem to require some additional explanation.

There are two questions.

First, what sort of criterion was used to distinguish patented and unpatented drugs at various points in time? And, second, why did the price index for patented drugs seem to drop so appreciably?

Neither question is answered by Firestone, although one suspects that to answer the first question may largely answer the second. A detailed explanation of the criteria used to distinguish patented and unpatented drugs should have been provided.

Senator NELSON. When they use the term "patented drugs" here, are they referring to drugs that were patented but subsequently the patent ran out?

Dr. STEELE. That would be true of any drug which was patented.

Senator NELSON. It is one thing to say patented drug prices declined while the patent was still in effect and another to say they declined, if they declined, after the patent expired, is it not?

Dr. STEELE. Quite true.

Senator NELSON. Then if during a certain period of time, as you suggest, when costs are rising, the nonpatented drug prices rose, you might very well expect that, as in most products.

Dr. STEELE. Yes.

Senator NELSON. Would it not indicate that if during the same period, patented drug prices declined, they had set an arbitrarily high price in the first place, since drug industry costs are increasing, too?

Dr. STEELE. Yes; I would agree they must have set the price arbitrarily high so there is only one direction in which it could change.

Firestone does refer to large drops in hormones and antibiotics prices, but one must not forget that a major antibiotics price cut was announced in 1960 just before the Kefauver hearings were to investigate the antibiotics market. Since this was the first price change in almost 10 years, the motivation for that price cut at that particular time is somewhat problematic. The significance of the reported price trends for nonpatented drugs, however, may not be very great. Since the PMA index is restricted to brand name drugs, it is doubtful if it is very representative of nonpatented drug prices, since much of the sales of these drugs—in physical if not in dollar terms—is probably under the generic name.

(4) On page 19, Firestone states: "An index cannot tell us whether prices are too high or too low." Quite true. This should be kept in mind when appraising the significance of reported declines in price indexes for brand name drugs.

(5) On page 14, Firestone refers to "initial exploratory prices" for drugs during the introductory period of their use. This is an interesting phrase and its implications should have been enlarged upon since it suggests market testing by a seller possessed with discretion over prices and an interest in experimenting with prices to determine what the traffic will bear.

(6) Although Firestone states that the 17 items included in the BLS Consumer Price Index for all prescriptions since 1967 "should be reasonably reliable to measure price movements for all prescriptions"; (p. 18) it is apparent from the study by Agnes Brewster, "Examination of Anomalies in Prescription Drug Prices and Utilization," that neither the drugs included nor the method of pricing them is such as to permit the BLS index to make any claim of being representative. Of the 14 drugs in the 1964–66 index, 11 could be purchased generically. Only 12 of the 200 most frequently prescribed drugs in 1965 were not sold under trade names, and these 12 drugs constituted only 6.2 percent of all prescriptions. Yet six of the generic drugs included in the BLS index were members of the group of the 12 most frequently prescribed generic drugs.

It is likely that these six drugs accounted for only 3 or 4 percent of all prescriptions. Yet they constituted over 40 percent of the number of drugs in the 1964–66 index. More important, brand-name drugs account for 90 percent or more of all drug sales, but only about 57 percent of the number of drugs could be purchased under brand names. Hence generic drugs were overly intensively represented, and brand-name drugs underrepresented.

The method of pricing the drugs is even more unsatisfactory. All drugs were priced generically, even though over 90 percent of the prescriptions are written by brand name, and probably half or more of the remainder are dispensed by brand name.

For only three of the 14 drugs would the generic and brand-name prices be identical, since these three drugs were sold exclusively by patent monopolists.

(7) The entire issue of the relative movements of drug prices and average prescription charges merits more unraveling than Firestone has attempted. The price of a prescription is based on two factors: The cost of the drug to the druggist, and the druggist's monetary makeup. The cost to the druggist varies with the identity of the drug, the dosage form of the drug, the unit cost of the drug, and the number of units embodied in the prescription.

The druggist's markup is a monetary sum added to his cost, although it may be determined either as a percentage markup added to cost, or as a service charge which does not vary directly with the drug cost itself. In either case, the amount of the markup will be influenced by the druggist's costs and the state of competition in his marketing area.

(*a*) As Firestone suggests, one possible explanation for the decline in drug prices as measured by certain indexes and the increase in average prescription charges is that an increase in the distributor's cost has more than offset the decrease in the price of drugs to the distributor.

(*b*) Elsewhere Firestone makes a point of expressing his conviction that pronounced variations in prescription prices for the same item cannot be due to "the misdeeds of the manufacturer" (p. 22). One may infer that this conviction includes a concern to show that increases in prescription charges are similarly not to be attributed to misdeeds at the drugmaking level. ("What has been most serious in the misuse of average prescription prices is the use of these prices for measuring what has happened to manufacturers' prices," Firestone states on page 21.)

