COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON MONOPOLY

OF THE

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

NINETY-FOURTH CONGRESS

SECOND SESSION

ON

PRESENT STATUS OF COMPETITION IN THE PHARMACEUTICAL INDUSTRY

PART 30

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COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

WEDNESDAY, APRIL 28, 1976

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

The subcommittee met, pursuant to notice, in room 318, Russell Senate Office Building, Senator Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist; and Karen Young, research assistant.

Senator NELSON. The Monopoly Subcommittee of the Senate Small Business Committee resumes its hearings on competitive problems in the drug industry. Today, on May 10 and 24, and on other days we shall be concerned with the problem of how the medical profession gets information about drugs and the relationship to prescribing practices, competition, and the health and welfare of the public.

Dr. Charles D. May, the eminent medical educator and clinician, 15 years ago warned [1] that the traditional independence of physicians and the welfare of the public are being threatened by the new vogue among drug manufacturers to promote their products by assuming an aggressive role in the "education" of doctors. Dr. May asked the following questions:

Is the public likely to benefit if practicing physicians and medical educators must perform their duties amidst the clamor and striving of merchants seeking to increase the sales of drugs by conscripting "education" in the service of promotion?

Is it prudent for physicians to become greatly dependent upon pharmaceutical manufacturers for support of scientific journals and medical societies, for entertainment, and now also for a large part of their "education"?

Do all concerned realize the hazard of arousing the wrath of the people by an unwholesome entanglement of doctors with the makers and sellers of drugs?

These questions are still relevant today. The courses which doctors take for their postgraduate education, the books, journals, and other printed material they receive, the exhibits at conferences and medical conventions they see, the closed circuit TV and radio programs they see and hear, are virtually all sponsored by the drug industry. No one

[1] Charles D. May: "Selling Drugs by 'Educating' Physicians," Journal of Medical Education, issue of January 1961.

can ignore the many important contributions the drug companies have made, but the intrusion by the industry into the education, perhaps it would be more accurate to say the almost complete takeover by the industry of postgraduate medical "education," is cause for alarm.

The London Observer on October 1, 1967, stated in its comments on the Sainsbury Committee's report on the pharmaceutical industry:

> Far more alarming is the basic conflict between the aims of the industry and those of good medical practice. The industry must seek to maximize consumption of its products; doctors (good doctors at any rate) seek to minimize it.

Dr. Richard Crout, Director of FDA's Bureau of Drugs and one of today's witnesses, told the Pharmaceutical Advertising Club on January 17, 1974, that:

> In any discussion of drug advertising, it is important to recognize that the intrinsic objectives of the advertiser are by nature in conflict with certain principles of good therapeutics. The principle of parsimony in exposing patients to drugs is an obstacle to the sales objectives of the drug industry, and it is unrealistic to expect the industry to promote this principle with enthusiasm.

Given this irreconcilable conflict between the interests of the drug industry and what medical experts regard as good medical practice, how can we trust any program sponsored by the industry as being educational rather than promotional?

This is, in short, the subject of these hearings. Specifically, we shall inquire about the various "educational" courses offered to the medical profession, their contents and sponsorship; how "education" is distinguished from advertising and the resulting regulatory problems; the identification of individuals who select the program content; whether the postgraduate "education" which doctors receive is reflected in drug prescribing practices; the general problem of the transfer of medical information to doctors; the role of advertising companies in medical "education"; the pretesting of drug advertising, and the measurement of the doctors' response to it; the purpose and content of commercial and scientific exhibits at medical conventions, the dependence of conventions on drug-company-supported exhibits; the effect on competition and small business.

Our witness today is Dr. Richard Crout, Director of the Bureau of Drugs, Food and Drug Administration, the Public Health Service of the Department of HEW.

Dr. Crout, please identify for the reporter your associates so that the record will be accurate.

STATEMENT OF J. RICHARD CROUT, M.D., DIRECTOR, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY PETER H. RHEINSTEIN, M.D., DIRECTOR, DIVISION OF DRUG ADVERTISING, BUREAU OF DRUGS, FDA; AND WILLIAM W. VODRA, ASSOCIATE CHIEF COUNSEL FOR DRUGS, FDA

Dr. CROUT. Thank you very much, Mr. Chairman.

I am accompanied this morning by Dr. Peter Rheinstein on my right who is Director of the Division of Drug Advertising of the Bureau of Drugs, Food and Drug Administration, and by Mr. William Vodra on my left who is Associate Chief Counsel for Drugs for the Food and Drug Administration.

I am delighted to appear today to discuss at your invitation the relationship between the pharmaceutical industry and medical education. This is an important topic and a timely one. There is considerable evidence that the pharmaceutical industry plays a very important, perhaps a dominant, role in the postgraduate education of physicians, dentists, and other health professionals. This role of the pharmaceutical industry in supporting postgraduate medical education has increased rapidly in recent years and, in my opinion, is a problem deserving of national attention.

Let me emphasize from the start that I do not consider this issue to be primarily a problem in drug regulation. While I will draw upon the experience of the Bureau of Drugs in citing a number of examples in this testimony, my remarks will also reflect views developed during two decades of personal experience as a student and a teacher of medicine before coming to the Food and Drug Administration. I testify today as a concerned physician who believes that the growing influence of the pharmaceutical industry on medical education is a long-term threat to the integrity of my chosen profession.

Before considering the many ways in which the pharmaceutical industry is involved with the education of physicians, I would like to comment briefly on trends in medical education since the turn of the century.

Today the education of medical students is under the control of universities and customarily consists of a 4-year curriculum, at the end of which the student receives his M.D. degree. A century ago, however, there were, in addition to university-based medical schools, a number of private trade schools training physicians. Because of the low professional competence of the graduates of these trade schools, the training of physicians became a national scandal early in the 1900's. After publication of the Flexner report in 1910, medical education came under the full control of universities; thus nearly every physician now in practice in this country was trained at a university as a medical student.

The second great advance in medical education in this century was the development of full-time faculties in medical schools. This has occurred as a result of our national investment in biomedical research and training since World War II. Today's medical student thus graduates with a rich and broad education in medical science after a 4-year exposure to university faculties dedicated to teaching, patient care, and medical research. In such an environment professional competence, commitment to scientific principles, and high personal standards are emphasized as the physician's primary and necessary attributes.

After graduation from medical school, the modern physician then takes several additional years of training in a medical specialty or in family medicine. This training typically occurs in medical institutions, including university hospitals, military and Government hospitals, larger private hospitals, and some community hospitals. After such experience many physicians take advanced examinations, known as board examinations, to become certified as specialists. At this point the physician is probably as highly trained technically as he will ever be in his life, and he enters the practice of medicine, the product of an extended and expensive educational process.

From this point on, the physician is in large part left to his own devices to maintain and update his fund of knowledge. He can maintain his university contacts by joining a clinical teaching faculty, an excellent approach to staying abreast of advancing medical knowledge, but an opportunity usually available only to board-certified specialists in cities with medical schools. He can also seek out any of a number of short courses sponsored by specialty societies and conducted in medical institutions. He can also read the medical literature, attend medical meetings, and take advantage of a variety of audiovisual presentations, either in the privacy of his car, home, or office, or in staff meetings at his local hospital.

In recent years, several States and specialty societies have recognized the physician's need for continuing education to keep his medical knowledge current and have attempted to encourage greater efforts at self-education. These States and societies have imposed on the physician requirements for a specified number of credit hours, usually 150 in 3 years, to qualify for license renewal or recertification. The American Medical Association grants a physician's recognition award to physicians completing 150 hours of continuing education in 3 years.

There are aspects of continuing education for physicians that are unique. While other professionals must also maintain their skills and be aware of new developments, as the tax lawyer must be aware of changes in the tax code, there is no field I can think of in which keeping up is so closely related to learning about new products or new uses of old products. Certainly, there is other information necessary also—knowledge of newer diagnostic techniques and new insight into disease mechanisms—but a significant portion of what an up-to-the-minute doctor needs to learn about is related to advances in therapeutics, especially drugs and medical devices.

Senator NELSON. May I go back to your statement on the bottom of page 3, top of page 4, in which you say that:

> In recent years several states and specialty societies have recognized the physician's need for continuing education to keep his medical knowledge current and have attempted to encourage greater efforts at self-education. These states and societies have imposed on the physician requirements for a specified number of credit hours, usually 150 in three years, to quality for license renewal or recertification. The American Medical Association grants a Physician's Recognition Award to physicians completing 150 hours of continuing education in 3 years.

How many States have licensing on relicensing requirements? Do you have those figures?

Dr. CROUT. I don't think we have those precise figures. It is on the order of a third or something, or it is less. I am sorry. I am told it is less than that.

Senator NELSON. Less than a third?

Dr. CROUT. It is an increasing number.

Senator NELSON. Do you have the statistics at the FDA?

Dr. CROUT. We do not at the FDA.

Senator NELSON. And then you refer to recertification. I assume that includes the professional societies and the various disciplines?

Dr. CROUT. Yes, or to maintain membership in these societies, for example in the American Academy of Family Physicians, is a requirement of that type.

Senator NELSON. Do all the various disciplines such as internal medicine have such a requirement?

Dr. CROUT. Not yet. There is a good deal of effort toward voluntary education and I believe that within a few years——

Senator NELSON. What is the nature of the courses of study that are required? Are these self-assessment tests mostly?

Dr. CROUT. That is an interesting question. Some are. Some are courses that people go to at medical meetings and some, as we will see, are articles in journals. Some courses and teaching materials we will see this morning.

Senator NELSON. How many of them have self-assessment tests, I think internal medicine may have a self-assessment test?

Dr. CROUT. Many have self-assessment tests.

Senator NELSON. What is the quality of these tests? Do they have a chance to review and evaluate?

Dr. CROUT. Some excellent and some poor. By and large the quality of the exam is good. The monitoring of them, the fact that they are graded by an outside party is not—but the examinations per se as teaching devices, I think, are acknowledged as good.

Senator NELSON. These tests—are most of them or all of them self-assessment tests?

Dr. CROUT. Yes.

Senator NELSON. Are they graded by somebody else?

Dr. CROUT. Usually not. One simply certifies that he has taken the test and will get an hour's credit.

Senator NELSON. How does he know whether he has kept up to date in some aspect of his discipline if it is not graded by an independent person? How does that work?

Dr. CROUT. This largely is a voluntary system at this point. The tests per se are rather good. The monitoring of them is poor. It is the monitoring, however, and the grading by an outside party which is the voluntary part of it, or at least is not done in the classical education mode of an outside teacher.

Senator NELSON. Does the one who takes the test get the results of the test?

Dr. CROUT. The self-assessment test comes with the answers in the same package. It is like doing a crossword puzzle and looking and finding the answers.

Senator NELSON. What is the objective of the test?

Dr. CROUT. Tests are, I think, rather routinely aimed at content, scientific content in particular articles. These are technical tests and you would recognize similar kinds in medical school.

Senator NELSON. The objective is to expose physicians to the most modern techniques and practices in his discipline, and then permit him to find out whether or not he is up to date. Is that correct?

Dr. CROUT. It is a test of what was in a particular article. The test will concern itself with the content of that particular learning system.

Senator NELSON. I thought the objective was to allow the physician to find out whether or not he is up to date on the most modern diagnostic practices, the utilization of drugs, or whatever he has in his discipline. Isn't that the function?

Dr. CROUT. You are correct. There are some special societies that give tests that are of a general and broad nature, not related to any particular course or magazine article or what have you, which are in the nature of a broad review—they give those. They are excellent. They are taken on a voluntary basis. That is correct. That sort of test is something different from what we are talking about this morning.

Mr. GORDON. As I understand it, some specialties, some organizations like the American Medical Association gives a certain number of credits if you go to a medical convention; is that correct?

Dr. CROUT. That is correct.

Mr. GORDON. Suppose you go to a convention and you do not even know what is said. Instead, you spend your time in the barroom or you are outside in a neighboring poolroom. Do you still get credits for that?

Dr. CROUT. One can falsely certify to the AMA, I suppose, that he is at scientific parts of the meeting.

Mr. GORDON. As I understand it, also, there are credits given for reading certain articles in some throwaway magazines.

Dr. CROUT. That is correct.

Mr. GORDON. What assurance is there that the person really read the article?

Dr. CROUT. This is an honor system.

Senator NELSON. Perhaps you should be given more credit for not reading it! Go ahead.

Dr. CROUT. To understand the importance of postgraduate education to the physician's use of drugs, one must appreciate how rapidly information on drugs changes. Ninety percent of prescriptions written today are for drugs which were not even on the market a generation ago. New information about the uses and potential adverse effects of drugs appears almost continuously. Since the professional career of the average physician spans 30 to 40 years, it is evident that most of what he learns about new drugs occurs after he completes his formal medical training.

It thus is not surprising that the drug industry is vitally interested in the educational materials the practicing physician receives. In view of the great financial resources available to the industry it should also not be surprising that it has come to support a large and growing proportion of such educational materials.

It has long been recognized that the industry-supported detail man is an important and influential source of information on drugs for the practicing physician. Drug labeling and drug advertising, which are closely regulated by FDA, also provide information. It is less well recognized, however, that much of the written and audiovisual teaching material supplied to the physician on all medical subjects throughout his professional career is also supported by the pharmaceutical industry. This includes the vast majority of medical magazines which fill his mailbox, the clinical symposia that discuss specific drugs or general approaches to therapeutics, the audiovisual teaching systems he studies in his spare time, the films and closed-circuit TV tapes he sees in his hospital conferences, and even the scientific exhibits and presentations by panels of experts he en-

counters at medical meetings. This extensive underwriting of postgraduate medical education and communication by the drug industry has occurred primarily in the past decade, and is the problem I want to emphasize in this testimony.

Mr. GORDON. Would you contrast this vast array of industry-supported material, medical information with nonindustry-supported material?

Dr. CROUT. There has also been a growth of courses offered by our medical schools, usually sponsored by our medical societies like the American College of Physicians and the American College of Surgery, and these are excellent and widely attended. I do not want to give the impression that the sole source of information in the postgraduate years to the doctor comes from industry-supported endeavors. What I do want to emphasize is that the information which he does not actively seek out himself, which comes to him in the array of encounters with hospital staff meetings, mail, et cetera, that largely comes from the drug industry. I think that medical specialists who maintain their professional ties with medical schools and postgraduate courses feel such contacts are their primary source of information and would not finger the industry-sponsored material as their primary source. But certainly that would vary a lot from physician to physician.

Mr. GORDON. Even the Medical Letter has only about 55,000 subscribers and they have to perform a conscious act to subscribe, whereas the industry material generally comes unsolicited.

Dr. CROUT. Correct.

Senator NELSON. You have to be on some sort of mailing list?

Dr. CROUT. That is easy to get on.

Mr. GORDON. What percentage of the doctors are likely to take these courses that you are talking about—the ones connected with medical schools?

Dr. CROUT. Again, I could not give you a percentage. I think that—certainly a large number and certainly those who——

Mr. GORDON. We heard a long time ago, in the earlier part of our hearings, that probably fewer than one-tenth of the doctors take these courses. Does that sound reasonable to you?

Dr. CROUT. In what period of time, one-tenth per year?

Mr. GORDON. Say, per year.

Dr. CROUT. I hate to speculate on that. I am sure it is a rapidly changing scene because of the postgraduate education imposed by the State and professional society requirements.

Let me note that while the drug industry has a natural interest in the postgraduate education of physicians, it is not alone in fostering this trend. Pharmaceutical industry financing of such endeavors has been encouraged by medical institutions eager for attractive teaching materials, by respected investigators and clinicians eager to make their work and opinions more widely known, by practicing physicians under increasing pressure to participate in formal training to maintain licensure, and by medical societies facing growing demands to make such training available. These groups are well aware of the vast resources the industry has at its

disposal, particularly in comparison with medical institutions and medical societies. Make no mistake, modern educational materials are costly. There has been a growing sophistication in the techniques used to educate people, and the old methods—lectures, review articles, textbooks—are perceived by some as dull and tedious. Instead we now have learning systems generally involving films or videotapes accompanied by elaborate graphics and self-instruction materials. It may well be true that these newer kinds of materials can be prepared only with special subsidies, assuming their added value as educational instruments is worth the extra money.

There is a cost involved, however, in giving substantial control over that subsidy to the drug industry. That cost is the introduction of systematic bias. Without contending that industry-supported materials are regularly inaccurate, which is not the case, I believe that these sponsored materials are consistently tilted in the direction of therapeutic enthusiasm. There has been a rapid growth in expensive, slick audiovisual materials, conferences, symposia, and publications which have the appearance of independent, scholarly productions but which are in fact an integral part of the drug industry's overall promotional efforts, a more subtle part, of course, than straightforward promotional materials like advertising.

Let me emphasize that the systematic bias I am describing does not arise because the medical authorities who contribute to these teaching programs present knowingly biased views because of pharmaceutical industry support. The problem is not that drug industry money corrupts medical experts, in my view, but rather that the industry sponsor can choose from among the many medical authorities on any given topic to support only those whose views already coincide with the interests of the sponsor. This ability of the pharmaceutical industry to select the medical authorities it wishes to support is the basic cause of the biases we shall see.

Mr. GORDON. Let's take a specific example. The Pfizer Co. sponsored on January 21, 1976, a nationwide, live, closed-circuit television symposium. Do you have a list of the physicians participating in the symposium?

Dr. CROUT. Yes.

Mr. GORDON. Were the participants generally those who use the oral hypoglycemia drugs?

Dr. CROUT. I am not sure that I would say that was their uniform position. Let me phrase the question slightly differently. Do they favor the use of oral hypoglycemia drugs without what I would consider sufficient sensitivity of the University Group Diabetes Program [UGDP] study? The answer is, yes.

Senator NELSON. We had some rather extensive hearings on this question on two occasions and my memory is that even the critics of the study and proponents of the use of hypoglycemics—I would have to check the record on the percentage—stated that probably not more than about 1 percent of diabetics who use these drugs should be using them in contrast to a diet, and that in those cases, they were simply people who could not be relied upon for some reason or another to stick to their diet.

Dr. CROUT. I think the consensus figure might be closer to 20 to 25 percent.

Senator NELSON. Twenty to twenty-five percent?

Dr. CROUT. In either event the number is substantially lower than prescribed in practice. The 1 percent figure, if I recall, was given by the Commissioner, and the 20 percent figure was given by Dr. Bradley.

Senator NELSON. I know there was something in the 1 percent figure.

Mr. GORDON. Dr. John Davidson of Grady Memorial Hospital and the Commissioner gave 1 percent.

Senator NELSON. According to Dr. Davidson of Atlanta, almost everybody was taken off the drugs and the patients did very well on diet. For about 1 percent of the diabetics, however, one of the hypoglycemics might be indicated; is that correct?

Dr. CROUT. Yes.

Senator NELSON. Now, does the FDA have advanced script of what was said on this nationwide closed-circuit television symposium?

Dr. CROUT. No, Dr. Rheinstein was at one of the sessions, but we do not have a transcript.

Senator NELSON. Can you summarize what they were saying on this subject, particularly any evaluation of the UGDP study?

Dr. RHEINSTEIN. In terms of that particular study, there was not much emphasis on it.

Senator NELSON. In terms of the conclusion of the study, what posture were they taking? Were they pushing the use of the drugs? What was your impression?

Dr. RHEINSTEIN. They were neither actively pushing it nor were they actively advising additional caution. What in fact they were doing in the context of the program though was reassuring the physician of Pfizer's role in the treatment of diabetes.

Senator NELSON. They were doing what?

Dr. RHEINSTEIN. They were reassuring the physician of Pfizer's role in the treatment of diabetes. You have to look not only at the words that were said but at the entire context of the program.

One went to a ballroom in the best hotel in the city, sat there with a large number of physicians, saw a panel of experts before the program began. The Pfizer detail men for that city were there, shaking hands with everybody——

Senator NELSON. May I interrupt? At that moment were you seeing closed-circuit programs conducted in various hotels, that sort of thing paid for by the Pfizer Co.

Dr. RHEINSTEIN. It was a single seminar held at one university. It was by closed-circuit television transmitted to a number of cities, I think 23, and physicians saw it in each of these cities in a ballroom of a major hotel. There was a locally prominent physician acting as the chairman at each hotel ballroom. There was a question and answer session where one question was taken from each participating city so the panel was seen on closed-circuit TV screen answering questions taken from the cities in which the seminar was meeting.