(*c*) However, certain drug firm practices might increase prescription charges even though drug prices were declining. In terms of the above analysis of the factors determining prescription charges, the following avenues might be exploited to increase prescription charges despite declining prices for each dosage form of each individual drug.

These points are possibly quite significant.

First, with regard to the nature of the drug: Sales promotion may succeed in changing prescribing habits so as to increase both the prescribing of drugs in general, of the more expensive drugs in particular, and even of the more expensive dosage forms or modes of each drug. Drug industry critics have claimed that overselling the doctors means overprescribing and overmedication.

Last year, I think Dr. Frederick Wolff testified before the subcommittee that in his opinion, which he thought was shared by most of his colleagues, something like 60 percent of all prescription drugs prescribed were unnecessary. Thus doctors may be persuaded to prescribe more expensive dosage modes, such as sustained-release and combination forms, instead of the simpler mode. They may also be induced to prescribe the drug in situations where they would previously have recommended the use of a proprietary preparation, or simply no medication at all.

(2) With respect to the identity of the drug: Doctors may be induced to use newer products as rapidly as they are marketed, and these drugs may be marketed at successively higher prices. If this is the case, then steady declines in the price levels of individual drugs may be quite consistent with increases in average prescription charges since new drugs are being prescribed at higher prices in the place of the older drugs the prices of which are declining.

Senator NELSON. So if the price index being used is composed of older drugs and this process is in effect, it does help explain at any rate the average prescription cost increases, is that correct?

Dr. STEELE. Yes; and this could be a real factor in the BLS index. Firestone's index is the chain index type, so possibly some of this may be allowed for. But not immediately.

Senator NELSON. So you would have to keep updating the drugs in the index in order to have a really accurate reflection of a large proportion of the prescriptions in the country, right?

Dr. STEELE. That is true, but there are also some unavoidable biases in the construction of chain indexes—well, in any indexes. An index has a number of problems which cannot be allowed for satisfactorily. I will say a chain index is better than an index which does not ever change its weights and allow for such biases, but even a chain index can't allow for all of them.

Senator NELSON. But if you use an index to look at drug prices and the number of dollars spent for drugs, and the index includes only old drugs no longer being widely prescribed, that does not give you a very informative view of what is happening to drug prices; does it?

Dr. STEELE. If as you say the drugs now included in the drug index are no longer being used, this is quite true.

With respect to the quantity of the drug prescribed: the greater the number of chronic conditions which doctors can be persuaded to treat with continuous drug therapy, the greater the average prescription quantity is likely to be, to the extent that such patients buy less frequently but in larger individual sizes, to take advantage of any economies of the "large economy bottle" variety. (Presumably this trend could continue until long-term drug therapy was available for all chronic conditions—and possibly even beyond that, to the extent that the progressive superannuation of the population as a whole increased the incidence of chronic disorders.)

However, the emphasis should be placed upon the possible difference between the need for such therapy, and the degree to which drug firms are successful in creating the impression of the need for such therapy. As Dr. Frederick Wolff, of the George Washington School of Medicine, has stated before this subcommittee:

> It is known that with appetite suppressants, the patients become tolerant to them after some eight weeks and they have no effect. This is not generally recognized by physicians, so they are being prescribed indefinitely, and occasionally with very harmful side effects (Part 3, p. 836).

d. Each of the above avenues would tend to increase total revenues from drug sales as a conscious end in itself. But the net effect of the various means used to gain this end: a steady stream of "new" drugs; an ever-increasing number of combination drugs, and a medically aimless proliferation of brand names—all these would act as an uninten-

tional "misdeed" on the part of manufacturers in that they would increase the druggist's inventory and other costs of a related nature, and give him an incentive to charge higher prices to cover these increased costs.

VI. COMMENTARY UPON THE STATEMENT OF G. R. CONRAD AND J. W. MARKHAM

The argument that "somewhat peculiar" riskiness attaches to the drug companies because of their failure adequately to discharge their responsibilities for conducting every stage in the product development process in sufficient depth to eliminate all hazards of "unanticipated side effects," of deficient quality control procedures, of addiction potentials, and of toxicity or inefficacy in use, is in itself somewhat peculiar.

If drug development were undertaken from the perspective of the best interests of the public health in the long run, such evaluation might easily take 20 years before a suitably conscientious management could satisfy itself that the drug merited general commercial use. During such a time period, many related drugs might be evaluated concurrently. If during this period a new drug were discovered which proved clearly superior to other drugs being tested, none of the inferior drugs would ever be marketed. Hence the risk of "the development of a competing product superior to" another already on the market should scarcely exist if drug development were as thorough as it should be. (As far as present market risks per se are concerned, however, the word "superior" can be replaced simply with "newer".)