Senator NELSON. Were the reservations for these hotels in the 25 cities, motels, whatever they were, made by the Pfizer Co.?

Dr. RHEINSTEIN. Pfizer did not put anybody up in the rooms. They did take the ballrooms.

Senator NELSON. For the symposium room, they paid for it?

Dr. RHEINSTEIN. Yes, and for the refreshments.

Senator NELSON. They selected the physician panels?

Dr. RHEINSTEIN. The physician panels were selected either by Pfizer or by the company which put the program on for Pfizer. Pfizer contracted with another company called Health Learning Systems to do the entire production.

Senator NELSON. Did the panel, at any place in the program, indicate that the UGDP study and the Food and Drug Administration concluded that there is almost no use for oral hypoglycemic drugs?

Dr. RHEINSTEIN. They certainly did not say that. However, in response to one of the questions which was let through by the local chairman, the question was asked and was heard by the entire audience—should a physician get informed consent prescribing a hypoglycemic drug? The panel member, to whom that question was addressed, stalled for a few moments and then started to say something on the order of "considering the source of funding" and at that point looked off to the side of the stage and stopped speaking. Then he resumed in a moment or two and talked a little bit about the caution that should be taken in using these agents. Then the chairman of the symposium came on and he said, at any rate such a consent would not be useful in malpractice cases. Then he went on to the next question.

Senator NELSON. But they did not at any time call attention to the 10-year study of the UGDP and the conclusions reached by it?

Dr. RHEINSTEIN. I believe it was mentioned in a way that it was quite deemphasized and you came away reasonably reassured that you could go on using the product at least to the extent used previously in your practice.

Senator NELSON. We have a copy of a letter indicating that physicians attending the symposium are entitled to 2 credit hours under category I of the American Medical Association's Physician Recognition Award. Well that is not newsworthy because it is typical of the American Medical Association.

Is there any other observation you had about the symposium?

Dr. RHEINSTEIN. In line with what you are saying about people getting credit hours and being absent and not hearing the whole thing, a number of people left early.

Senator NELSON. Is there any indication how many people attended the symposium in these 25 cities?

Dr. RHEINSTEIN. There were only about 40–50 physicians in our room in the Lord Baltimore, which is where I attended. They had apparently expected a much larger crowd because they had reserved a very large ballroom. It was said that previous seminars sponsored by Health Learning Systems had up to 8,000 physicians seeing closed-circuit broadcasts at one time. I did not get specific figures from Pfizer.

Senator NELSON. What is the name of the company, the Learning what?

Dr. RHEINSTEIN. Health Learning Systems Inc., an independent producer of media in New Jersey. It is owned by two former program detail men who are very skilled in medical communications. I believe there is a little bit about it here in the testimony.

Senator NELSON. Are they hired by drug companies to put on programs, is that it?

Dr. RHEINSTEIN. Yes, they would work on contracts for anyone who had an idea that they would want to communicate or that they would want to develop the program on particular diseases or particular drugs.

Senator NELSON. Do you have anything else?

Go ahead Dr. Crout.

Dr. CROUT. Because of time consideration I will skip along certain paragraphs and not read the testimony in its entirety.[1]

Senator NELSON. Go ahead.

Dr. CROUT. In the discussion to follow, I will present a number of examples of medical communication which will illustrate the problem I have been describing. In some cases these merely present a particular point of view. Other examples will be shown of medical communication which, in my judgment, do not constitute the sort of disinterested, balanced, scholarly products we expect educational materials to be.

I recognize that I have selected these examples to make a particular point. They will show that drug promotion can masquerade as education. I have certainly not attempted to present a full review of all the medical communication sponsored by the drug industry. I am aware of many examples of excellent industry-sponsored materials. Nevertheless, I believe it is inevitable that the educational materials produced by and for an industry with an interest in increasing sales of drugs will, on balance, be biased in a direction intended to promote drug use. The examples presented in this testimony are not atypical and were not difficult to find.

I also believe the growing proportion of medical communication that is supported by the drug industry threatens the integrity of the whole process of postgraduate medical education. I would now like to turn to some examples to illustrate my concerns.

Appendix A is a list of the 28 medical publications having a circulation of 70,000 or more. The list was compiled from the March 24, 1976 issue of Standard Rate and Data Service which contains circulation figures for all major publications. Of these 28 publications, only one, *The New England Journal of Medicine*, is financed to any major extent by subscriptions; 25 of these 28 leading publications are sent to physicians free of charge and are paid for entirely by industry funds.

Senator NELSON. Are these the 28 largest circulation publications?

Dr. CROUT. Yes.

Two other publications, *American Medical News* and the *Journal of the American Medical Association*, are financed through a combination of dues paid to the American Medical Association and by pharmaceutical advertising.

[1] See prepared statement and supplemental information submitted by Dr. Crout beginning at page 14064.

Only two of the journals, *The New England Journal of Medicine* and the *Journal of the American Medical Association*, are scholarly journals, that is, journals which primarily print reports of original research submitted by the investigator after review by independent expert reviewers. The remainder are publications which the pharmaceutical and publishing industries call "controlled circulation" publications. They are also known popularly as "throwaways". They generally do not publish original work and usually do not have a rigorous review of papers of the type conducted by the scholarly journals. They are sent to physicians, not because they are requested, but simply because the physicians' names appear on mailing lists.

Senator NELSON. You state that these are entirely supported by drug advertising, is that what you were saying?

Dr. CROUT. Or directly by a drug firm, a single firm.

Senator NELSON. What is the total circulation of these 25 that are sent to physicians free of charge and paid for by industry funds. Do you have any notion what that total is?

Dr. CROUT. If you will turn back to appendix A, the distribution figures for each one are listed there.

Mr. GORDON. There are others that are not on this list. Isn't that right?

Dr. CROUT. Yes.

Senator NELSON. This is a list of publications with 70,000 circulation or more?

Dr. CROUT. Yes.

Senator NELSON. So there are a good many others that have fewer than that.

Dr. CROUT. Yes.

Senator NELSON. What is the total number of practicing physicians in this country? Do you know?

Dr. RHEINSTEIN. About 200,000. I say on the order of 200,000.

Dr. CROUT. Practicing—probably 220 or 230 thousand practicing.

Senator NELSON. So some of these publications like the American Medical News is going to a number, which is the equivalent of all practicing physicians plus some others.

Dr. CROUT. I assume medical students and others.

Senator NELSON. Please proceed.

Dr. CROUT. Of the 26 leading journals which are throwaways, four concentrate on legal and socioeconomic aspects of medical care. The remaining 22 focus on medical treatment. The medical publications sent to the physician thus constitute a literature overwhelmingly supported by the drug industry.

We have brought with us today a number of examples of these journals. Each one consists of a number of drug advertisements plus a number of articles which appear to be independently written.

It is not easy to assess the scientific quality of the controlled circulation journals. Much of it appears, on its face, quite reasonable, tending to be oriented toward review articles and articles dealing with particular clinical problems, as how to diagnose and treat lower back pain. At the same time, however, I must wonder whether a journal that subsists wholly on sales of advertising space to the drug industry is able to present a skeptical attitude toward drugs in

general or toward specific drugs. I have some comments about editorial policies.

FDA has received complaints from some authors that when they prepare an article unfavorable to drug products the articles are rejected by the controlled circulation journals even when they were solicited by the journal in the first place. The reasons given for rejection are that the article does not meet some unspecified technical standard, but whether or not this is the entire reason is difficult to determine.

Members of our staff have had several meetings with editors of controlled circulation journals asking specifically about editorial policy regarding articles adverse to the product of an advertiser. A common answer is that such articles rarely are received because physicians are more interested in reporting successes than failures and that, furthermore, successes make more interesting reading than failures. Another common answer is that the journal sells space on the basis of reader interest and to sustain this interest the journal must contain objective articles. Usually, however, it is acknowledged that whenever material severely adverse to a sponsor is received, that sponsor is given the opportunity to rebut that material before it goes into the journal.

Mr. GORDON. What happens if the advertiser does not like the material?

Dr. CROUT. I am told another article rebutting it would be placed next to it.

Mr. GORDON. Do you have any specific examples?

Dr. CROUT. This is information that is hard to come by. Let me relate a personal experience, which I feel comfortable about discussing, rather than relating what I have heard from someone else.

I was interviewed on FDA policy in relation to bioavailability and my interview was sent back for editing and I did get a chance to edit it. It was then without my knowledge sent to the Pharmaceutical Manufacturers Association and published in association with an article from the PMA, so they got the chance to publish their point-by-point rebuttal to my interview from their standpoint. But I got no chance to see their rebuttal prior to publication.

Mr. GORDON. Sort of a one-sided deal.

Dr. CROUT. That is the one personal experience in this area that I have.

Mr. GORDON. Mr. Chairman, I ask that a letter from Dr. Schumacher, University of Vermont to Dr. Alan B. Lisook, of FDA's Bureau of Drugs be inserted in the record of these hearings. Apparently he was invited by Modern Medicine to write a piece on headaches. He was told that it does not make any difference how you feel about this subject. You can take a radical position or any kind of position. So he wrote the article and the editors knocked out or tried to knock out a section in which he decried the use of a drug called Fiorinal, which, incidentally, the National Academy of Sciences said, had no evidence of efficacy. I would like to put the whole series of letters between him and the journal into the record.[1]

[1] See letter dated April 8, 1974, to Alan B. Lisook, M.D., Bureau of Drugs, FDA, from George A. Schumacher, M.D., Professor of Neurology, University of Vermont, page 14022.

Senator NELSON. The letter will appear in the record at the appropriate place. Please continue.

Dr. CROUT. In any event, and for whatever reasons, the editorial content of these controlled circulation journals is overwhelmingly optimistic about drug therapy. A recent editorial appeared in the January 1976 issue of Current Prescribing. The article, entitled "The Undermedicated Society," laments that underprescribing and not overprescribing is a major problem in American medicine. The author states:

> The family physician's alleged propensity to overprescribe has provoked well-publicized investigations, both Congressional and clinical.
>
> But what of the other side of the problem—underprescribing? Do doctors sometimes prescribe too little? In interviews with experts in several specialties, *Current Prescribing* found that the answer is yes. For many conditions, and with a number of drugs, M.D.'s may be giving their patients therapeutic short change.

I am submitting a copy on this article for the record.[1]

The editorial position is not without merit, but several questions arise. The editorial writer was not a physician and had to seek advice about matters like underprescribing and overprescribing from physicians. In selecting his consultants, could the support of his magazine have affected his choices? Is a journal wholly dependent upon the pharmaceutical industry for support willing to editorialize on the excessive use of a drug class? Perhaps the answer is "yes," but one must wonder.

Senator NELSON. Well, let me ask a question. This committee has taken extensive testimony over an 8-year period from distinguished pharmacologists and without exception in that 8-year period there has not been a single medical expert who addressed himself to that question who did not say that drugs are widely overused or overprescribed. Is there any evidence that you are aware of that these experts are wrong? Chloramphenicol, is an example right off the top of my head. We took testimony from the late Dr. Dameshek of Mt. Sinai, and a half dozen others, I think Dr. Dameshek said that in his judgment perhaps the drug was indicated for only about 5 percent of the people who died from using it. The pathologist who testified thought that at the most it would be only 1 percent and that he had never seen a person who died from the use of chloramphenicol who had been given the drug for an indicated purpose. Go back to the studies by Drs. Stolley and Lasagna and other distinguished physicians who found that 95 percent of the doctors prescribed something for the common cold and that 65 percent prescribed an antibiotic.

In all the testimony we have taken, medical experts have testified that drugs are vastly overprescribed. Do you know of any studies which indicate that there is a massive underprescribing of drugs in this country?

Dr. CROUT. I think your subcommittee has very properly focused heavily in the area where there are more historical examples of overprescribing.

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[1] See article, "The undermedicated society—charges of overprescribing are all the rage—but what about the equally dangerous tendency to underprescribe?," from Current Prescribing, Jan. 1976, page 14117.

In the hypertension area there is a general concensus among experts in the field that they are not yet treating many hypertensives, and this is an example which is usually focused upon when talking of underprescribing.

You will see in a film we want to show here later at least one medical view of the treatment of depression. I do not subscribe to it, but you ought to see what is being said by certain physicians in that area and you make up your own mind about it.

I believe one has to look at overprescribing in relation to drug classes.

Mr. GORDON. I presume there are some people who cannot afford to buy drugs. Some of them should be getting drugs and they do not get them. But in those terms——

Dr. CROUT. I am simply saying that a general phenomenon of overprescribing and underprescribing is, I believe, a case harder to make than when one looks at specific drug classes.

Senator NELSON. Well, Let's look at total sales. We have had extensive testimony on overprescribing in the tranquilizer field and in the whole antibiotic field. These are the two largest classes of drugs used. Even assuming that in certain specialized categories as hypertensives there is underprescribing. What can we say about drugs as a whole? Are they being overused? Certainly, as we have seen, many widely used drugs or classes of drugs like the oral hypoglycemics are overused. Would you be equating the size and dimension of the problem in hypertension or some other field against the antibiotics or tranquilizers?

Dr. CROUT. One could. The underprescribing in hypertension is at least as great today, or certainly was 2 or 3 years ago when the Department began the task force on Hypertension Education, as overprescribing is in the antibiotic area.

Senator NELSON. I can't remember who the witness was a few years ago who said that the available evidence indicates that the damage from overprescribing in the antibiotic field may very well be greater than the benefit from it, or words to that effect.

Dr. CROUT. Mind you, I do not want to endorse the concept of overprescribing. But if you are asking where do I believe overprescribing is the biggest problem, it is most conspicuous in the antibiotic area. I think you will find more argument about other drug classes.

The lesson to be learned is that other drug classes can get out of hand in the future, which is one of the things we are talking about this morning.

Let me comment on the unproven uses of drugs. The pages of the controlled circulation journals frequently are employed to bring to the physician's attention new uses for a drug product which are not yet approved by the Food and Drug Administration, something the manufacturer is not permitted to do through the usual channels of drug advertising and detailing. A typical example is an article entitled "Migrane . . . and More. Treatment and Prevention" from the April 1976 issue of *Current Prescribing*. I will also submit a copy of this article for the record.[1]

[1] See article, "Migraine . . . and More Treatment and Prevention—Serotonin inhibitors, antihistamines, antidepressants, beta blockers—they're all in the new wave of 'headache remedies'," from Current Prescribing, April 1976, page 14120.

The American Medical Association grants 1 full hour of category I, the highest category of continuing education credit, for study of this article. This article describes unapproved uses for Ayerst's Inderal, Knoll's Octin, Carnrick's Midrin, Merck's Periactin, and Sandoz's Sandomigran. Sandomigran is an investigational drug not marketed in this country. The issue is not whether the article is scientifically correct or whether it is proper to publish such information. There can be no doubt that scholarly medical journals should contain new information about drugs and should not be limited to the contents of approved package inserts. The issue here is whether such an article in a controlled industry circulation journal presents, in the guise of a scientific paper, promotional information which otherwise could not be legally published as drug advertising or drug labeling. The article in question did not pass through the rigorous independent editorial review common to scholarly journals.

I would point out, in addition, that the editorial policies of these journals are often consistent with the position of the large pharmaceutical manufacturers. For example, in a special supplement of the March 1976 issue of *Private Practice*, a controlled circulation journal sponsored by the Congress of County Medical Societies, the editors report on a campaign launched with the help of the publishers of *Private Practice* to fight repeal of Oklahoma's strong antisubstitution law. A copy of this article will be submitted for the record.[1]

Later in an editorial in the April 1976 issue of the same magazine, the editors report on the success of this educational campaign in changing public opinion in regard to drug substitution. The publisher of *Private Practice* offers to make available, free of charge, the newspaper mats, video and audio tapes, and brochure text to any county medical society wishing to mount a similar campaign. A copy of the pertinent section of this editorial is attached as appendix B.

Let me emphasize that I am not implying, for purposes of this testimony, that these campaigns are improper or not in the public interest. The important question is: Is it likely, or even possible, that a controlled circulation journal dependent upon drug industry support would take another point of view?

Senator NELSON. The publication you just mentioned, Private Practice, pointed a violent assault on the Department of Defense because of the Department's posture respecting one of its own employees. The long story, also included an attack on this committee. Private Practice misstated the facts and drew conclusions which were unjustifiable. The whole article was nothing, in short, but a mishmash of misrepresentations. So we wrote a detailed, and very careful refutation of everything the magazine had said, but they refused to run it anyway. They also refused to run a letter which devastated their assertions because it made them look like fools. They do not run, I can assure you from personal experience, anything that is contrary to their posture or the posture of the people who are supporting the magazine. I guess that is to be expected.

Go ahead.

Dr. CROUT. I would like to call your attention to one of these publications, the March 1976 issue of Primary Cardiology. It would

[1] See article, "County Medical Societies Campaign to Beat Drug Substitution—Medicine and Politics Don't Mix," by the editors of Private Practice, March 1976, page 14130.

take a perceptive reader indeed to see the fine print at the bottom of page 5 of this issue which says: "USV Pharmaceutical Corporation sponsors PRIMARY CARDIOLOGY ™ as a continuing educational service to the practicing physician." A copy of the page on which this quote appears is attached as appendix C.

The controlled circulation journals represents a large proportion of the total literature reaching physicians, are entirely dependent on the drug industry for support, and appear to be generally enthusiastic about drug therapy. This is not to say they do not provide very useful information. These journals specialize in carefully presented practical discussions designed to help the physician deal with most common problems. These journals are excellent communicators and they must be having some impact. There is no avoiding the question of whether it is desirable that they be financed entirely by an interested party.

In addition to controlled circulation journals supported by the advertising of many pharmaceutical companies, there are a number of publications which appear to be independent but are actually sponsored entirely by a single pharmaceutical company. We have brought with us today several examples of this type of publication, which we will submit for the record.[1] Such house organs are regulated as drug labeling and cannot be inconsistent with the approved package insert for the drugs discussed.

Senator NELSON. Does the magazine indicate on the editorial page or any other place who is the owner or publisher?

Dr. CROUT. It is there, but is very difficult to see. I point this out for example, *Primary Cardiology*, which gives every appearance of being an independent medical journal. It has distinguished people writing for it, and one has to turn to the fine print on page 5. We have this in one of the appendixes. It is appendix C. If you look at the fine print at the very bottom underneath the table of contents to read "USV Pharmaceutical Corporation sponsors Primary Cardiology as a continuing educational service to the practicing physician."

Senator NELSON. Is this appendix C a reproduction of that whole page?

Dr. CROUT. Yes.

Senator NELSON. The article titles and so forth are on the same page as this fine print that identifies the publisher.

Dr. CROUT. Yes, down at the bottom.

Senator NELSON. What page is that on?

Dr. CROUT. It is on page 5 of the journal, it is the index page.

Senator NELSON. The table of contents page?

Dr. CROUT. If you glance through the magazine, you will see by coincidence that all the ads are USV drugs, from the same firm, and that might be the only other sign in this entire publication of this particular company.

Senator NELSON. All the ads are for what?

Dr. CROUT. For drugs manufactured by USV.

Senator NELSON. Oh.

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[1] See examples of publications which appear to be independent but are actually sponsored entirely by a single pharmaceutical company, page 14146.

Dr. CROUT. At this point I want to turn to the subject of industry-sponsored seminars. The drug industry sponsors numerous medical symposia and seminars. These have been discussed in *Pills, Profits, and Politics*, by Silverman and Lee, as follows:

> One customarily practiced device is the drug industry sponsored conference or symposium devoted either to a particular new drug product or to a clinical problem in which the product may seem to have value. The nominal host may be a medical group, a medical school, or a medical or scientific academy. The speakers may include various Americans, although European participants supposedly provide desirable glamor. It is generally considered useful to include a hundred or more physicians in the audience of newspaper, magazine and trade journal writers. The indoctrination of the doctor in the audience is viewed as helpful, but more importance is placed on the accounts filed by the press representatives present and on the formal published proceedings of the conference, which may be used for months as "scientific" background.

Since the publication of the Silverman and Lee book, the live audience has been extended by the use of closed-circuit television. In January 1976, Pfizer Laboratories, division of Pfizer, Inc., sponsored such a closed-circuit nationally televised seminar on the diagnosis and treatment of diabetes mellitus. The program seminar provided a learned discussion of this disease but attempted to steer clear of the findings of the university group, diabetes program and the resulting adverse publicity surrounding oral hypoglycemic drugs, including Pfizer's Diabinese.

Without debating in this testimony the merits of the UGDP study, it is difficult to imagine how a modern discussion of diabetes treatment fail to emphasize its findings. I am aware of at least one roundtable discussion in a controlled circulation journal, Patient Care, which discussed the implications of the study in a balanced way, ultimately taking a middle-of-the-road position which suggested that many physicians who treat diabetes felt the oral hypoglycemic drug should be used more sparingly. This certainly seems a minimum position. The Pfizer symposium, however, largely avoided the whole issue.

Another example is a symposium sponsored by Wyeth Laboratories which was devoted entirely to its product Serax—oxazepam—a benzodiazepine tranquilizer similar to Librium and Valium. The proceedings of this conference were published as a supplement to the May 1975 issue of *Diseases of the Nervous System*. The special issue did not reveal the symposium's sponsorship, but contains articles which suggest special advantages that the Wyeth product may have over the other benzodiazepine tranquilizers.

I want to emphasize again that medical investigators must be free to write whatever they wish about drugs and to speculate about advantages one drug may have over another. In this case, however, the investigators were selected by the manufacturer to participate in an industry-sponsored meeting, the proceedings of the meeting were published without reference to such sponsorship, and the papers all turn out to be favorable to Serax.

Even if the investigators, who are well-known physicians in their field and investigators of known integrity, are accurate in everything they say, the process through which this supplement to a medical publication was produced is cause for concern.

The fastest growing areas in continuing medical education today are audiovisual materials and multimedia learning systems.

One example is that of radio broadcasts. The physicians radio network, PRN, broadcasts the latest news of medicine to physicians 24 hours a day. I will demonstrate a PRN radio portion of one of these broadcasts in a moment, but I would point out that the radios themselves and the programing on them are financed entirely by the sale of advertising time to pharmaceutical manufacturers. Each 60 minutes of programing contains 8 minutes of advertising for brand-name drugs. Routine listing to PRN is approved for category 5A continuing medical education credit by the American Medical Association.

We can turn on the radio right now, I do not know what is going to come out. This broadcast goes on 24 hours a day.

[At which time a radio broadcast was heard.]

Senator NELSON. You didn't plan it that way?

This is a letter to physicians from Thomas Bird, director of broadcast services of the Physicians Radio Network. He stated that the services called the Physicians Radio Network, is now broadcasting in Chicago, providing 24 hours, 7 day a week coverage, broadcasting political, socioeconomic news about the practice of medicine. The broadcasts are heard only by those who have a special PRN radio. The radio and all programing are free, supported entirely by pharmaceutical advertising. "You need only fill out and return the enclosed form and your radio will be shipped without charge. The instrument is compact, attractive and fits nicely on your bookshelf" and so forth and so on.

This letter will be printed in the appropriate place in the record.[1]

Dr. CROUT. Visual Information Systems also produce the network of continuing medical education, a biweekly, hour-long video tape distributed to hospitals, courtesy of Roche Laboratories, division of Hoffmann-LaRoche, Inc.

Nearly every major pharmaceutical company is engaged in producing materials for continuing education. These materials commonly use formats one associates with disinterested educational efforts—as expert panels and lectures by distinguished physicians. Despite their appearance, and despite the fact that they may be generally accurate, they are often promotional of particular drugs or drug classes and, on the whole, are one-sided. One does not often find in these materials the sort of healthy skepticism of a particular therapy that a journal like the "Medical Letter" brings to its readers. Typically, one does not see on such panels those physicians who believe oral hypoglycemic agents are dangerous, who believe antianxiety agents and sedatives are overprescribed.

I want to illustrate the kind of examples I am talking about. The first example is a video tape on depression. This is the longest tape, it will run about 10 minutes, but I think you will get a flavor of what we are talking about, recognizing this as an educational tape sponsored by the American Psychiatric Association, financed by Pfizer Pharmaceuticals. The program is made available to groups of physicians by Pfizer detail men. Some segments of the program will demonstrate that the tape, while probably reflecting the participants' views fairly, strongly encourages use of antidepressants generally and to some degree Pfizer's product Sinequan specifically.

[1] See letter dated December 30, 1975, from Thomas F. Bird, director, broadcast services, Physicians Radio Network, page 14034.

[At which time a tape recording was heard.]

Dr. CROUT. I wanted to spend a little time today so that you get the flavor of what is in the hour the physician puts in.

As you will see, the tape begins by mentioning that there are 4 to 8 million people with depression, and that the tape is sponsored by the American Psychiatric Association and financed by Pfizer.

A series of scenes then suggested that depression is far more pervasive than one might have suspected. First an estimate of 20 million people per year is proposed as a more probable alternative to the 4 to 8 million figure. Depression is broadly defined as "the absence of joy, anhedonia" and various examples illustrate its ravages: The housewife, the underachiever, people with psychosomatic complaints, insomnia, or sexual dysfunction. The increase in recent years of the use of tricyclic antidepressants is noted and is accounted praiseworthy. Finally, the last speaker of the symposium suggests that tricyclic antidepressants are particularly good drugs and indicates certain advantages that Sinequan, Pfizer's tricyclic, has.

The message is quite clear:

Depression is everywhere and being underdiagnosed.

Patients need not be actually depressed—insufficient joy, psychosomatic complaints, or underachieving, may be the only signs or symptoms and may be enough to make a diagnosis of depression.

Sinequan is the best of a good group of drugs, whose use, fortunately for the American public, is finally increasing to high levels.

The physician should join this welcome trend and use the drugs more.

There is every reason to believe that the physicians participating in the taped discussion are voicing with full personal integrity, their best medical opinions. It is also likely, however, that the drug firm knew what each physician would say before they invited him and thus assured the emergence of a particular point of view in its educational production.

Audio cassette tapes come to physicians in ever-increasing numbers. They are particularly useful to the physician because they allow him to make use of time that ordinarily is lost while driving in his car.

I would like to play for you an excerpt from a February 1976 tape from the American Osteopathic Association audio educational service, sponsored by Abbott Laboratories; the speaker is an osteopathic physician interviewed for this particular program.

Senator NELSON. May I ask a question before you proceed. Your statement earlier suggested that certain drugs—your example was hypertension, not depression—were underprescribed.

Dr. CROUT. Yes.

Senator NELSON. With respect to the question of underprescribing, I take it that that was what the panel was saying of drugs for depression. I assume that the specialty best qualified to diagnose the problem of depression is the field of psychiatry.

Dr. CROUT. Yes.

Senator NELSON. Would it also have indicated that there are not very many psychiatrists, and that not very many people get to visit a psychiatrist as compared with other physicians.

There is quite a difference between diagnosing depression and detecting an infection, although care should be taken to identify the target organism. But in any event it is not too difficult to conclude that there is a sore throat or an elevated temperature and to give an antibiotic. On the other hand, to prescribe an antidepressant properly requires some sophistication in the psychiatric field. The symptoms which show a need for an antibiotic are clearer than those for an antidepressant.

Dr. CROUT. I would agree with the thrust of your remarks. Depression can be difficult and complex and its diagnosis subject to ambiguity. It is seen by a large number of physicians and is a common enough problem that depression has to be handled by physicians well beyond the field of psychiatry. My suspicion is that most of the drugs in this class are actually prescribed by nonpsychiatrists. This is a problem handled by a large number of practicing physicians.

Your question was: "Who is best qualified to make the diagnosis?" I believe that psychiatrists are, but the facts of life are that a large number of patients——

Senator NELSON. Maybe I did not make it very clear.

There are a large number of people who feel a bit depressed and do not even know that they are depressed. Doesn't that give some explanation for the claim that there is underprescribing in this field?

Dr. CROUT. Yes; I agree with that.

This tape you are about to hear will last about 2½ minutes. The speaker is an osteopathic physician sponsored by Abbott Laboratories.

Again a clear message is given: Anxiety is everywhere and chemotherapeutic agents are the treatment of choice. The program tells the physician that minor tranquilizers are the preferred drugs and mentions that a once-a-day regimen is best. Abbott's Tranxene SD happens to be the only minor tranquilizer with a once-a-day dosage regimen.

[At which time a tape recording was heard.]

Dr. CROUT. Again I point out you are hearing what is factually correct but is in a point of view many would consider one-sided. Also I point out that Abbott Tranxene happens to be the only minor tranquilizer with a once-a-day dosage regimen, which explains the coincidence that Abbott is sponsoring this particular speaker who prefers a once-a-day regimen.

Before I am accused of the same thing, let me plead guilty to some selective editing in showing you these particular samples. We have edited portions of these tapes to make a point, and I would point out that in the course of the entire tape some degree of balance may emerge and some of these programs may be excellent. On the other hand the problem of selection by the drug firm is the issue I am concerned with in this overall process.

This is a lecture on Stress, Anxiety, and the Cardiovascular System by Hans Selye, M.D., Ph. D., D.Sc. In the words imprinted on the audio cassette, the lecture is, "Sponsored as a service to physicians by Pfizer Laboratories Division."

[At which time a tape recording was heard.]

Dr. CROUT. Again without a hard sell, the message is the same: More people need more tranquilizers for longer periods of time. Pfizer Labs manufactures the minor tranquilizer Vistaril and the trade

name Vistaril is displayed prominently on both sides of the cassette. Transcripts of the excerpts I have just played are attached as appendices D and E.

As another example, Roche Laboratories, manufacturer of Librium and Valium, sends out records of heart sounds in various types of heart disease. The records themselves are excellent and I believe quite useful. Each record is jacketed with promotion for Librium and Valium, interspersed with textual material. The unmistakable impression given is that the presence of heart disease, rather than the presence of anxiety, calls for tranquilizers, despite a fine print disclaimer, "the editorial content of this series is not intended to suggest the use of any specific drug or treatment program."

Our experiences with several organizations which planned to produce a large number of educational materials provide some interesting insights. As an example, 2 years ago, Synapse, a subsidiary of the J. Walter Thompson Co., proposed to produce a series of 48 disease-oriented video tapes to be sold to physicians under the auspices of the American Academy of Family Physicians. The cost of producing each tape was to be paid by a pharmaceutical manufacturer. The first tape was on urinary tract infections and was to contain commercials for Eli Lilly's cephalosporin antibiotics. The advertising agency expressed considerable dismay when FDA ruled that if the products advertised were intended to treat the disease discussed by the tape, then the entire tape would be considered drug labeling. This meant that the content could not deviate significantly from the labeling in the package insert. Synapse's contention was that no company would sponsor such an educational undertaking unless it could be related to one or more of that company's drugs, and, indeed, the series did not go forward. This contention has been repeated over and over again by media suppliers in discussions with the Agency.

Increasingly, pharmaceutical companies are providing continuing education materials for use at hospital staff meetings. These materials generally are produced by independent companies such as Medcom and Health Learning Systems on contract for pharmaceutical manufacturers.

Now let me give you examples of multimedia presentations. In a multimedia presentation a closed-circuit television tape is coupled with a brochure which the physician uses as a self-learning device.

On a positive side, there is the Health Learning System in cooperation with the National High Blood Pressure Education program, the Council for High Blood Pressure Research of the American Heart Association, and the National Kidney Foundation has produced an excellent series of materials on hypertension. The series, called Dialogues in Hypertension was produced under an educational grant from Smith Kline and French Laboratories (SKF), manufacturers of Dyazide, a fixed-combination diuretic indicated for hypertension. Let me emphasize that none of the materials produced were favorable to Dyazide specifically and, if anything, deemphasized the product.

In this instance the educational materials, while industry supported, were under the total control of a Federal-private program of unquestioned independence and prestige which was furthering the widely accepted goal of assuring that more people with high blood

pressure were diagnosed and treated. SKF did no more than pay the bills. The goal of the overall program happened to coincide with the goals of manufacturers of drugs used in treating hypertension and with good medical practice.

In many other cases, however, increased use of medication is not necessarily consistent with good medical practice.

One such example is a learning system on the subject of stroke developed by Health Learning Systems, Inc., and sponsored by Marion Laboratories. The learning system consists of two motion picture films, accompanying workbooks, tests to be taken by physicians, plus materials used to advertise the learning system to directors of medical education and to hospital medical staffs.

Marion Laboratories markets papeverine hydrocloride in a sustained release oral dosage form named Pavabid. The drug is claimed to be a cerebral vasodilator and to improve circulation to the brain; let me note parenthetically that the usefulness of this drug has not, in our view, been demonstrated.

Senator NELSON. How could you make that claim?

Dr. CROUT. It is a complex problem relating to the claimed "grandfather" status of the drug. We are currently planning to review its effectiveness, in spite of its status as an old drug and that point is now under review.

In the April 5, 1976, issue of the *Federal Register*, the FDA called for marketers of papaverine to submit evidence of safety, efficacy, and possible "grandfather" status of the drug. The *Federal Register* statement said that the drug would be removed from the market if such evidence were not submitted.

At a September 1974 meeting of the Western Pharmaceutical Marketing Research Group, held in Chicago, a representative of Health Learning Systems explained why Marion Laboratories was interested in sponsoring a learning system on stroke. Marion's Pavabid already had more than 60 percent of the cerebrovasodilator market and Marion felt that no amount of advertising would increase this percentage very much. It was also felt, however, that if the total market for cerebrovasodilators could be expanded, Marion Laboratories would get a high percentage of the increased sales. One way to expand the market for cerebrovasodilators was to convince physicians that these drugs were useful in the prevention and treatment of stroke.

The first segment of the learning system made no direct claims for the effectiveness of Pavabid in the treatment or prevention of stroke but simply focused on the transient ischemic attack [TIA], a brief episode of focal neurologic deficit, as an early warning sign of stroke. It then provided prescribing information for Pavabid and a logo of a linegraph superimposed over a longitudinal slice of a brain.

The second part of the learning system discussed the "Diagnosis and Treatment of Cerebral Vascular Insufficiency." The relatively uncommon cases which can be helped by surgical intervention were discussed in a superb presentation by Dr. Michael E. DeBakey, president of the Baylor College of Medicine.

The final segment of the learning system considered vasodilator therapy. The accompanying workbook pointed out that intravenous papaverine, which is not marketed in the United States, is one of the most effective vasodilating drugs and then proceeded, in a leap in

logic, to recommend the use of oral papaverine in patients recovering from completed strokes and transient ischemic attacks.

Again, despite the educational format and the appearance of distinguished physicians, the learning system is not a disinterested effort. First of all, it is directly linked to a frankly promotional effort. The linegraph-brain logo that appeared in the film was subsequently reproduced in journal advertisements and promotional labeling for Pavabid. Those promotional efforts are directed, just as the learning system was, at the use of Pavabid in the treatment and prevention of transient ischemic attacks. In addition, although some physicians believe cerebrovasodilators are useful, a great many others disagree. The learning system did not refer to these negative views and a user of the system would necessarily gain a very incomplete view of the current opinion of experts regarding these agents.

Another new continuing education modality is the medical telephone conference system. These telesessions, sponsored by pharmaceutical firms, enable physicians from around the country to discuss a disease for which the company's product is offered with the guidance of a company representative.

Appendix F is a leaflet intended for pharmacists describing telesessions to be held for Pennwalt's Zaroxolyn. Noteworthy are the statements "AMA Credit" and "Positive Effects on Sales Shown by Previous Participating Companies in Other Therapeutic Categories: Roche, Abbott, Burroughs Wellcome, Smith Kline & French."

While we do not know precisely what fraction of educational materials is industry-sponsored, we believe it is large. The examples provided show clearly that the educational content is commonly promotional in intent.

At most medical meetings there are numerous exhibits, some of which are commercial exhibits promoting various drug products, others of which are scientific exhibits describing the work of independent scientists. These latter are usually not bound by the kind of limits our regulations place on drug labeling or advertising, because they have been considered equivalent to scientific publications. As a result, such scientific exhibits frequently discuss new uses of drugs, drugs not yet approved, and comparative properties of drugs not made in approved labeling.

Recently, agency action related to the regulation of drug labeling has raised serious questions about these exhibits. In an attempt to define ways in which a drug company could distribute independently prepared educational materials, such as standard textbooks of pharmacology, we suggested guidelines under which such information would not be considered drug labeling. For the most part, these guidelines attempted to assure that such materials were wholly independently developed and edited. We did not feel that materials which discussed products of a single manufacturer or which discussed drugs and were produced with drug company funds could avoid being labeling if a drug company distributed them.

We have discussed these guidelines with representatives of the American Medical Association and the Pharmaceutical Manufacturers Association who indicate that many scientific exhibits depend upon the support of individual pharmaceutical companies whose products are described in the exhibits.

Senator NELSON. Did you state that the AMA protested that many scientific exhibits could be wiped out? Did they formally protest to the FDA about the guidelines?

Dr. CROUT. Let us say we formally discussed it. Protest is not quite the word. The guide gave them a good deal of concern. Yes, we met on several occasions with their representatives.

Senator NELSON. Did the PMA have the same position as the AMA on this question?

Dr. CROUT. Let us say that from their point of view neither one endorses our guidelines, each for somewhat different reasons.

Senator NELSON. Did you modify the guidelines?

Dr. CROUT. They have not yet appeared in a formal sense and will appear as part of our proposed revisions of regulations made.

Mr. GORDON. I have a document from the Committee on Scientific Exhibits of the AMA concerning industry support of scientific exhibits. It states that according to the FDA's definition, approximately 80 percent of the scientific exhibits at AMA meetings are promotional and probably half of those are in noncompliance with the regulations of pharmaceutical products as set forth in the *Federal Register*. This is a document signed by James M. Moss, M.D., who is the head of the AMA here in Washington on scientific exhibits.

Are you familiar with that statement?

Dr. CROUT. That is quoted from the memorandum in our testimony.

Mr. GORDON. Mr. Chairman, I ask that the letter be included at the appropriate place in the record.[1]

Dr. CROUT. In the same memorandum, the author estimated that the total cost of a scientific exhibit is $5,000 to $40,000 and concluded:

> Few physicians or scientific investigators can afford to have an exhibit unless they receive financial support. In the past, large clinics and medical centers supported exhibits as part of their public relations and professional education programs. The source of these funds has been severely reduced lately. Some exhibits have been supported by professional societies and lay health organizations, but too often these organizations are more interested in recruiting members and raising funds than in educating physicians. Support from the Federal Government through the National Institutes of Health, the Armed Forces Institute of Pathology, the Food and Drug Administration and the military forces has helped in the past, but this has been greatly reduced. The only other source of financing exhibits has been pharmaceutical companies. Either directly or indirectly this pays about 80 percent of the cost of the scientific exhibits.
>
> Using a scientific exhibit for promotional purposes is contrary to the spirit of the regulations of the AMA. However, the AMA cannot be responsible for anything that happens to an exhibit or to the brochures after the meeting. In this highly competitive society, few pharmaceutical companies can afford to support a purely educational exhibit.

In the use of scientific exhibits to promote unapproved drugs, appendix G shows, as an example, pages 66 and 67 and 76 and 77 of the official program for the Twenty-seventh Annual Scientific Assembly of the American Academy of Family Physicians, AAFP, held in October 1975. A large percentage of the exhibits are drug related. Appendix H shows pages 138 and 139 of the program of the American College of Physicians' Fifty-seventh Annual Session held in April 1976. In both programs, there is an exhibit by the same physician describing the development of an antihypertensive drug, prazosin hydrochloride.

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[1] See statement of Committee on Scientific Exhibits in regard to pharmaceutical support of scientific exhibits, page 14019.

Let me note that under FDA regulations pharmaceutical manufacturers may not promote their drug products prior to approval for marketing. In this case, although it was not noted in the program, the investigator was a full-time employee of the drug manufacturer which had developed prazosin. Prazosin had not been approved for marketing at the time of either meeting.