In describing the operation of risk in drugs, the author states: "The types of collapse we refer to do not offer hope, in most cases, of subsequent recovery of the product's market position" (p. 3). But in his oral presentation, Markham illustrated his somewhat peculiar risk No. 2, "the discovery of unanticipated side effects," by reference to Parke, Davis' brand of chloramphenicol, the so-called Chloromycetin. This was an unfortunate choice. When, as early as 1950, this drug proved that its lethal potential extended to the infected, as well as the infecting, organism, some apprehension regarding its use developed, and it was even taken off the market for a 2-month period during 1952. When reinstated, it was only on condition that strong warnings regarding its use be placed on the label and the package insert. For a considerable period of time, chloramphenicol sales were greatly reduced. But Parke, Davis marketing strategies rose superior to FDA precautions. The firm's detail men were given instructions which included memorizing clever and misleading sales spiels and gambits—see the report on the Kefauver administered prices in drugs hearings, pages 192–198—and before too long chloramphenicol sales had risen to the point where it was the most lucrative single brand name drug.

It would appear that the period of temporary shrinkage in sales, even though limited in duration, had benefited the drug in the long run. Micro-organisms had less exposure to it than to other antibiotics, and fewer strains resistant to chloramphenicol developed in the early 1950's. In this instance, the somewhat peculiar risk turned out to be a windfall in disguise.

Senator NELSON. Thank you very much, Dr. Steele.

Do you have any questions, Mr. Gordon?

Mr. GORDON. No.

Senator NELSON. Your critique and your original statement were very well done and a very fine contribution to these hearings. They will be very valuable in the hearing record. The committee appreciates very much your taking the time to come up here today to testify.

Thank you very much.

Dr. STEELE. Thank you, Senator Nelson.

(The supplemental information submitted by Dr. Steele follows:)

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MONOPOLY AND COMPETITION IN THE ETHICAL DRUGS MARKET[1]

(By Henry Steele, Rice University)

Great concern has recently been expressed in regard to the ethical drugs industry as an object of public policy.[1a] At first glance such concern seems disproportionate in view of the relatively small fraction of the consumer's dollar which is devoted to drug purchases. In 1959 total sales by manufacturers to dealers of all pharmaceuticals were estimated at $2.25 billion. Of this total, $1.7 billion consisted of ethical drugs, which are available only upon a doctor's prescription, and $560 million of proprietary drugs and medications which can be purchased over the counter without any prescription.[2] The conventional mark-up imposed by the druggest (66⅔ per cent of invoice costs) would increase the price to the drug consumer of ethical pharmaceuticals by $1.13 billion, making the total cost of ethical drugs to the final consumer $2.83 billion. This figure is only .9 of one per cent of the 1959 total personal consumption expenditures of $313.8 billion.

Concern with the policies of ethical drug makers is, however, not misdirected, since the industry occupies a position of importance in the economy out of proportion to its size. There are several reasons why it is very important to analyze and evaluate the performance of the ethical drugs industry. First, if competition is desirable and monopoly undesirable as a matter of principle, industry size is immaterial, and there is no reason why smaller industries should be permitted to misallocate resources even if, for example, increases in their prices do not have a dramatic effect on aggregate price indices. Second, for the policy maker, there are compelling reasons why the quality of the performance of the ethical drugs industry should be given greater relative weight in his social welfare function than its dollar volume of sales might seem to justify. During a given interval of time, the incidence of disease is far from uniform, and those who pay the largest drug bills are, because of their disabilities, likely to have incomes substantially below the average. The industry shares with the medical profession much of the responsibility for the maintenance of health, and health is naturally a value in itself as well as an important determinant of the productivity of human resources in the economy. The existence of drug regulation and inspection by the Food and Drug Administration testifies to the social premium placed upon adequate performance in this industry.

Third, the industry operates under certain unique conditions which provide an interesting case study for analysis by the economist. These conditions include (1) the separation of the authority to prescribe from the responsibility to pay, which in inherent in the status of the prescribing physician as an independent purchasing agent for his patient, and which minimizes the influence of prices on the volume of prescription sales; (2) the use of research to effect often minor product changes which can be marketed with surprising success as major therapeutic advances; (3) the extreme degree to which product differentiation may be

[1] The author is indebted to Professors E. O. Edwards, M. A. Adelman, G. V. Rimlinger, and J. H. Auten for valuable criticisms of earlier drafts.

[1a] See particularly, Report on Administered Prices of Drugs, Subcommittee on Antitrust and Monopoly of the Senate Comm. on the Judiciary, S. Rep. No. 448, 87th Cong., 1st Sess. (1961). (Hereinafter cited as "Subcomm. Report.")

[2] Data obtained from a survey made by Arthur D. Little, Inc., and published in Silberman, Drugs: The Pace Is Getting Furious, Fortune, May 1960, p. 139.