In the AAFP program, there are two scientific exhibits on Tolmetin, a drug developed by McNeil Laboratories for treatment of rheumatoid arthritis. At the time of the AAFP meeting, Tolmetin had not been approved for marketing in the United States. In response to the Agency's questions, a representative of the firm stated that the construction of both exhibits was financed by McNeil. The representative went on to state that his company customarily financed such exhibits when its medical monitor was pleased with an investigator's results. He stated that such scientific exhibits were shown at two to four conventions each year and that while attending the convention, each exhibitor received an honorarium of about $250 per day plus reimbursement of all expenses.

Mr. GORDON. You mentioned that under the FDA regulations, pharmaceutical manufacturers may not promote their drug products using certain marketing practices.

Was this a violation of the law and what can they do about it?

Dr. CROUT. I should point out that we have recently looked into the issue of scientific exhibits and are reporting to you some of the things we have found. In our view this type of thing is a violation of the current regulations on drug labeling.

But, as I pointed out, moving into that area would, according to the testimony of AMA, essentially wipe out 80 percent of the scientific exhibits. So I am reporting to you this problem that we have recently identified. We will attempt to address it in the advertising regulations, but we have not moved against specific cases at the present time.

Mr. GORDON. When are these advertising regulations going to be put in the Federal Register?

Dr. CROUT. We had hoped—it always seems to take longer than one hopes; I must say at this point it is unlikely before late summer.

Mr. GORDON. Is it true that, as Dr. Moss of the AMA stated, if these regulations being proposed are finally adopted, about 80 percent of their exhibits would be wiped out?

Dr. CROUT. If the guidelines which are stated in page 30 are adopted in final form, I believe that is what the AMA would say; yes.

So those regulations, which will make it clear that drug labeling laws extend to scientific exhibits and multimedia systems, will have an enormous impact in this area.

Mr. GORDON. Will you please explain briefly how you distinguish between scientific exhibits and commercial exhibits?

Dr. CROUT. At a medical meeting there is usually a large hall reserved for exhibits and there are a large number of commercial exhibits by drug manufacturers, instrument manufacturers, book salesmen, and so forth. These are little booths and displays with representatives there.

When a drug manufacturer maintains such a booth and promotes his drug there, that clearly falls under the drug labeling and drug advertising regulations.

In a separate section of the floor, or even in a separate room, there are booths where physicians or research scientists present their work as an alternate form of presenting their scientific discoveries. Sometimes people present their work as a speaker on a scientific program, and other times they will present it at a booth. So the scientific exhibit has always been viewed as equivalent to a scientific paper on a program.

The extent to which funding of the scientific exhibits has shifted to the pharmaceutical industry for support is a matter of concern and surprise to us.

Senator NELSON. Is that a recent phenomenon?

Dr. CROUT. Yes, that is a recent phenomenon.

I think the AMA memorandum points this out. Many of these were formerly supported by grant funds from NIH and so on.

Again, let me stress that I have no reason to believe that these industry-supported scientific exhibits represent anything other than the honestly-held beliefs and legitimate findings of the investigators involved. Many contain high-quality work. It is nevertheless a matter of great concern that most of the content of scientific exhibits is to a great degree selected by the drug industry. The exhibit committees of the conventions no doubt can eliminate the more frankly promotional exhibits, but they can do little to alter the fact that an exhibit unsupported by a drug company will usually not be produced and submitted for their review.

Mr. Chairman, let me turn at this point to the possible role of regulation in addressing this overall problem. The FDA is responsible for regulating drug advertising and labeling, and I believe we do that well. On the other hand, we also have a responsibility not to restrict legitimate educational materials which are not under the authority of the Federal Food, Drug, and Cosmetic Act.

I would like to make one point unequivocally clear. Any scientist, physician, or other person can say or write anything he wants about a drug, so long as this effort is not subsidized by the drug industry. The Federal Food, Drug, and Cosmetic Act poses no threat whatsoever to scientific communication and debate on drugs, to the reporting of research on drugs, or to the voicing of any medical opinion on drugs, providing industry funding of that communication is not involved.

Once a drug firm distributes written or audio-visual materials about a drug, or in association with one of its drugs, however, that material comes under the labeling provisions of the law. Labeling has been defined quite broadly in the Federal Food, Drug, and Cosmetic Act and by the courts and includes virtually all printed materials about drugs placed into interstate commerce and supported by a drug firm.

Senator NELSON. Are you saying that an article by a scientist—physician or otherwise—in a throwaway journal supported by the drug industry that make claims for drugs that were not supported by scientific evidence is controlled by the FDA, but if written for a

scientific journal or some other journal which is not entirely supported by drug advertising, then it could not be controlled by the FDA?

Dr. CROUT. I think it is important to emphasize that any piece of material distributed with a drug, or information sent by a manufacturer about a drug can be called drug labeling, so we have to look at both the content and its distribution. I can't answer your question clearly for every case. It would depend a little on what the physician wrote in the article, his independence from the industry, and whether it was distributed by the industry as a promotional effort.

Now the guidelines we have proposed here are an attempt to separate out what material we believe should properly be called drug labeling and what should properly be called medical education that is not under the Federal Food, Drug, and Cosmetic Act. The policies on this will be in our proposed regulations that are coming out.

Senator NELSON. You say the Food, Drug, and Cosmetic Act poses no threat to scientific communication, reporting research or to the voice of any medical opinion, providing industry funding of that communication is not involved.

Suppose a physician simply disagrees with, say, the FDA approved indications for the use of a drug as included in the labeling. He writes that he has been using the drug for many, many years, and in his judgment and experience, the FDA is wrong. The drug has been, in his judgment, very effective in controlling a certain illness. He writes an article on this subject and takes a very strong position, also recommending to other physicians that they use it in nonindicated cases, or at least he argues the case.

If that is published in a nondrug publication with no drug advertising involved, I assume what you are saying is that the act does not affect this kind of a situation.

Dr. CROUT. That is correct.

Senator NELSON. If I have such an article published in a magazine wholly supported by the drug industry, would that be controllable.

Dr. CROUT. That is the marginal case in which our policy is being developed at the present time and will be in the proposed regulations. We are not acting against those cases per se at the present time.

Let me cite one extension of this, however, which we do take action on. Once an article is used in a promotional effort, meaning literally distributed by a detail man in association with the drug, then that article becomes drug labeling and if the article references to unproved uses and so on, we will take action against it.

Senator NELSON. Is it another level of case if the physician or scientist is paid for writing the article as contrasted with one writing it totally unsolicited and not paid for.

Dr. CROUT. That is an important issue in our view, yes.

Senator NELSON. Go ahead.

Dr. CROUT. Under present law, FDA has regulatory authority over some of the materials I have been using as illustrations. Cassettes which discuss a particular drug, for example, must meet standards for drug labeling and may not promote nonapproved uses of drugs, minimize hazards, or make comparisons not supported by evidence. This still does not, of course, mean that they are neutral educational materials as their formats might suggest.

Recently, FDA was asked by a medical society whether a drug company could legally distribute a monograph prepared by the society without including prescribing information. The society objected strongly to the presence of such information because it would, they felt, have suggested that the monograph was promotional or prepared by the drug manufacturer when in fact it was not. In an attempt to define the circumstances in which we would consider informational material disseminated by a drug manufacturer not to be drug labeling, and thus not obliged to contain package insert information or to maintain strict conformance to the content of the approved package insert, we suggested the following five tests:

One: The material has been prepared solely for educational use and not with any intent that it be used for other purposes, as sale to or distribution by the pharmaceutical industry.

Two: The material is not promotional in nature taken as a whole, and is in the form of balanced educational materials. For example, the material may not contain any significant emphasis on uses for drug products that are not approved by the Food and Drug Administration as safe and effective, such as use for unapproved indications or in derogation of required contraindications and warnings. Although the material may contain occasional references to such cases, such references may not be frequent or be given major consideration or importance.

Three: The material has been prepared independently; that is, the pharmaceutical industry has not participated in the preparation of the material and has not exercised editorial review over the content of any of the material.

Four: The material covers a number of different drugs, and does not support use of one particular drug or the drugs of a particular pharmaceutical company.

Five: The material is not associated in any way with a promotional campaign for any drug product by the pharmaceutical firm supporting the exhibit. The material may contain reference to support by a pharmaceutical firm.

These tests, let me stress, were intended to permit truly independently prepared educational materials which do not have an overall promotional message to be distributed by drug manufacturers. When we were asked about scientific exhibits, we suggested essentially the same criteria.

We are currently drafting an extensive revision of our drug advertising and labeling regulations, and we expect to include guidelines such as those noted above in these proposed regulations. We are concerned that both the American Medical Association and the Pharmaceutical Manufacturers Association believe that these criteria would virtually eliminate scientific exhibits and industry-sponsored symposiums. These regulations could thus have an enormous impact on postgraduate medical communications and we would not take such a step lightly. We expect extensive comment on these regulations and will consider such comments carefully. At the same time, the extensive influence of the drug industry in these educational media is well illustrated by the profound effect our suggested guidelines could have.

In brief, then, regulation under the Federal Food, Drug, and Cosmetic Act is an important restraint on some promotional efforts sponsored by the drug industry. I would not want to suggest, however, that regulation is the best approach to take for all of the educational materials supported by the drug industry. The idea of the Federal Government and Madison Avenue locked in eternal battle over every piece of educational material sent to physicians is not particularly attractive. Neither of these parties should have primary control over educational materials. Such control properly belongs with the profession itself and its medical schools.

Mr. Chairman, I would like to summarize the problem in broad terms. The technical knowledge required for the optimal practice of medicine is continually advancing at a rapid pace. Because of this, there is need for excellent courses and teaching materials to assist the modern physician in maintaining his professional competence throughout his career. This need is increasingly recognized by specialty societies and State boards of licensure. Thus, physicians are coming under increasing pressure to demonstrate in a formal way their participation in various courses, hospital seminars, and other teaching programs.

To fill the need for teaching materials the communications industry has moved aggressively in recent years to produce an enormous variety of brochures, books, monographs, magazines, controlled circulation journals, closed-circuit TV video tapes, movies, audio cassettes, and self-instructional learning systems. Many of these are sent free to physicians, some under the sponsorship of professional organizations. These materials are highly professional from the standpoint of communications technology and obviously expensive to produce.

Outstanding medical authorities commonly are featured, and the scientific content of these communications is often excellent. While some of these communications relate to specific drugs and are readily recognizable as promotional material, many others deal with broad issues in medicine, including the diagnosis and general management of various diseases. Others may describe specific technical advances in a variety of specialty fields. The financial support for all of this activity comes predominantly from the pharmaceutical industry, which in turn obviously passes the cost along to the consumers of drugs.

The proliferation of industry-supported educational materials has increased to the point where they now constitute the bulk of educational information provided to the practicing physician in his practice.

Mr. GORDON. How much money is involved in this, actually?

Dr. CROUT. The round figure for the total promotional effort by the drug industry in the particular area of prescription drugs is on the order of $1 billion.

Senator NELSON. You are talking about all promotional activities?

Dr. CROUT. But the bulk of that must be for detail men but also a big piece of it must be for the kinds of promotional efforts we have been talking about this morning.

The smallest piece today is probably advertising in medical journals, which is the classical form of drug advertising.

Mr. GORDON. I understand that expenditures on medical schools per year are a little over $500 million and that the expenditure by the pharmaceutical industry on advertising and promotion is about twice as much as the money we spend in this country on education in medical schools.

From the material that we have read—we got a figure yesterday from the Library of Congress—annual expenditures on all medical schools in the country was a little over $500 million.

Dr. CROUT. I am not in a position——

Mr. GORDON. You mentioned $1 billion for advertising and promotion so that makes it about twice as much.

Senator NELSON. But you are saying that the bulk of the educational information with respect to drugs is sponsored by the drug industry.

Dr. CROUT. Everything provided to physicians is supported by the pharmaceutical industry.

Senator NELSON. You stated that industry-sponsored material now constitute the bulk of educational information encountered by the practicing physician in his practice.

Dr. CROUT. I meant provided. I am sorry. The final version of the testimony says "provided to the practicing physician in his practice."

Senator NELSON. You have the word encountered. You changed that.

Dr. CROUT. Right. Provided to the practicing physician in his practice.

Senator NELSON. What does that mean—provided to? What are you talking about, something that comes free?

Dr. CROUT. Where his information comes through attendance in hospital seminars, through the mail, through listening to tapes and so on.

The next sentence goes on to say that I think he has other opportunities for postgraduate medical education, including a variety of courses conducted by medical schools, scientific meetings, and the medical literature.

The relative impact of these different educational opportunities on physician behavior is not clear. Physicians are trained to think for themselves, to be critical, and to engage in lifelong learning. I do not consider my colleagues to be pawns of the communications industry. Nevertheless, it is reasonable to ask why our profession should be subject to an onslaught of allegedly educational material, not subject to the kind of independent review given the scholarly medical literature, which is financed by the drug industry, and ultimately paid for by our patients.

My concern, Mr. Chairman, is with this system, because it places the postgraduate education of an entire profession too much under commercial, nonuniversity influence. I believe it is self-evident that the drug industry would not be supporting this field so heavily if it did not believe such support was beneficial to the sale of drugs.

Let me emphasize that, while I have used the words "physician" and "drug industry" throughout this testimony, a similar situation applies to other health-related professions and industries. The postgraduate education of dentists, veterinarians, and pharmacists is also heavily influenced by the drug industry. Nor is this industry alone

in its behavior. My testimony applies equally well to the medical device industry and the diagnostic products industry.

The best solution to this problem is easy to describe in concept, but difficult to envision without major changes in the whole structure of postgraduate medical education. As I have emphasized repeatedly, I believe that control of the educational process for physicians properly resides with university-based medical schools. The pre-Flexnerian era taught us that medical education should not be entrusted to a commercial trade school environment, and our society should not have to learn that lesson over again. Medical schools, however, are not financially in a position to accept responsibility for the postgraduate education of physicians.

I believe it is important that this problem be discussed openly, and I commend your subcommittee for undertaking these hearings. If the extent of the problem is as great as I suspect, and if my concerns are confirmed by others, society must entertain innovative solutions, even drastic changes in some of our current behavior.

The possibility of permanent pharmaceutical industry dominance over the total postgraduate education of physicians and other health professionals is too serious for us to ignore.

Thank you.

Senator NELSON. You made some reference—I think very briefly—to medical textbooks. Has the FDA done any survey about how many companies that are in drug advertising or in the publication of drug-industry-supported magazines also publish textbooks. McGraw-Hill is one, I guess, that publishes textbooks in this field.

Mr. GORDON. Does McGraw-Hill produce medical textbooks?

Dr. CROUT. I believe so, yes.

Senator NELSON. Here is an ad which claims that McGraw-Hill is the largest healthcare publisher in the world. It says that Dr. Seymour Schwartz, who edited "Principles of Surgery", a basic text for medical schools, is also chief editor of one of its industry-supported magazines. Are you familiar with textbooks that are published by McGraw-Hill and/or any other companies in similar business?

Dr. CROUT. I cannot speak specifically about McGraw-Hill or any survey of the industry. I suspect that some firms are very likely to produce both textbooks and the kinds of multimedia communication systems you have seen today.

Senator NELSON. Would anybody in your medical library be knowledgeable about that?

Dr. CROUT. We can try to get knowledgeable if that would be helpful.

Senator NELSON. I would not want to put you to all kinds of extra work. I think it would be worthwhile to know how much involvement in the formal textbooks publication business is the pharmaceutical industry, directly or indirectly.

Dr. CROUT. Interesting question. I am not aware of direct or indirect——

Senator NELSON. Maybe we could find it out from the Library of Congress. If anybody in the FDA happens to be knowledgeable please submit it for the record because it may or may not be of consequence.

Dr. CROUT. May I make a comment. I think many of these teaching materials that are produced in postgraduate education are finding their way into medical school training, so that it is conceivable to me that some of the material is competing with the standard textbooks and the classical medical scientific journal as a source of information to medical students. This I think would be highly variable from school to school, and testimony on this from others might be interesting.

Senator NELSON. We will put this in the record. This is a letter written a couple of years ago by the head of the Department of Pharmacology, School of Medicine, University of Miami. It is addressed to Dr. Young of Cook County Hospital in Chicago.[1]

Is there a considerable involvement by the pharmaceutical industry in the pharmacy schools, department of pharmacology in medical schools and teaching hospitals? In their teaching consulting programs?

Dr. CROUT. To my knowledge most medical and major teaching hospitals do not permit detail men to freely meet with students or house staff. This is a practice which is discouraged.

The letter you have here came about from unusual circumstances. I talked about it with Dr. Palmer on the phone, and Dr. Palmer along with several other clinical pharmacologists is engaging in an experiment incorporating a detail man into their own teaching programs for medical students and for graduate fellows.

Mr. GORDON. Would you repeat that?

Dr. CROUT. Training detail men to be better presenters of drug information.

Senator NELSON. You mean this is a program of educating detail men?

Dr. CROUT. Yes; this is a program of educating detail men and the spirit is one, a little bit of, if you can't lick them, join them, or let us try this as an approach.

So this letter is admittedly ambiguous, I think an embarrassment to Dr. Palmer, but that is the context in which it is written.

Senator NELSON. Well, does the detail man have a valid scientific function to transmit pharmacological information to the practicing physician. Should that be the physician's source of knowledge about what he is prescribing.

Dr. CROUT. I think that we would all say the answer is "No."

Senator NELSON. Why even a secondary source?

Dr. CROUT. The issue is, the detail man exists because of the nature of our free enterprise system, should he have some kind of training in the area that is independent from his employer. I am not endorsing that notion or rejecting it at this particular point.

Senator NELSON. If the whole system is bad, then it is even worse to make the promoter more sophisticated than he is and give him better-looking credentials. If he is the physician's source of knowledge, then I wouldn't go near his office. I would like to have him consulting the experts, not a promoter of the drug.

So if that is a program at the University of Miami—that kind of infiltration of our medical schools—I wonder about what else the

[1] See letter dated Oct. 29, 1974, to Quentin Young, M.D., Cook County Hospital, from Roger F. Palmer, M.D., School of Medicine, University of Miami, page 14035.

industry is doing in the medical schools and the effect on sound scientific practice.

Dr. CROUT. Dr. Palmer could speak for himself on that issue. I just want to be sure his intent was represented properly.

Senator NELSON. We do not have any way of getting a good survey but here is another case of involvement, this time in a pharmacy school. Here is a letter to Jere E. Goyan, Ph. D., School of Pharmacy, University of California, San Francisco, College of Pharmacy. It was written February 5, 1976, and is signed by nine scientists including some Ph. D.'s and an M.D.[1]

They refer to distribution, so apparently the school was distributing this publication. It just raises another question as to how deeply involved are the pharmaceutical manufacturers in the education at the college level. Are you aware of any studies of this kind of involvement made at medical colleges in the country?

Dr. CROUT. Studies, no; I believe that any knowledgeable dean or chairman of a major department could tell you, though, with reasonable accuracy about the pharmaceutical funding of research, teaching, and so on in medical schools. Dr. Rheinstein knows of a study being done now.

Dr. RHEINSTEIN. Mr. Chairman, Dr. William Haddad of the Committee of Legislative Oversight in the State of New York is currently looking into the amount of involvement of pharmaceutical manufacturers in medical education and is in contact with the deans of the medical schools in the State of New York.

Senator NELSON. Just within the State of New York?

Dr. RHEINSTEIN. Yes.

He has commented that there is substantial involvement at each of these schools and I think we will have more at a future date.

Senator NELSON. Who is doing the study?

Dr. RHEINSTEIN. The man's name is Dr. William Haddad and he works for the Committee of Legislative Oversight for the State of New York.

Mr. GORDON. Has the FDA or the Department of HEW done anything to encourage medical schools to adopt extension courses or continuing education courses?

Dr. CROUT. The FDA does not support this area directly. I could not comment extensively on that, but certainly the Federal Government has supported postgraduate education. This is a feature of many of the regional medical programs, and that sort of support was undertaken with some enthusiasm several years ago and it is still going on.

I think, if you would be willing to call demonstration projects and communications systems postgraduate education, and a number of such communications systems that have been set up, there is a fair amount of public support.

Mr. GORDON. The public pays for these courses, anyhow. Ultimately they pay in purchasing drugs, so if they pay ultimately why not do it directly through Government; Federal and/or State grants? Do you see any possibilities there?

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[1] See letter dated Feb. 5, 1976, to Jere E. Goyan, Ph. D., School of Pharmacy, University of California, page 14040.

Dr. CROUT. That is an option to be considered. Certainly the funding of postgraduate educational materials and courses would clearly appear to be available. We are talking about somebody paying for what you see today. It will be paid for in one of two ways. I should say one of three ways: (1) by Government; (2) by the profession, the medical profession—that is, payment for their own postgraduate education; and (3) by the manufacturers of drugs, or some combination of these three. Right now Government is clearly running third among those three.

Senator NELSON. The medical society's memo indicates that a substantial percentage of these are promotional. Since they are tax deductible, 50 percent of the cost of the exhibit are paid for by the taxpayer, anyway.

Thank you very much Dr. Crout for your very interesting presentation.

Dr. CROUT. Thank you Mr. Chairman.

Senator NELSON. These hearings will resume at 9:30 on Monday, May 10.

[Whereupon, the hearing adjourned at 12:45 p.m.]

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

MONDAY, MAY 10, 1976

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

The subcommittee met, pursuant to recess, at 9:30 a.m., in room 318, Russell Senate Office Building, Senator Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist; and Karen Young, research assistant.

Senator NELSON. Today is the second in a series of hearings on the role of the drug industry in the postgraduate education of physicians.

The Monopoly Subcommittee of the Senate Small Business Committee has been studying for quite some time problems related to the development, marketing, and use of drugs. Since the prescribing physician is in reality the purchasing agent for the patient, our subcommittee has been particularly interested in the sources of information on which doctors depend for information about drugs.

It is well known that the drug industry spends vast sums of money on advertising and promotion. It is not well known, on the other hand, that the drug industry has also come to occupy a significant role in the postgraduate "education" of the doctor. This situation, in my judgment, is bad both for the public and for the medical profession. On April 28, Dr. Richard Crout, Director of the FDA's Bureau of Drugs expressed grave concern that the growing influence of the industry-sponsored medical education is a long-term threat to the integrity of his profession.

Dr. Crout testified that much of the written and audiovisual teaching materials on drugs and all other medical subjects a physician encounters throughout his professional career, are supported by the pharmaceutical industry.

This includes the vast majority of medical magazines which clog his daily mail, the clinical problems, the audiovisual teaching systems he studies in his spare time, the films and closed-circuit TV tapes he sees in his hospital conferences, and even the scientific exhibits and presentations by panels of experts he encounters at medical meetings.

The drug industry has vast resources at its disposal. Its expenditure for advertising and promotion of drugs is now well over $1 billion per year or about $5,000 per physician per year.

This is about twice as much as we are spending each year to educate our doctors in our country's 116 medical schools.

These massive expenditures on advertising and promotion are ultimately borne by the public. A more important cost to the public, however—not measureable in monetary terms—is the systematic bias in what industry passes off as educational material but which is in reality part of the industry's promotional efforts. These activities should be of grave concern to the medical profession and its educational establishment.

The subcommittee plans to hear from those who prepare this material, arrange conventions and exhibits, as well as medical organizations that sponsor them. In addition, at future hearings we expect to hear from outstanding medical educators. These are the people—the medical profession and its schools—who have the responsibility for educating physicians not only in undergraduate medical education but also in postgraduate education.

Our first witness this morning is Mr. Jay Raeben, president, Visual Information Systems, Division of Republic Corp., New York, N.Y.

Mr. Raeben, your statement will be printed in full in the record. You may present it however you desire.[1]

Mr. RAEBEN. Would it not be preferable simply for me to read it as written, Mr. Chairman.

Senator NELSON. However you desire, sure.

STATEMENT OF JAY E. RAEBEN, PRESIDENT, VISUAL INFORMATION SYSTEMS, DIVISION OF REPUBLIC CORP., NEW YORK, N.Y.

Mr. RAEBEN. This statement identifies Visual Information Systems' activities. I will describe briefly those concerned with medical communication or education, and at a somewhat greater length, deal with those likely to be of special interest to the subcommittee. As each activity is discussed, I will make an effort to respond in that section to the subcommittee's concerns as suggested in its invitation letter of April 6.

Our company was formed in October 1962 and became part of Republic Corp. in 1969. Its first activities were in closed-circuit television at conventions. Since then we have provided business and university instruction on video tape and made smaller forays into sports and entertainment.

VIS' principal activities and those of interest to the subcommittee are in medicine and this statement is limited to them.

Senator NELSON. May I interrupt, Mr. Raeben?

I note that you state that VIS became, in 1962, a part of the Republic Corp. What is the Republic Corp. and what other business activities are they engaged in in addition to what VIS does?

Mr. RAEBEN. Republic Corp. I think was referred to at its peak about 1970 or 1971 as a conglomerate. It was during that process of conglomeracy that we were acquired in 1969. I think it has since

[1] See prepared statement of Mr. Raeben beginning at page 14246.

shaken out into a more coherent company with two principal branches, one in communications—printing, graphics, film processing of which we are a part, and another branch, steel specialities—not to be confused, however, with Republic Steel. It is a moderately sizeable company traded on the New York Stock Exchange. We are one of 24 divisions.

Senator NELSON. VIS is one of 24 divisions?

Mr. RAEBEN. Yes.

Senator NELSON. All right. Go ahead.

Mr. RAEBEN. Thank you.

Our medical activities are: Convention television, which we began in 1962; the Network for Continuing Medical Education [NCME], which we began in 1965; Audio Visual Education in Neurosurgery [AVENS], which we began in 1969; the American Academy of Ophthalmology and Otolaryngology Continuing Education on Television, which we began in 1971; and the Physicians Radio Network, or PRN, which we began in 1974.

Convention television began in 1962 at a meeting of the American Dental Association. The service, to which we attached the name Hotelevision, enabled dentists in their own hotel rooms to watch programs on dentistry prepared by the association. Since that date, Hotelevision and other forms of convention television have been supplied by us to about 70 association meetings, predominately for physicians. All programing is developed under the direction of the association and the service has been supported by perhaps a dozen pharmaceutical companies in all. When product messages accompany the telecast, they are always unrelated to the content of the program. To my knowledge, no studies have been done to measure the impact on physicians prescribing practices.

Senator NELSON. You say when products messages accompany the telecast, they are always unrelated to the content of that particular program. So if a program dealt with infectious diseases there would not be the promotion of any drug that was an anti-infective. Is that what you are saying?

Mr. RAEBEN. I would expect that that would be the case, yes, sir.

Senator NELSON. Does each one of these programs have some drug promotion in the program?

Mr. RAEBEN. Perhaps that is more easily understood if I explain it more fully. Most of these services were fairly lengthy, perhaps 35 to 40 hours of television programing over, let's say, a week-long convention; usually early morning from 7 to 9 before physicians would leave for regular meetings, and then beginning around 5 p.m. until perhaps around 11 or 12.

Senator NELSON. You mean these would be closed-circuit television programs delivered into the rooms?

Mr. RAEBEN. Yes, sir, into the individual sleeping rooms of the physicians, the thought being that through the service, the convention hours, which are normally 9 to 5, could be extended to make the convention day a little longer. And the programs are frequently taped either that day or the day before at the convention with, usually, physicians who are attending the meeting and who had been assembled by the association as having something that the association wished to receive wider dissemination.

Senator NELSON. I do not follow that.

You mean these programs were simply a closed-circuit television repeat of what had actually occurred live at the convention itself?

Mr. RAEBEN. I would say an extension rather than a repeat. Either, for example, a physician who was not going to be on the formal meeting program speaking during the day in one of the meeting rooms would be given time on the closed-circuit telecast. Or in some instances, a physician who had a paper of some importance, which, let us say, was allowed 30 minutes for presentation during the meeting day, would be given maybe an additional half-hour or an hour on television that evening or the next day to amplify on his comments, frequently questioned by his fellow physicians.

Senator NELSON. On page 2 you state "Since that date, Hotelvision and other forms of convention television have been supplied by us to about 70 association meetings, predominately for physicians." Do you mean to 70 different associations or to 70 different meetings, some of them being repeating?

Mr. RAEBEN. The latter.

Senator NELSON. Now, do any of these programs involve a prepared television program on some aspect?

Mr. RAEBEN. Yes. In a couple of instances I can think of, the American Medical Association was quite interested in developing materials which would be, oh, perhaps accreditable by the association itself. These programs were developed, unlike the bulk of those seen, well in advance of the meeting, weeks and sometimes a couple of months ahead. The association would pick physicians, and a topic, and normally we would videorecord them, although in some instances, the association made arrangements for that itself.

In another case—a couple of cases that I can recall—one association, Southern Medical Association, which was not able to fill all the hours of programing with materials that would be taped at the meeting, asked us to supply from our current library of programs developed for another project which I would be speaking about later, NCME, to supply some of those programs for exhibition on this closed-circuit Southern Medical Association network.

Senator NELSON. Back to the original question about advertising or mention or promotion of a drug on any of these programs, whether they are repeats or run live on closed-circuit television at the convention—do any of those contain any promotion of any drugs at all?

Mr. RAEBEN. Yes. The programs are accompanied by—that is to say—the advertising always appears between program subjects. There might be speakers on one subject for half an hour, and speakers on another for, say, 15 minutes, and there may well be a product message or occasionally an institutional message in between those two.

Senator NELSON. If you had a 6-hour program or something with 10, 12, 14 different subjects or presentations, would there always be an ad between each one? Is that what you are saying?

Mr. RAEBEN. Not necessarily between each one, but I would guess in each hour. I am trying to recall; the pattern has varied so. But there might well be three or four certainly in each hour.

Senator NELSON. And how is this financed? Your organization supplies this service. Is all or part of it paid for by the drug com-

panies or all or part by the medical association or what? How does that work?

Mr. RAEBEN. Well, there have been two methods. I guess you might ultimately say that the bulk of the monies have come from the pharmaceutical industry. In some instances, the industry pays the association which then hires us to supply the service. In other instances, industry has paid us to supply the service to the association, which has then accepted the service, and the association is always in control of the programing under either arrangement.

Senator NELSON. So in some cases the drug company would pay a medical association, which would hire VIS. In other cases, the drug company would directly retain or hire VIS to supply the programs. Is that correct?

Mr. RAEBEN. That is correct.

Senator NELSON. And then what happens? The association itself then requests the kind of programs it wants or how does that work?

Mr. RAEBEN. Well, normally I believe they actually arrange for the programs. That is to say once they have learned—normally several months ahead of the meeting that the television service will be available, their own staff selects physicians and subjects to be part of the television service. Most of the programs—in some cases a 100 percent, in some cases perhaps only 80 or 90 percent—are taped at the meeting itself. Doctors come into a temporary studio which we erect during the week of the meeting, and they are brought in by association officials and then they speak on whatever it is they feel important.

Senator NELSON. What drug companies participate in sponsoring these programs? Does its trade association, for example, itself ever participate, the Pharmaceutical Manufacturers Association as an association, or is it individual firms?

Mr. RAEBEN. It is individual companies.

Senator NELSON. And which individual companies?

Mr. RAEBEN. Well, over the years there have been quite a few. I guess the first one that we were involved with was Wyeth Laboratories, which was a sponsor of the American Dental Association meeting. I believe Upjohn has sponsored some. Hoechst Pharmaceuticals, Roche Laboratories, quite a substantial number, in our own experience, more than any other company. I believe Ciba. I cannot recall the names at this moment.

Senator NELSON. This could be the American College of Physicians or it could be in the field of surgery or family practice or what have you. Is that correct?

Mr. RAEBEN. Yes.

Senator NELSON. Conventions for any one of the medical disciplines. Is that what you are saying?

Mr. RAEBEN. That is correct.

Senator NELSON. And then VIS provides the professional expertise in managing these programs. Is that it?

Mr. RAEBEN. That is correct.

Senator NELSON. Does VIS design and develop programs of its own in the field of medicine?

Mr. RAEBEN. We do, yes, sir, in other projects, not the convention television service but in other services that I was going to describe in more detail.

Senator NELSON. All right. We will get to that then. Go ahead.

Mr. RAEBEN. Thank you.

Mr. GORDON. Excuse me. May I ask one question at this point?

I am trying to get the rationale as to why, if you were having a program on infectious diseases, you would not have advertisements for antibiotics or other such products instead of, let us say, tranquilizers or other products unrelated to the program. What is the rationale behind that?

Mr. RAEBEN. You are speaking of the convention television service now?

Mr. GORDON. I am talking about what we were just talking about, the hotelevision.

Mr. RAEBEN. To begin with, I would say that the product messages which were provided by the pharmaceutical company in advance of the meeting in prerecorded form, given to our directors and technical staff for insertion between programs, were done at a time when the sponsor would have no idea of what the content of individual programs would be like.

Mr. GORDON. But do you know?

Mr. RAEBEN. Yes.

Mr. GORDON. Because you arrange it.

Mr. RAEBEN. Correct.

Mr. GORDON. And this sounds like a policy of yours.

Mr. RAEBEN. Yes.

Mr. GORDON. What is the rationale behind that policy?

Mr. RAEBEN. We have ourselves felt sensitive to possible implication of, for example, implied endorsement of a product. If the physicians were speaking about a clinical entity, and then there were to be a product advertised just before or just after that program which dealt with that clinical entity, a casual viewer might think that there was an implied endorsement by the doctors in the program of the advertising message. We would not like that confusion to occur.

Mr. GORDON. It does not appear that you would have any casual viewers. People would be planning on seeing it. You would have experts. You would have physicians. This is what bothers me. I would like to know why you have this policy.

Mr. RAEBEN. Well I think when you consider the environment in which people would watch these particular programs—in their hotel rooms perhaps while dressing to go to the meeting, or at the end of the day while changing their shirts before going out to dinner or something of that sort—they might see a telecast, and they might see a product message, and they might have even looked away from the screen and had just been looking for a few minutes. It would not be difficult for some kind of connection erroneously to be drawn. I do not think the listening is all that careful. I think any of us could testify to that from our own television viewing experience. So it is to prevent just such a confusion, we felt that it was wisest to make a clear separation where this was possible. It was not always possible, I might add. Sometimes in a program intended to be, maybe, on a socioeconomics subject somebody might have introduced at the last moment, let us say, on a live telecast—although

these are normally taped—some comment about a disease entity. But I say that where we could plan, we avoided the connection. And I am pleased to say that our sponsors seemed content with this separation.

Senator NELSON. What is the length of most of these association conferences or conventions? A week?

Mr. RAEBEN. Yes; the major associations tend to gather on the weekend and then people start going home on Thursday or Friday.

Senator NELSON. And could you give us a figure on what the average cost to the drug companies would be for retaining your organization to present the convention and whatever else you present? What would that cost be usually?

Mr. RAEBEN. I would say the services ranged in cost from, in one instance for a somewhat abbreviated version of what we are speaking about, as low as perhaps $7,000 or $8,000 up to perhaps as much as $45,000, and perhaps $50,000.

Senator NELSON. And that involves the presentation of the closed-circuit television. It does not involve displays or things of that kind, or do you do that, also?

Mr. RAEBEN. No; we do not. It's just the television.

Senator NELSON. Yes; all right, go ahead.

Mr. RAEBEN. Thank you.

The activity I think that we are probably best known for, at least prior to our radio effort, is called the Network for Continuing Medical Education, NCME. This was established in 1965 with the support of Roche Laboratories. This was the first effort in any field to use the emerging video technology for publishing. We employ what we think of as a "journal" concept with three "articles" or programs in each reel. Unlike the way motion pictures have been used, we put forward the notion, which was then unusual, that an audience as small as a single viewer was adequate and that viewing should take place at the convenience of the viewer, not the exhibitor. These ideas I think now seem commonplace.

In 1972, with the introduction of the video cassette machine, a cassette subscription plan was developed. This has enabled hospitals to build their own video cassette libraries and offer them as community resources. Today, all 70 NCME hospitals subscribe, paying $1,200 to $1,600 yearly.

Senator NELSON. You say "all NCME." What do you mean "NCME hospitals"? That is just a hospital that subscribes to that service, you mean?

Mr. RAEBEN. Yes, sir, that is correct.

Senator NELSON. You have 700 of them paying $1,200 to $1,600 yearly. For that they receive these cassettes?

Mr. RAEBEN. Yes.

Senator NELSON. Does VIS then develop the cassettes? It that it?

Mr. RAEBEN. We do. I was going to get into the process of their development in another moment.

I want to point out also that the remainder of the cost of the service is borne by Roche Laboratories.

Senator NELSON. What do you mean "the remainder of the cost"?

Mr. RAEBEN. The moneys that the institutions pay represents about one-third of the total cost of the service.

Senator NELSON. So this annual subscription fee paid by the NCME hospitals of $1,200 to $1,600 yearly represents about one-third of the total cost of the product that they are receiving. Is that it?

Mr. RAEBEN. That is correct.

Senator NELSON. What is the total cost for those 700 hospitals? Over a million dollars, I suppose.

Mr. RAEBEN. Well, it would be more than that. It would be between $1½ and $2 million, I would say.

Senator NELSON. The cost to the hospital is one-third of the total cost which is around $2½ million; is that correct?

Mr. RAEBEN. That is correct.

Mr. GORDON. Perhaps you have not mentioned it yet, but the next thing you say in your prepared statement is: "About 145,000 physicians have regular access to these programs."

Now, who pays for that?

Mr. RAEBEN. Well, nobody pays for that. The physician is someone who attends at the 700 hospitals. The 145,000 includes, I should add, interns and residents. Perhaps 20,000 to 25,000 of the 145,000 are house staff. The remaining—perhaps 120,000—are attending physicians who in the normal course of their workweek would spend several hours in the hospital perhaps coming in to see patients, and it is on that occasion that they would see these programs. They would presumably pay nothing as their institution had subscribed.

Senator NELSON. Do the 700 hospitals you mentioned have a regular scheduled showing time for these cassettes on various kinds of medical problems which are announced so that physicians who practice within the hospital would have an opportunity to look at them or is it just something the doctors view at their convenience?

Mr. RAEBEN. Well, many do have such a regularly scheduled showing time. In the days before the video cassette machine, prior to 1972, that was the practice. Since the video cassette machine came along, that is somewhat easier to operate—easy enough for a physician or any nonexpert technical person to operate. The machinery is usually kept in some location such as, say, the library, and the physician looks at the cassette on the same demand basis that he might go into the library to pick up a copy of the Journal. And that, in fact, is the form of use we encourage. We think it is much better than having a schedule which he would have to try to meet.

Senator NELSON. Are there also occasions when physicians, who may be experts in the subject matter being shown, are available for questions or is that not a common practice?

Mr. RAEBEN. Yes. Particularly in smaller communities, I would say this service itself is one which is more useful in the smaller community hospital than, let us say, the big city medical center where there is an awful lot of live expertise available. But in the smaller institutions, quite commonly at their monthly staff meetings, for example, they will play a program or two and arrange for a discussion to take place at that time. That is a frequent practice.

Senator NELSON. Do any of the medical colleges produce these kinds of cassettes and make them available to hospitals?

Mr. RAEBEN. There have been a number of efforts. First of all, a number of medical colleges do. In fact, I would guess all now have

video tape producing capability. Probably 100 percent of the medical colleges do. They vary greatly in their effort to extend the service outside their own walls.

Briefly, during the heyday of the regional medical program, an effort was made to have the medical center be sort of a production fountainhead for the general and community hospitals within its region. In most instances, that did not go very far. There have also been efforts in one or two States—California, notably—to have programs produced. For example, UCLA had a fairly extensive service to about 60 or 70 hospitals which it had going for some time. As a matter of fact, during its early stages we gave it considerable support. They did not have the duplication facilities and we supplied them for them gratis just to encourage them.

Senator NELSON. Go ahead.

Mr. RAEBEN. This is further to your questions.

When we began the service we really thought that we would be a clearinghouse. I expected that the programs would be produced by medical schools, which were at that time just acquiring video tape equipment or, in some instances, by Government facilities, for example, the National Naval Medical Center, or Walter Reed Army Medical Center, which were interested and active in medical television.

In short, we expected to vest responsibility for producing the programs in the academic medical community. We expected just to be a duplicator. That programing, however, proved to be quite often not suitable for distribution for technical or production reasons. In a few instances, it was simply not available to us. It became more effective for NCME to provide direct production assistance to the physicians at those very same medical centers whose work was to be the subject of the programs. In short, the doctor who would have been in the program produced by his institution produced the same program. We supply the director, the cameras, the medical artwork and so forth.

Senator NELSON. Well, if an institution—a teaching hospital for example—was going to supply the expertise for some program, the practicing and teaching physician would participate and VIS would supply the technical personnel to film whatever is presented. Is that what you are saying?

Mr. RAEBEN. That is correct. And normally a writer as well to work with the physician in developing the script.

Senator NELSON. How many university teaching hospitals or hospitals of any kind do you have an association with of that nature?

Mr. RAEBEN. Well, it is a very large number. I can hardly think of a medical center in this country where we have not produced programs. I guess you would have to say over a several year period we have produced programs at virtually all major medical centers in this country. There may be some exceptions.

Senator NELSON. I notice you refer in your statement to "700 NCME hospitals." Let me ask the question another way. Can you separate out those that are medical-college-affiliated teaching hospitals from those that are not? My question being, how many of the medical colleges in this country, through their teaching hospitals

and staff, produce programs to be video taped by VIS? Do you know them?

Mr. RAEBEN. Well, again, I think it is virtually all. However, I think it would be perhaps misleading if I do not reorient my statement here. It is not so much that the medical center has itself said we wish to produce a program. Would you, VIS, please come in and do it for us? Rather, what has happened over the years increasingly is that physicians at those medical centers who are teachers, whose work has been identified by our medical advisers as being good, are nominated as presenters of program subjects. We have then actively gone to them and said, "Would you care to present your work on television?" So you might say the initiation, the start of the effort, has come from us. At least, that is how it is nowadays.

Senator NELSON. Of the 700 affiliated hospitals, that is, those of the NCME, do you have some regular program development with all of them, or is it sporadic, or was it regularly with some and irregularly with others?

Mr. RAEBEN. Yes; it is actually not done by institution basis. It is done by subject or scientist basis.

Senator NELSON. Now, when one of these programs is developed, is there drug advertising in each of the programs then?

Mr. RAEBEN. Well, yes; there is. Again, I think if I might cover it in the statement itself.

Senator NELSON. All right; go ahead.

Mr. RAEBEN. Thank you.

I guess I might close this particular sequence to which you have addressed questions with a comment that programs produced totally by a medical center still are occasionally distributed on NCME. I think in the past year, for example, Ohio State University produced some programs and just simply made them available to us for national distribution.

We distribute each year 69 different program subjects, and they are assembled onto 23 1-hour reels; that is, 3 subjects on a reel.

Senator NELSON. Twenty-three 1-hour reels?

Mr. RAEBEN. Twenty-three 1-hour reels in the year. Basically, it is a biweekly service, except in the summertime when it is every month.

Senator NELSON. These reels have advertising on them?

Mr. RAEBEN. They do, and I do intend to describe that in a moment unless you prefer to ask questions about it right now.

Senator NELSON. Go ahead.

Mr. RAEBEN. Thank you.

I would like to have entered in the record if it is possible the catalog of our programs and their participants that have been recorded over the years. The subjects themselves in a sense, you might say, testify to the direction of the network.

Senator NELSON. We will receive it and have the staff examine it to see whether it is appropriate for printing in the hearing record. Otherwise, it will go into the files. We would be glad to look it over.[1]

Mr. RAEBEN. Thank you.

[1] See Programs Catalog of the Network for Continuing Medical Education, page 14259.

The program subjects themselves and their content are determined in the following way. First of all, we have a national board of physicians concerned with education. They include such persons as Lowell Coggeshall, who was formerly vice president at the University of Chicago and, as it happens, the Nation's first Assistant Secretary for Medical Affairs at Health, Education, and Welfare; George Aagaard, who, I think was the Nation's first dean of continuing medical education, who is now a professor at Washington University School of Medicine; Edmund Pellegrino, chairman of the board, Yale-New Haven Medical Center. I have a complete list which I have provided in the appendix to this statement.

This board provides overall direction to the network. For example, at the board's meeting later this May, it will discuss steps NCME must take to meet the accreditation requirements of various accrediting bodies.

Another group, the Medical Advisory Committee, is made up of physicians. I have listed all of their names in the appendix to my statement as well. They meet regularly to select the specific program subjects and often to suggest participants for them. The participant himself then determines the specific content of his program, although NCME staff guide him on ways to make the programs more visual. The staff also sometimes recommends for or against programs based on their suitability for television. The sponsor does not ask us, and we do not volunteer, to produce particular programs or to treat programs in any particular way. As with any publisher or broadcaster, our goal is to provide subjects likely to be of interest and value to large audiences, because if they are not, doctors will not watch, hospitals will not subscribe and our sponsor will cease his own support. If one were to view these programs he would find that the majority of them do not deal with drugs, and that when they do, it may be as much against as for their greater use.

Product messages appear preceding each program on the reel. The schedule of product messages is prepared months in advance by the sponsor without knowledge of the programs they are to accompany. However, when the reel is assembled, our staff takes care to avoid even the accidental juxtaposing of product messages with programs dealing with the same clinical subject. No study has ever been done to determine the extent to which product messages on NCME affect drug prescribing practices. And, of course, no studies have been done on the influence of the programs themselves on drug prescribing. Few of these programs, if any, would lend themselves to such studying in any event.

Mr. GORDON. May I interject a question at this point?

Is it reasonable to assume that drug firms would be spending their money if it did not affect in some way their drug sales? Maybe you do not have a study, but I am just wondering if the drug firms who advertise have studies to indicate to them whether they are spending their money wisely.

Mr. RAEBEN. Well, I know that drug firms regularly do study media in many ways. I would say that we have probably, at least in what we do, have not been carefully studied because of the clear nondirect relevance between the advertising they can do in our media

and what they might be seeking to measure. For example, input on sales. I just think we do not lend ourselves to such a study.

Mr. GORDON. But if, as you say, the drug companies do studies—and I am sure they do these studies—and they keep on spending the money, is it not reasonable to assume that it does have a favorable effect on their sales, or at least that is their decision?

Mr. RAEBEN. Well, I cannot say.

Mr. GORDON. We all agree that they must think it does them some good. Is that right?

Mr. RAEBEN. I certainly think that would be the way I would put it. Thank you.

I suppose it would be nice for us in some ways if we could show a more direct connection perhaps on their fortunes to their support of the things we do.

Senator NELSON. Well, I assume your next sentence tends to answer that. You say "Surveys are done to determine if physicians watch our programs and find them useful." If those surveys indicate a positive response, obviously, the doctor watches the program and thinks the program is useful, then the advertiser can assume that if his advertising is any good it also helps his product. I assume that is the case.

Mr. RAEBEN. I think he makes just that assumption.

Senator NELSON. Who does the surveys, Mr. Raeben, to ascertain if the physicians watch the programs? Are they done at the convention or are these the ones at the hospital?

Mr. RAEBEN. These are the ones at the hospital. And we do quite a bit of surveying ourselves. It is very important for us to know, both with respect to individual programs as well as annually, what the viewership is. And I know that the advertiser—the sponsor—surveys it directly to find out as well as he can what the tendency is.

Senator NELSON. Well, of the 700 NCME hospital affiliates—as I recall, you stated that those programs are available to 145,000 physicians, which included interns—do you collect any statistics from the affiliated hospitals as to how many times these programs were run and how many viewers saw them? Do you have those statistics?

Mr. RAEBEN. Yes; we do collect such information. I have to say that—and this is probably another common phenomenon—information provided to one by hospitals that receive our programs probably is biased in an optimistic direction. They tend to say everybody watches them a whole lot. And we have to go behind that level of surveying, and literally call a sample of physicians on the telephone and ask them what their own experience has been. And it is I think that data that is somewhat more trusted by us in determining the accuracy of that answer.

Senator NELSON. And you do make those kinds of surveys. Is that correct?

Mr. RAEBEN. We do and the sponsor does as well.

Mr. GORDON. Mr. Raeben, you say that your Medical Advisory Committee meets regularly to select specific program subjects and often to suggest participants for them. Who has the responsibility for selecting the participants?

Mr. RAEBEN. Well, I suppose you would ultimately have to say that our own staff does. What the Medical Advisory Committee will

do in identifying a program subject at normally the meeting, say, held at our offices, they will then say Dr. Jones is very good in this field, and if you cannot get Jones get Smith. And then our staff will be in touch with, let us say, the recommended physicians. If it turned out that neither of them was available to appear in the program, they might look for an alternative. If they found an alternative physician, they would then go back informally to the Medical Advisory Committee, in this case, by telephone, and say we have found Dr. Brown, Jones and Smith being unavailable. What do you think of him? And if the committee says, oh, he is a splendid man, so we would proceed with him.

Mr. GORDON. I see. The committee merely gives suggestions and recommendations, but your staff makes the final decision as to what programs will be shown, who participates, and so on. Is that correct?

Mr. RAEBEN. I do not think I would say it that way, particularly as the subjects, first of all, are pretty much determined by the advisory committee. They pick the subjects, not we. The only area in which we exert discretion—I guess there are two—if the physicians that they recommend are unavailable or if they are unavailable to appear on the day scheduled, then we have to find a physician, and, by phone or correspondence say here is someone who has been identified to us as a good presentor. What do you think? And if the committee then endorses him, we proceed with him.

Mr. GORDON. Do you or your staff exercise any editorial review?

Mr. RAEBEN. Only in respect to, you might say, the television verities. There are some subjects, which do not seem to do well on television, for which print, I would say, is a far better medium to present certain conceptual subjects which are hard to justify television for. Television is best for procedures or behavioral matters. In that sense then we might vote against doing a program, or maybe having developed a program, not go ahead and release it because it would just turn out to be boring.

Mr. GORDON. Well, let me ask a specific question.

Suppose that you had a program—or perhaps you would avoid it completely—which denigrates the product of a particular advertiser. Would you run it? And have you ever run such a program?

Mr. RAEBEN. Well, over the years there are denigrating statements in our programs about the products of many, many pharmaceutical companies, including those of Roche Laboratories, which has been the sponsor of NCME. I do not believe there has been, let us say, one program whose title would be, oh, I do not know, "What is Wrong With the Drug Industry," something of that sort. But there are many unfavorable comments made about the products of our own sponsors as well as others.

Mr. GORDON. Do you have any specific examples?

Mr. RAEBEN. Well, I did not bring any. I would be very pleased to assemble I think probably a very, very long list of such for you subsequent to today.

Mr. GORDON. Did you ever have any programs on diabetes, for example?

Mr. RAEBEN. Oh, we have had a number of programs on diabetes.

Mr. GORDON. Did you ever have a review of the UGDP study; that is, what it found, and any of the confirmatory studies which

show that there is a higher rate of mortality in those who use the oral hypoglycemic drugs as against those who do not use them?

Mr. RAEBEN. I cannot answer that from memory. It is just possible that I will discover that in the catalog. Now, I am afraid, however, I may be under pressures of time and I might not.

Mr. GORDON. How about the dangers of chloramphenicol, and clindamycin and lincomycin? Have you ever had programs like that?

Mr. RAEBEN. Yes; we have had many such programs. And I do think I deleted because it seemed melodramatic as I reread it to myself this morning, the statement that these programs are our silent witnesses here. There were many programs or portions of programs which do indeed point out hazards of drugs in ways that perhaps would not make some members of industry happy. The physician is not told what to say or what not to say at all, and presumably he expresses his own best judgment.

I do think that in assessing the dispassionateness on those issues of these programs, the best witness is the program. And if you would like I would be pleased to assemble examples for you where you are welcome to select at random from the catalog and your staff can examine them.

Mr. GORDON. Could you submit those for the record?

Mr. RAEBEN. I would be very pleased to.[1]

Mr. GORDON. Well, let me ask you this: Do you know of any relationship between the members of your national board, your Medical Advisory Committee, and the drug industry? In other words, have they ever been consultants, investigators, officers or any way connected with the industry?

Mr. RAEBEN. Well, I think Dr. Coggeshall was on the board of directors at Abbott Laboratories at one time. I guess that is the only relationship I know of. I cannot speak from my own knowledge beyond that.

Mr. GORDON. Well, we asked the Food and Drug Administration if they had any record of the people that you have on the board of consultants and the Medical Advisory Committee, and they said that their records show that 9 of the 19 are connected in some way with the pharmaceutical industry. About the rest we do not know. They may be or they may not be. But we know of at least nine.

Mr. RAEBEN. Excuse me. Are those nine connections of the sort that would cause you to call in to question their probity?

Mr. GORDON. Well, they are investigators for the industry. They have some connection. Of course, as you stated, Dr. Coggeshall was a director of the Abbott Laboratories. What that means, I do not know, but it is an interesting fact, nevertheless.

Go ahead. You were on page 5.

Mr. RAEBEN. I guess I was going to say that we have worked with Government organizations at some length. We have rendered assistance to the National Library of Medicine. We have disseminated information to physicians at the request of the National Center for Disease Control, and for many years we have supplied programs without cost to VA and other Government hospitals and institutions.

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[1] See letter dated July 9, 1976, to Senator Nelson, from Jay E. Raeben, president, Visual Information Systems, page 14400.

Another project in which we are active is called AVENS, audiovisual education in neurosurgery. That is a video cassette, monograph, and slide service, what is popularly termed a multimedia system. Subjects and their presenters are chosen by the Society of Neurological Surgeons which began the project with the support of a grant from the John and Mary R. Markle Foundation. The programs are sold to neurosurgical training centers and to individual neurosurgeons. But as the number of subscribers is small—about 125 have bought the first series of 10 programs—the project is far from self-sustaining. Because the distribution and production apparatus constructed for NCME is available to us, we can continue AVENS at our own expense and we are doing so. Some of the programs are said to be among the better teaching of any sort ever done in neurosurgery. Without foundation support, however, AVENS could not have been begun and without our own assistance, I am not sure it could continue.

Senator NELSON. How does AVENS, audiovisual education in neurosurgery, fit in with your NCME program? Are they related? How does that work?

Mr. RAEBEN. Well, there is an overlay of some staff and technical facilities. Were it not for that overlay, I think the point I was making was that AVENS probably could not exist. It is independent of it in every other sense. And, of course, there is no pharmaceutical company involved in AVENS.

Senator NELSON. What you are saying, then, is that there is no funding directly for this specific project by pharmaceutical companies.

Mr. RAEBEN. That is correct.

Senator NELSON. Go ahead.

Mr. RAEBEN. The next project we are engaged in is the American Academy of Ophthalmology and Otolaryngology which was established in 1971 as continuing education in video cassette form. We act as the academy's video publisher. Production moneys have been provided by the academy. Program subjects and presenters are selected by the academy, and the majority of programs are produced by the presenter, often with university television facilities. The programs are sold to ophthalmologists and otolaryngologists. About 200 subscriptions have been sold to each group. The cost to duplicate, market, and distribute these programs is borne by VIS. The service will require a very substantial increase in sales to be self-sustaining. As with AVENS, we are pleased to be associated with the project because, in the long run, it should enhance our position as a publisher of good medical education in television form. As with AVENS, however, it raises the question, can such education exist at present, and in these forms, without subsidization?

Physicians Radio Network, or PRN, is our most recent service. It is a 24-hour-a-day, 7-day-a-week medical news, information and education service for physicians. It is transmitted over special FM frequencies. It requires a special receiver provided by us without charge to the doctor.

Senator NELSON. Does Physicians Radio Network then have an FM channel of its own?

Mr. RAEBEN. No; we lease what I refer to as SCA's or sidebands of FM stations in different cities and transmit from our offices by wire the same way that, let us say CBS or NBC transmits really, to the transmitter of the individual station which is the FCC licensee which holds those frequencies.

Senator NELSON. The Physicians Radio Network does not have any stations of its own.

Mr. RAEBEN. That is correct.

Senator NELSON. You lease a band from an established licensed radio station. Is that it?

Mr. RAEBEN. Yes. That is correct.

Senator NELSON. And then you broadcast your programs through the station from which you had leased a band and they run it. Is that correct?

Mr. RAEBEN. No.

Senator NELSON. Well, how does it work?

Mr. RAEBEN. We broadcast from our offices to the individual cities where the stations are. The signal then goes out into the air just as a radio signal normally does.

Senator NELSON. That is what I thought I was saying.

Mr. RAEBEN. Oh, I am sorry.

Senator NELSON. You send it to this station from which you leased a band on FM, do you not?

Mr. RAEBEN. Yes.

Senator NELSON. And then they broadcast it on that band. Is that correct?

Mr. RAEBEN. Yes.

Senator NELSON. They are transmitted from your headquarters or office. Is that correct?

Mr. RAEBEN. Exactly, yes.

Senator NELSON. Then it goes to this special receiver which the physicians will have.

Mr. RAEBEN. That is correct.

Senator NELSON. I see.

Mr. RAEBEN. I am sorry. When you used the word "company," for a moment I thought you were referring to pharmaceutical companies. I was confused.

Senator NELSON. No, I did not intend that.

Go ahead.

Mr. RAEBEN. We began research on the technical feasibility of PRN in 1965.

Over a period of several years I tried unsuccessfully to interest both the Federal health establishment and major medical associations either in supporting this project, or in joining me in a common search for support.

In April 1974, broadcasting was started in two cities to test whether physicians would listen and whether they might pay for the service. We learned that a physician-subscription approach was impractical. However, listenership was quite high and it encouraged us to go to industry for support. We offered PRN both as a new advertising medium and one with high prospective social utility. Today, five companies advertise on PRN. They are: CIBA Pharmaceutical Co., Merck Sharp & Dohme, Pfizer Laboratories Division,

Roche Laboratories, Smith Kline & French Laboratories and S.K. & F. Co. We hope to have more sponsors in time.

There are eight 1-minute advertising messages in each hour. These fall in a strict rotation planned weeks ahead, clearly with no knowledge of the news items they will eventually be adjacent to. The service now broadcasts in 23 cities to about 21,000 physicians. By yearend we should be on-the-air in 30 cities, reaching 75,000 physicians. Our longer-term goal is about 150,000 physicians, half the Nation's doctor population but far more than half of those active in patient care.

At present, PRN programing is a single hour, repeated 24 times and changed each day. In each city, local medical news is also broadcast every hour, generally with the cooperation of the local medical society. This summer we expect to begin updating the programing twice each day and we can broadcast an important bulletin any time. Although PRN has been primarily a news service, we are now beginning a continuing education series as well. This is a program, 15 minutes or so long, and repeated 20 to 30 times in the week. It is accompanied by printed self-assessment forms mailed to the physician. If our audience finds this programing useful, we think it should be a regular part of the radio service.

Senator NELSON. May I interrupt there? Two or three sentences above you say, "At present, PRN programing is a single hour, repeated 24 times and changed each day." And you say that you are "beginning a continuing education series," which would be 15 minutes or so long and repeated 20 to 30 times in the week.

What is the 1-hour program that you have now that is repeated 24 times a day?

Mr. RAEBEN. It is essentially news, 1-, 2- or 3-minute long segments. If there was a medical meeting going on someplace this week, reporters might have interviewed a physician at the meeting to get a statement from him. If there was something that happened in Washington that might affect the practice of medicine, that sort of thing.

Senator NELSON. So it is a 1-hour program each day run 24 times?

Mr. RAEBEN. Yes. It is just run continuously.

Senator NELSON. And that is just news on medical events of some kind or another. Is that it?

Mr. RAEBEN. Yes, that is correct.

Senator NELSON. And now you have started an education program of 15 minutes?

Mr. RAEBEN. We are going to try to take portions of this great amount of time, this 24 hours in the day, and see if we cannot provide materials that can have additional benefits to the audience. So a sort of an obvious thing is to take longer periods rather than the 2 or 3 minutes devoted to news and try to teach something.

Senator NELSON. What is the current cost of putting on these programs and what is the project cost when you initiate it? How large an audience do you expect to have—around 175,000?

Mr. RAEBEN. Perhaps 150,000 physicians if we are successful.

Senator NELSON. What is the current cost now to the drug companies for sponsoring these programs?

Mr. RAEBEN. The drug companies'—depending upon the size of their advertising commitment—cost ranges from about $200,000 for a year up to perhaps $700,000 for the year. This is a function of the amount of advertising time they have purchased.

Senator NELSON. What is the total cost for all the companies?

Mr. RAEBEN. Well, this is a fluctuating number as we hope to be acquiring additional advertisers.

Senator NELSON. I was wondering, what is the current annual cost of the program, not to the advertiser, but the total cost?

Mr. RAEBEN. Well, the cost is at this point substantially in excess of our revenues since we are in the building stage. This is really an investment activity of our corporation and it is substantially in excess of what we can recover from advertisers. I think it will be some time before advertising has caught up to our own expenses.

Senator NELSON. I am interested in the total costs, if you have it at hand. Receipts from advertising don't cover all your costs. You have your own costs, which are higher than that, because you are making some capital investments. Is that it?

Mr. RAEBEN. Yes.

Senator NELSON. Well, then what is the total advertising budget thus far on an annualized basis?

Mr. RAEBEN. Well, at the moment I suppose our advertising revenues might be running at the rate of $2 million for the year. It is a difficult calculation for me to do at this moment. And as I say, we hope that for any given period—say, the calendar year—it will be a different number.

Senator NELSON. All right. Go ahead.

Mr. RAEBEN. If practicable, we intend to offer blocks of time for teaching purposes to the general and special medical associations which presently have the training and education responsibility for their constituencies.

It seems surprising to us that until PRN, medicine had no medium to transmit important information quickly. If regional or national health crises threatened, there was no way, except in sometimes inappropriate public media, for medicine to communicate about it. Setting aside the matter of emergencies, if a scientific advance of any importance takes place, many months normally elapse from authorship to publication. Many more months elapse before confirmation or rebuttal by others. Our hope is that by accelerating this process, by telescoping into a few months, or even weeks, a dialog that now may take years, PRN can have a genuine impact on medical progress not achievable in any other way.

PRN news is reported by medical correspondents throughout the United States and by a permanent office staff of experienced medical journalists. Decisions on which 25 or 30 stories make up the daily broadcast are made solely by the editorial staff. Advertisers play no part. We have made a considerable effort to determine how much physicians listen to PRN and I believe we have excellent information on this, better perhaps than that possessed by many other media used for medical communication or education. We assume also that sponsors will ultimately try to employ advertising measurement techniques on PRN messages.

We do feel it is certainly important to protect education from undue bias. And it is always reasonable to fear that he who pays the

piper may call the tune. That, however, has not been our experience and I hope that my presentation bears this out.

Thank you.

If I might add a comment to my presentation.

Senator NELSON. Yes.

Mr. RAEBEN. It has been difficult to think while speaking, but I have been reflecting briefly over Mr. Gordon's observation that nine of our medical advisors appear to have or have had some relationships to the pharmaceutical industry. Two thoughts come to mind. One is there may be a very considerable difference between having a relationship to an industry and being in some sense controlled by or responsive to it. Again, it is certainly well to look into it. But I think in respect to people we know on the board we have worked with, it would be astonishing for me to discover that they were indeed especially compliant to industry and I think that should not be left as an inference for anyone to draw from that earlier statement.

The other observation is that the board has been assembled by us normally one educator identifying another, saying Dr. Smith is very active in the American Academy of Family Practice and is very interested in continuing medical education. And then we would go see him and ask him if he would be willing to serve. If it turns out that at some time in his career he had done some clinical investigation or something of this sort for a pharmaceutical firm, we have never done the research that the FDA apparently has been diligent enough to do so we would not know that. And I have to say, and again I think our programs bear this out, there would appear to us to be no industry bias in the programing content, and I do think they are the witnesses that the subcommittee should examine with respect to that point.

Senator NELSON. Thank you very much, Mr. Raeben, for taking time to appear this morning.

Mr. RAEBEN. Thank you for having me.

Senator NELSON. We appreciate it.

Our next witness is Dr. Henry Simmons, senior vice president, J. Walter Thompson Co., formerly Director of the Bureau of Drugs in the Food and Drug Administration.

Dr. Simmons, the committee is very pleased to have you take the time to appear this morning and give us your views. We appreciate it.

STATEMENT OF HENRY E. SIMMONS, M.D., M.P.H., SENIOR VICE PRESIDENT, J. WALTER THOMPSON CO., NEW YORK, N.Y.

Dr. SIMMONS. Thank you, Mr. Chairman.

Likewise, I appreciate your invitation to testify today, the subject being the transfer of medical information, or technology transfer, how to bring about appropriate behavior changes in the use of drugs by the public and health professionals, but most specifically, how the tool of social marketing can help bring about necessary improvements in these areas.

We are all aware of the serious problems which today face the health care system. Those include rising costs, quality of care, lack of standards for care, problems in compliance with therapeutic regimens and problems on information and technology transfer. And for the purposes of this discussion, I will consider any useful new medical

information as synonymous with technology which must be transferred from its point of origin to those who need it—in other words, to health professionals and consumers—to enable them to make rational decisions and ultimately to maximally enhance or preserve the health of the public.

Many of our problems in the health care system are due to deficiencies in information transfer or deficiencies in efficient and effective technology transfer. And there is a wide and probably widening gap between what we know should be done and what is done or practiced in this Nation's medical care system. Problems here exist in the premature introduction of inadequately tested technology, the failure to eliminate outmoded technology promptly and the failure to rapidly adopt new technology which has been established as beneficial. Examples of the latter include the inadequate use of drugs available for the treatment of hypertension and immunization against the common childhood diseases. We have all witnessed with dismay the spectacle of important new scientific information falling on deaf ears, or, worse, remaining unspoken at all. Time and time again, the objective of research, which is benefit to the consumer public, has been frustrated as the communications abort.

Mr. GORDON. Dr. Simmons, where are you reading from?

Dr. SIMMONS. I am on page 2 of my statement.

Mr. GORDON. All right.

Dr. SIMMONS. The disparity between our operant knowledge of communications and its application is crippling and, finally, intolerable. Mr. Chairman, you are well aware of the frustrations of the Congress as it surveyed HEW's efforts in technology transfer.

And that is why I ventured into the world of communications, to see if there were elements we have been overlooking in our efforts to implement the health information we possess. And the answer to that inquiry is resoundingly positive. A brief overview of the technology process of biomedical research communications point them up.

There seem to be two factors which necessitate taking a fresh look at how effectively biomedical communication or technology transfer are conducted. One is the fact of the sheer volume of information now being generated, many thousands of discrete items per year, and the other is the fact that many of these findings now require the active cooperation, oftentimes necessitating a reversal of long-term practice, attitudes and behavior, not only of health professionals but of the public at large in order to become beneficial. A pair of communications tasks are then manifest: Sensitive priorities and persuasive messages. The two tasks are inextricably intertwined at each of three stages of communication between: (1) Scientist and scientist; (2) between scientist and practitioner; and (3) between scientist/practitioner and the public. Communications between scientist and scientist are the most effectively managed at present, and a communications expert would probably attribute that to the following factors:

(*a*) Biomedical scientists are a relatively homogenous population conditioned by a well-understood set of procedures and underlying principles of investigation;

(*b*) Scientists communicate with considerable precision through the use of an assiduously defined and a carefully used set of language and symbols;

(*c*) The scientific community is largely premotivated to understand and implement accurately what new information is communicated to them, as the price of neglect to do so is eventual if not immediate failure at one's life work, given the high degree of peer review and testing operative in science; to discover error is to further one's success, in pure terms;

(*d*) The channels of communication—primarily scientific journals, seminars, and working papers—are relatively few in number and are attended by virtually all scientists active in a given field; additionally, they have ready access to supplementary data through efficient storage and retrieval systems now in place;

(*e*) The context of communications' reception is businesslike and absent of significant diversionary messages or efforts to persuade opposite conclusions for nonscientific reasons.

Although some of the assumptions above may be subject to thoughtful evaluation in the field, requiring some modification, they are probably reasonable, for our purposes. Taking the same categories, however, and applying them to subsequent stages of communication en route to the goal of consumer-benefit, it quickly becomes clear why the process breaks down.

Between scientist and practitioner, the factors are different:

(*a*) Practitioners' diversity is encouraged by such forces as the development of medical specialities, the emergence of para- and subprofessionals, and the flourishing of competing attitudes and philosophies of treatment, oftentimes influenced by such idiosyncratic elements as practitioners' personality;

(*b*) The motives of practitioners are highly diversified, ranging from the totally altruistic to the totally materialistic, and the responsiveness of practitioners to new information is not as subject to the rigorous process of peer review and interdependence which characterizes the scientist-to-scientist communication; nor is the controverting of previously held data taken as sheer advance of knowledge: The authoritative contradiction of current practices may be thought—by both the practitioner and his client—to reflect unfavorably on the practitioner;

(*c*) Channels of communication drawn upon by the practitioner include not only professional literature from sanctioned scientific sources but also professional polemics, pharmaceutical and other medical industry information or rebuttals, Federal and other regulatory documents, continuing education materials of uncertain consistency, and popular media; and

(*d*) The context of reception of communication is awash with diverting and/or competing messages.

Now as complex as the factors in the scientist-to-practitioner stage appear, they all but pale when compared with efforts to communicate with the public whose informed cooperation is increasingly the sine qua non of translating scientific advance into personal health benefit. And here we have to contend with awesome obstacles:

(*a*) The diversity of the public is patent, manifested in literally dozens of subgroups segmentable by demographics, and medically relevant predispositional factors.

(*b*) And far from sharing a finely honed operational language constantly redefined in function, the various publics rely on figurative and connotative—and even nonverbal—communications for the

most part; and these, of course, are subject to a nearly infinite range of local and regional expressions and interpretations;

(*c*) Whereas the motives of the scientist to heed new knowledge are relatively clear-cut and positive, the motives of the individuals in the public are thoroughly contaminated with inhibiting forces, ranging from fear of discovering disease or risk, to unconscious perpetuation of self-defeating behaviors, to lifestyle habits; and the example of their peers tends, by and large, to support a willful resistance;

(*d*) The channels of communication used by the public are legion, including every imaginable medium of mass communication, local health professionals, family and friends;

(*e*) And, finally, the context into which health communications come, is cluttered with stimuli to an unimaginable extent; it is estimated that in a given day, the average person is subject to more than 5,000 separate communications seeking to promote some response; no small number of these seek to reinforce the behaviors which may be inimical to health, and others reinforce misinformation and confusion.

Now, in addition to recognition of the awesome obstacles to communication mentioned above, a communicator must be aware of certain principles of effective communication. They are:

One: The first of these principles is to assume noncompliance from your audience. In the case of physicians, we know that they are bombarded with literally thousands of messages in the course of a month which deal with technical drug information, new drug introductions, new research findings on existing drugs, new FDA regulations, and so forth. We should assume that these physicians will not necessarily do what the messages ask them to do or even listen to the messages.

Two: A mistake is commonly made in communications to assume that information is enough to produce behavioral change. Now, if information were enough, very few people in this country would still be smoking. On the side of every pack of cigarettes sold in this country there is a warning from the Surgeon General stating that cigarette smoking is harmful to health. We can assume that every smoker has been informed. Many, however, have not yet been persuaded.

Three: It is unwise to assume that a need is recognized by the intended consumer of a product or program. As an example, personal hygiene is a self-evident need from the point of view of health departments everywhere, yet in country after country that need has had to be explained, or, if you will, sold. And very few farmers recognized that they needed a tractor the first time they saw one.

Four: Do not take relevance for granted. It is possible to perceive a need without understanding its applicability to you. It is possible to listen to a message and yet not hear it because the language is that of another age group, another social class, another ethnic group.

Five: The mass market is a fiction. Our population is made up of an accumulation of special markets with special attitudes and interests. Communications must be designed with a precise knowledge of the group or groups to which they are addressed.

Six: Repetition is necessary both for widespread awareness and for the maintenance of that awareness.

Seven: Conflict of information exists in most significant communications areas. It must be allowed for and dealt with.

Eight: In all areas there are barriers to persuasion. In the health care area these are frequently profoundly emotional and must be clearly understood before communications are undertaken; and

Nine: The relationship between stimulus and response must be clearly understood. A message is a stimulus, the receiver's reaction to that message is the response. Professional communications start by identifying the response that is desired from the target audience before developing the message. The desired response should dictate the message, not vice versa.

It is very dangerous to assume that your audience will receive your idea exactly as written. They will color it; they will change it; they will interpret it. In short, by making it their own, they can also make it different from what you intended.

Mr. GORDON. Dr. Simmons, may I interrupt you for a second?

At one time you were the Director of the FDA's Bureau of Drugs, and you had a lot to do with professional review organizations, too, the PRO's. During that time studies have shown that certain drugs have been misused and overused, and the FDA and its expert advisory committees have tried to change the prescribing habits of the medical profession.

What methods were and are being used by the FDA to try to accomplish this end?

Dr. SIMMONS. Mr. Gordon, it is difficult for me to answer that because, remember, I have been away from FDA for 3 years, and it would really be unfair for me to answer that question. I think that is more appropriately posed to the Bureau Director or somebody else. I assume they are at least using what we used at the time. I am not clear enough on what has been added to that armamentarium since that time. At that time, as you remember, we had warnings, regulations, drug bulletins, and sometimes press conferences, those traditional kinds of things. How much that has been buttressed since that time I do not know.

Mr. GORDON. All right.

I think it is about the same at this time, the FDA bulletins, Dear Doctor letters, FDA consumer messages.

Is it your opinion, then, that the methods now being used are inadequate and do not achieve the desired results?

Dr. SIMMONS. Well, I think you would have to answer the point question by question, frankly. In some areas, clearly, the information does get over; in some areas it does not get over. The drug industry has the same problem, you know, in getting the profession to understand the need to treat hypertension. Both Government and the pharmaceutical industry have been trying very hard to get across a very important and worthwhile message and it is a terribly difficult kind of a thing. So in that area, I would say both Government and the pharmaceutical industry have been less successful than would be warranted in the public interest. In others, you know, I think, as I said, case by case it would be easier for me to answer that.

So in the marketing of goods and services, which for 106 years has been the daily business of the J. Walter Thompson Co., they have developed a plan for the production of communications which help solve a client's marketing problem. This is called the "T" plan and consists of five steps.

The "T" plan process contains no magic. It is simply organized commonsense, a method designed to help arrive at an accurate fact base and to help avoid operating under false assumptions. It involves the posing and answering of five very basic questions, questions designed to focus and concentrate thinking where it will be most productive. And though I will list these questions in a certain order during the development process, as the environment changes or new information becomes available, we will backtrack, reasking and reanswering certain questions. It is, in short, a fluid process that we can never assume is finished. And even when success is achieved, continual pressure must be used to maintain that degree of success.

In attempting to motivate people, in making a deliberate attempt to influence change and not just passively react to events, we need the best planning possible. In answering the following questions, we make important strides toward that end. Those questions are:

Where are we and why are we there?

Where do we want to be?

How do we get there?

Are we getting there?

And should we change direction?

In the application to social problems of the principles I have described, coupled with the asking and answering of the questions I have just posed, is what we describe as "social marketing." Social marketing is defined as the design, implementation, and control of programs, calculated to influence the acceptability of social ideas. It involves considerations of program or product planning, pricing, communication or education, distribution, and marketing research. And these marketing techniques serve as the bridging mechanisms between the simple possession of medical or health knowledge and the socially useful implementation of what such knowledge allows. So that in the hands of its best practitioners, "social marketing" is applied behavioral science.

I would now like to describe how the technique of social marketing would be applied to solve a major current medical problem involving a type of drug use, and the case in point is the necessity to immunize almost 200 million Americans against swine influenza before a new flu season begins this fall. A related and also urgent problem is the need to raise the present dangerously low immunization levels of many American children to the recommended levels for the common childhood diseases. Now without use of these social marketing techniques it is unlikely that success in either area will be achieved since both problems are much more complex than they would appear to be at first glance, and both will require wide public understanding, acceptance, and support if we are to succeed.

So the first question posed in such a program would be where are we and why are we there? And we find that posing the question in this problem seems simple, but the intelligent answering of the question will probably require the employment of a number of dif-

ferent research techniques. We must know what consumers' attitudes are toward immunization in general and toward the swine vaccine in particular. Does the very name "Swine Influenza" create confusion? In other words, someone asking, since I have not been near a pig in the last year, am I safe? What do doctors think of this immunization effort? Do they agree with the position taken by authorities? And certainly not all agree. And the press in recent weeks has given a great deal of attention to doctors of opposing views who maintain that immunization itself poses a greater risk than the imagined epidemic it wants to alleviate. Will newspapers and journalists considerably hamper this effort or are they doing so now? And those are but a few of the points that must be clarified.

The second question we must ask is one that sets the goal we are attempting to achieve, "Where do we want to be?" And, again, we should attempt to answer this in the most detailed manner possible. Not only do we wish to have immunization of all Americans by later this year, but we would like to have immunization of high-risk individuals first. In short, a complete timetable must be developed for different audience segments, identifying high-risk groups and areas as well as a host of other factors.

The third question takes us from the area of planning and into the harsh reality of execution. Question No. 3 is "How do we get there?" And I will not go through a detailed listing of all the strategies that are involved in the process, but I would like to mention a few.

First: In the area of audiences and audience segmentation, we would begin by specifically identifying our target audience, their geographic and demographic characteristics; in short their profiles and what groups they would logically fall into. And having identified our audience, we would define through market research those specific appeals most effective at eliciting the desired response from each segment. For instance, it may be found that the suburban housewife should be the primary target for our communications in Midwest areas where the median income is $20,000 and above; and it might be determined that the appeal most effective with her would be love of family or the desire to be a "good mother." It may, however, be found that in other income areas of the city that the father should be the target, and perhaps the most effective appeal with him would be pride in being a good protector.

In short, we must develop the most appropriate fact base and make the most effective appeals to the proper audiences, and we must rigorously resist operating under false assumptions.

We would also identify the actual materials and messages, and the actual public relations strategies and approaches that would be needed.

Mr. GORDON. Dr. Simmons, may I interrupt you for a second?

Dr. SIMMONS. Yes.

Mr. GORDON. Are these the principles that drug companies use to construct the programs to sell drugs?

Dr. SIMMONS. I do not know if they use all of them, Mr. Gordon. I would imagine that they use some of them. And I think that the technique you would use would depend on what particular thing you are trying to accomplish. And I am trying to describe for you

the most complex kind of a social change involving a drug use that we have on our doorstep right now, to point out to you that it is much more difficult than most laymen realize, and that is what I am trying to get across in this whole piece of testimony, that simple solutions are probably not going to work. And maybe at the end of this testimony some other questions might be helpful to clarify.

Mr. GORDON. Well, many of these principles are used, though, in constructing a campaign to sell drugs or a particular drug. Is that not correct?

Dr. SIMMONS. Some of them are, yes.

Mr. GORDON. Now, since the doctor's character, personality, social status, and so on, has been analyzed before he is even approached, how can he resist the sales campaign when it comes? It is rather difficult, is it not?

Dr. SIMMONS. Well, I am not sure how difficult it is. I think it would be the same way as you and I as human beings resist many of the thousands of messages we get every day. We all filter them. We all believe certain sources of information and automatically reject others. I am not sure that automatically because a message comes, somebody immediately collapses, and succumbs, and agrees. That is not an easy job to do. And, again, I think it would depend on who you are trying to reach. Some people are much easier to convince than others, and physicians being the same way. And one of the purposes of your research is to see what the background is, what the biases are, what the barriers are, in the whole variety of audiences that you must reach with what you consider a useful message. So there is no one answer to that. Some will be easy to reach, others will be difficult to reach. You have got to identify that before you can be successful in accomplishing your goal.

I will not go through then the number of things you might have to prepare for the campaign, but as you can see, it is a fairly impressive list of things that would have to be produced. And all of those materials that are outlined there in the upper part of page 13 have to be developed in various language versions for there are many in our society today who are illiterate or non-English speaking.

Having segmented the audience, identified the appeal, developed the creative materials, the next step is media placement; and in this step, as in all other steps, you must have planning which includes stated objectives, strategy to meet those objectives, an agreed upon timetable, and also a method of evaluation to find out if, in fact, you have met your objectives, and if not, how you can make adjustments in the overall plan.

In the area of media it is imperative that reach—defined as the percentage of each audience segment you wish to appear before—and frequency—or the number of appearances—targets be developed for all audiences, developed on a week-by-week plan, and that in the influenza campaign specifically, build toward a peak before October 1976, which might be your target date.

Another crucial factor is manpower. We might broadly subdivide this into three different areas, and those, of course, can be subdivided again and again. For purposes of this discussion, let us concentrate

broadly on volunteer organizations, professional organizations and business organizations.

Certainly the core of the effort in the influenza area will be the professional organizations, and we must secure the active assistance of such groups as the medical profession, nurses, and others outlined in that paragraph. In the area of implementation, certainly a detailed plan must be made for each group dovetailing their actions with the other manpower groups.

A second group would be volunteer organizations, and there is a vast reservoir of organizational and creative talent, a reservoir whose efforts are vital to the success of this effort. And the campaign we would have to enlist, train and supply with localized market plans, community action plans, timetables and quotas.

I will skip now, Mr. Chairman, to page 15 because there is detail there that I do not believe we need to go into. But strategically we want to plan for the optimum use for the system of delivery and the manpower that we have available. We want control traffic flow. And certainly that program will be a failure if all children appeared on Monday, October 25 for immunizations. We must control the flow of traffic. We must plan for and attempt as far as possible to guarantee the orderly use of clinics, school locations, and others. And having established the system, we must also, through communications, create an awareness of the locations, times of operation, the fact of its convenience. And those are just the highlights of some of the actions required for a successful program. But having put a plan in motion, question four arises. In other words, "Are we getting there?"

And in far too many cases, programs are enacted at great expense and never evaluated. Only by answering this question do we have a sufficient fact base for future decisionmaking.

As it pertains to immunization, we must ascertain what our success ratios are with each of our target publics. Are we reaching the inner cities but not the suburbs? If so, why? Are we 20 percent more successful in the Midwest than on the east coast? If so, why? Are our late night television commercials or television shows on shows that have a sufficiently high rating?

And only when we have this kind of information can we make the decision called for in our final question; in other words, "Should we change direction?"

We must believe that no part of a strategy is sacrosanct, and if we have been thoroughly objective in our answering of question four, we will have set the stage for effective decisionmaking at this point. We might simply engage in finetuning, such as seeking increased commercial exposures to the 20 to 30 age groups or by eliminating mobile van immunizations as inefficient delivery tools. We might, however, have to rework our entire appeal or possibly scale down our objective.

Now, Mr. Chairman, I apologize for going into such detail, but I thought here is a social cog in front of us. It involves the use of drugs that is a worthy purpose, and I do it mainly to illustrate for this committee the difficulties of the communication process.

Social marketing is a tool in the bringing about a social change. And the approach I have just described for a successful immuniza-

tion effort might be equally for the successful transfer of any new information on drugs, the achievement of appropriate behavior change in the use of the drugs in question, or improvement in compliance with therapeutic regimens which is today such a serious problem. A case in point would be the implementation of the drug-use changes warranted by the results of the coronary drug project or indeed the implementation of any new beneficial or adverse drug information.

Some of these same social marketing techniques should be applied before major fundamental procedural changes are promulgated in the drug area, such as the requirement for patient package inserts for all prescription drugs. For unless this is required, neither society or policymakers will have any way of knowing whether a desirable end is achieved by a new policy.

In summary, I have attempted to describe for you the difficulties inherent in the communication process, and the techniques necessary to bring about successful technology, and appropriate behavior change on the part of health professionals and the public.

It is clear that we are not doing this job well today. And it is equally clear that information alone, or a seminar report, or a scientific article, or a study report, or a drug bulletin, or a press release, or a regulation, or a warning alone, are not enough. The technique of social marketing does not share Government's apparent confidence that the public or health professionals care to listen, and to act on what they hear. Rather, the practitioners of social marketing assume just the opposite, that both are bombarded with a surfeit of messages day and night, and they will resolutely ignore all but the most carefully crafted and persuasively conveyed communications which attract their attention.

It is high time for all of us concerned about the health care system to acknowledge the clear truth of that assumption. There are many illustrations of the bankruptcy of a passive communications policy.

Mr. GORDON. Dr. Simmons, what you are talking about is not just the transfer of technology, as I see it, but a method of changing beliefs and values, also.

Do you see any possible dangers if the Government uses these techniques to influence the public's attitudes and behavior?

Dr. SIMMONS. There is always a potential danger, Mr. Gordon, in these techniques in the hands of all who would use them. Clearly, that has to be recognized. And that has been recognized in instances where social marketing has been used before.

In our society, where it is obvious to many groups as to what goes on. I believe that you can bring about the necessary controls and necessary watching of this kind of a system by Government. The point I wish to make is that there are some important ends that society is trying to reach through the actions of its Government. Just about every major government in the world uses communication differently than we do. The Government itself does. They use it because they feel the societal ends to be gained are appropriate to use the communication channels that way. I believe there are instances here in our society where that same exists.

Mr. GORDON. How can we guard against abuses?

Dr. SIMMONS. Well, I think by the very openness of the process that we work through in our society. There is a press. There are critics. There is the ability to speak out, the opportunity to comment. There are divergent views that can be brought to anybody's message. I believe those are the safeguards in this system. Clearly, it is important.

Mr. GORDON. Is there any greater danger if the Government uses these techniques than if large corporations use them?

Dr. SIMMONS. Well I think there are advantages to both entities using these techniques. Clearly, a businessman who has a product to sell has to let somebody know about that product. As you know, that is not only small business but big business has to do that. The Government also has messages that have to be made known. So, clearly, it should have use of that technology also. But they are certainly both appropriate, both warranted.

Mr. GORDON. I have a rather interesting example here. It is an example where the techniques you advocate have been used in what, I am sure, you would regard as contrary to the public interest. Here is a release from the Pontotoc and Pottawatomie County Medical and Pharmaceutical Group. It is for immediate delivery and here it is.

Generic Drug Substitution supporters are few and far between now in Oklahoma's Pontotoc and Pottawatomie Counties.

Through the month of February, local physicians and pharmacists ran an extensive advertising campaign to see if they could affect public opinion about the question and generate enough tangible evidence of this opinion to defeat a substitution bill currently pending in the Oklahoma Senate.

Wheeler reported that the first survey showed that in Shawnee * * * that is in Pottowatomie County test city—

*** * * over 38 percent of those questioned had heard about generic substitution, and of these, 52 percent were for substitution, the majority of this group indicating that they thought substitution would "help the elderly and make drugs generally less expensive". The survey indicated that 32 percent were against the question and 15 percent had no opinion.**

What happened was that the industry that they brought in conducted a campaign using techniques that you mentioned, and here is an official quoting.

We were surprised at the large percentage of people in both cities who had heard about substitution and had fairly definite opinions one way or the other. It would have been much easier to start with the majority being uninformed * * * we now recognized that our campaign had to not only implant an opinion but also to change existing opinions.

What are the results of this campaign?

Wheeler said that well over 2,000 cards and letters of protest were received by the legislators who represented these counties.

In addition to generating what we feel is more than enough tangible evidence of opinion, our second survey showed the campaign did an exceptional job of changing public opinion.

And it certainly did. For example, before the campaign, 54 percent heard about the problem and 89 percent afterward. There was a 35 percent change in one area after the survey. Then for substitution, 43 percent, and 38 percent against it. But after the campaign, 16 percent was for it and 84 percent against it. In other words, there was a change of 46 percent. And in another area there

was a change of 45 percent. In fact, the techniques you suggest were in changing the mood of the legislature and induced it to defeat any changes in the antisubstitution law.

This gives you an example of how that kind of technique can be used, not only to do things for the public but also—to do what I would regard and I think what you would regard as contrary to the public interest.

Dr. SIMMONS. Well, Mr. Gordon, the techniques we are talking about here obviously have potential benefits and potential harm to them.

My plea would be that clearly there has to be a balance. Everybody has a right to get their message across in this country as best they can. I personally would fight very hard to preserve that.

My concern is that in answer to the question possibly one view is getting across more than another, some people have suggested that we ban the individual's ability to give his view. And one case in a hearing just here 2 weeks ago, I guess, before this committtee suggested that part of the answer may be to limit the educational material flowing to physicians or to place some controls on that.

Now, my plea is that is one approach. You know, the answer may well not be that is the best one. It may be to enable others to make their message heard also. And in that debate that ensues, perhaps the public's interest will really be better served. In other words, I do not believe that the answer may simply be to band anybody's ability to tell anybody about what he does, whether it is a major corporation, the drug industry, or Government as far as that is concerned. And if we could get some balance into that, the balance could be brought by raising the ability of those who have information and technology—NIH, FDC, CDC—to be heard equally well. And I do become a little concerned that the answer may be merely to inhibit the ability of one side to give its message. I am not sure that is the best answer.

Mr. GORDON. All right.

Now let us take this specific case. The forces to retain the antisubstitution laws had a lot of money. This is a very expensive campaign. Those who wanted to change, to remove, the antisubstitution laws had very little money. The public is unorganized. How can a public, which is unorganized, compete against well-organized, well-heeled private interest groups using these techniques?

Dr. SIMMONS. Well, that is always going to be a potential problem. That is what Government is here for, to bring some balance into the arena in the public interest. Further in my statement I make this plea.

Mr. GORDON. Do you think the Government could have interfered in this local matter of antisubstitution laws?

Dr. SIMMONS. Well, I am not sure that that is a governmental problem. But that was the right of a particular person to espouse his views. And I do not think that anybody is recommending that we eliminate that right.

Mr. GORDON. It is certainly one sided.

Dr. SIMMONS. In that instance. it was. And the answer is not necessarily to eliminate that individual's ability to say that but to enable someone else with an opposing view to add his to the debate. And that really is, I believe, another possible solution to this.

At any rate, in final conclusion, the health establishment does have a "product," and it is a worthy one at that. And that product is information—vital, lifegiving information. But the lifegiving capacity of those data are often aborted in the absence of a determined and effective effort to make them heard and heeded.

The application of the techniques of social marketing will be necessary for the technology transfer that NIH and FDA and others are required to accomplish, and to impact on the prevention, early diagnosis of, and appropriate and timely therapy of disease. That will involve communicating with the public and the health professions in such a way as to bring about appropriate attitude and behavior changes.

At this point, it might be useful to recount some real life examples of social marketing in several other countries.

In Great Britain, we happened to undertake a 2-year educational effort to prepare the entire population for the changeover from pound-shilling to decimal currency. We believe that this represents the most intense and successful social marketing campaign ever undertaken. And this necessarily involved not only the comprehensive promulgation of somewhat technical data to a wide variety of publics—consumers, merchants, bankers, teachers—but also the cultivation of attitudes favorable to cooperating in the effort. After all, they were phasing out a custom and habit of 400 years' standing for the nation, and of perhaps 60 or 70 years' standing for many individuals. But the campaign was professionally wrought, governmentally financed, and publicly respected. It was effective beyond the most optimistic expectations.

The Harvard Business School has happened to develop a case study on that which is being used now for teaching, and Mr. Chairman, I would like to include that in the hearing record.

Senator NELSON. We will receive it for the record.[1]

Dr. SIMMONS. The same was true for an antidrug program in West Germany, directed primarily to potential teenage abusers. Once again, the professional marketing communicators employed their unparalleled understanding of their audience and of how communications might be used to effect real social change. They avoided mistakes made by other well-intended but less astute antidrug campaigns, and the project appears to have rendered a demonstrable public service in the eyes of the government of West Germany.

And I believe there are areas where we must now bend to our own ends the competence of professional communicators, in a deliberate stroke of public policy, to accomplish widely desired health benefits. Such a policy is prefigured in other areas of public priority; the military, for instance. All of the United States armed services routinely engage in the use of marketing communications and paid media to ensure fulfillment of their recruiting objectives. And surely the objectives of the National Institutes of Health, FDA, and innumerable other health agencies are no less worthy.

Every public agency which is party or privy to the development of technology has an obligation, it seems to me, to actively foster the fruitful application of that technology. It is clear that information dissemination alone does not necessarily bring about appropri-

[1] Material not available at time of going to press.

ate change. The Congress can make that obligation explicit and irrefutable by calling for each agency to demonstrate the provisions it has made to market its knowledge. Only then can we achieve a conscionable balance among medical technology, medical practice, the rights of the private sector to promote its viewpoint, agency accountability, and, ultimately, the health of our citizens.

Mr. Chairman, in the final reports submitted by the President's Biomedical Research Panel to the President just recently, which you I am sure have seen or read about. One of the major points they make is that the transfer of technology from whoever has it into the public arena for the public's benefit needs some significant improvements, that transferring technology down to where the rubber meets the road, the actual use by the public, significant problems in that area.

The purpose of my statement is to describe a tool that could be useful to bring that about. I mentioned as examples a major need in this country, the much more successful therapy of hypertension. We have useful drugs. We have a disease that have many millions affected by it. Many are being inappropriately treated. These kinds of techniques are what I am talking about being applied to an area of social need to bring about desired change.

Thank you very much.

Mr. GORDON. How can small business firms take advantage of these techniques in selling its products in competition with larger firms? Is there any way that you can think of that small business firms could do that?

Dr. SIMMONS. They do it reasonably successfully now, Mr. Gordon, when they have a good product. The examples that I would think of would be in the commercial area. You know, you could start back with the Xeroxes of the world. When Xerox started and when Polaroid started, they were not major giants, they were very small. They had something that was seen by society as an advance, as something useful, something that they wanted to use. They used techniques such as this to establish their product and themselves and now they are large.

I am sure it is not an easy process because the noise level in communication is very high. But is doable. And I think we have seen, as I have said, a number of examples in our own lifetime. Some of the small pharmaceutical firms that have developed good products that have gone from very small to having successfully entered the market through the use of these kinds of techniques.

Mr. GORDON. Do you know which small firms?

Dr. SIMMONS. I guess the one that I might think of specifically would probably be the Syntex example, for having developed a very useful class of products, having started as really a very small firm awhile back, now, you know, being recognized, a successful, reputable, useful firm.

Senator NELSON. Thank you very much, Dr. Simmons, for your very thoughtful testimony. We appreciate your taking time to come here to appear this morning.

Dr. SIMMONS. Thank you, sir.

[Whereupon, at 11:40 a.m., the hearing in the above titled matter was adjourned.]

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

MONDAY, MAY 24, 1976

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

The subcommittee met, pursuant to notice, at 9:40 a.m., in room 318, Russell Senate Office Building, Senator Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and Laxalt.

Also present: Benjamin Gordon, staff economist; and Karen Young, research assistant.

Senator NELSON. Our first witness this morning is Mr. Earl Scherago, of Scherago Associates, New York, N.Y.

Mr. Scherago, the committee is pleased to have you here this morning. Your statement will be printed in full in the record. You may present it however you desire. Would you identify the associates here with you today so that the record will be correct.[1]

STATEMENT OF EARL J. SCHERAGO, PRESIDENT, SCHERAGO, ASSOCIATES, INC., NEW YORK, N.Y., ACCOMPANIED BY JOHN RINGLE, ASSISTANT EDITOR, "SCIENCE" MAGAZINE; AND ROBERT ORMES, MANAGING EDITOR, "SCIENCE" MAGAZINE

Mr. SCHERAGO. Thank you, Senator.

On my left is Robert Ormes, the managing editor of "Science" magazine. On my right is John Ringle, who is assistant editor of "Science" magazine.

Senator NELSON. Go ahead, please.

Mr. SCHERAGO. I want to thank you for inviting me here today. I have been asked to alert you to a problem which is jeopardizing the scientific and technical capabilities of our Nation. It is a threat which, if not aborted, could well produce a serious delay in the solving of many medical and scientific problems.

Dr. Crout of the Food and Drug Administration, in his recent testimony before this committee, touched on the problems controlled circulation, or throwaway, publications have generated in

[1] See prepared statement and supplemental information of Mr. Scherago beginning at page 14402.

the medical field. I will discuss with you today the financial impact of throwaway journals, not only upon the medical profession, but the entire scientific research community as well.

Before I begin, however, I would like to tell you a little about what our firm does so that you will have a better understanding of how we fit into the picture.

Scherago Associates has for the last 20 years served as a publisher's representative for scientific and medical societies. In essence, this involves the solicitation of advertising for placement in peer review, or scientific journals.

As a scientist, I have long recognized that scientific societies need revenue other than membership dues in order to publish their journals. Most scientific societies do not have their own sales staff because they prefer not to be involved in the commercial aspects of publishing. Because of this, they leave such details to us. In the marketplace we compete with the advertising sales staffs of the throwaway magazines published by profitmaking organizations.

Because of our involvement with the sale or loss of advertising in society journals, we are in an advantageous position to evaluate the impact of throwaways on association publishing programs.

Before proceeding further with my discussion, however, I think it is necessary to define the meaning of peer review, as it applies to magazines.

From the beginning of scientific research, the accepted method of recording results has been through peer review scientific journals. Each area of scientific specialty has its own journal and serves as a means of communication with other scientists in the field. These scientists of like interest often band together into groups, which ultimately grow into scientific societies. Such societies range in size from a few members to the 140,000 constituency of the American Association for the Advancement of Science.

Early in the history of organized science it became apparent that a system of assuring the authenticity of the scientific work appearing in society journals was essential, for the scientific community was not without some charlatans.

Since each piece of research in a given area served as a basis for further work in the same scientific field, an erroneous piece of information could cause untold damage to the whole field.

Mr. GORDON. Do you know of any examples to illustrate that?

Mr. SCHERAGO. There was a recent case at Sloane-Kettering.

Mr. GORDON. Would you please speak a little louder?

Mr. SCHERAGO. There was a recent case at Sloane-Kettering, I believe, but I do not know all of the details on it.

Senator NELSON. Go ahead.

Mr. SCHERAGO. In its simplest form, this doctrine says that no piece of scientific research can be considered valid unless it has been reviewed by at least two recognized authorities in the field of science involved. Furthermore, these reviewers can have no financial or academic involvement in the work reviewed and in most cases are to remain unknown to the performer of the work.

Senator NELSON. Are you talking about every article on any scientific matter that goes into any scientific journal? Is it peer reviewed in this fashion?

Mr. SCHERAGO. Yes sir, every article of scientific content.

Senator NELSON. Is peer reviewed in the fashion you are talking about here?

Mr. SCHERAGO. Yes, sir.

Senator NELSON. That is true of all of the scientific journals that you are familiar with?

Mr. SCHERAGO. That we are involved with, yes; all of those that I am familiar with, yes.

Senator NELSON. Which ones are you involved with?

Mr. SCHERAGO. "Science;" "Clinical Chemistry;" "The American Journal of Medical Technology;" "Pathologist;" and "The Journal of Family Practice."

Senator NELSON. To your knowledge, the other scientific journals that you are not involved with use the same procedure?

Mr. SCHERAGO. Yes, sir. That is correct.

Senator NELSON. And are peer reviewed by at least two independent knowledgeable scientists in the field involved?

Mr. SCHERAGO. Correct.

Senator NELSON. Go ahead.

Mr. GORDON. May I ask a question at this point?

Senator NELSON. Yes.

Mr. GORDON. What about the "Journal of the American Medical Association?"

Is that supposed to be peer reviewed?

Mr. SCHERAGO. I could not say, sir. You would have to check with them. I am not aware of what procedures they use.

Mr. GORDON. I recall several years ago the AMA Journal had an article by Dr. Varley, who was the medical director of the Upjohn Co. in which he claimed that generic tolbutamide (Orinase being the trade name), does not have the same bioavailability as the trade name product manufactured by the Upjohn Co.

Well, the Upjohn Co. had an exclusive license from the patantee, a German firm, and there was no generic product on the market, the so-called generic product having been fabricated in the laboratories of the Upjohn Co. That was a lead article.

So, I am just wondering! It does not seem possible that any independent people had reviewed that article.

Mr. SCHERAGO. I cannot say. I am not familiar with their operation.

In its simplest form, this doctrine of peer review says that no piece of scientific research can be considered valid unless it has been reviewed by at least two recognized authorities in the field of science involved. Through the years scientists have tenaciously stuck to the peer review system of journal editing.

At this time I would like to turn the witness chair over to Mr. Ringle, who will give you some idea as to how "Science" magazine handles the peer review process.

Senator NELSON. Did you give your full name and identification to the reporter? She has that? Good.

Mr. RINGLE. Mr. Chairman, I will describe the peer review system at "Science."

Most scientific journals use some system similar to this. Most scientific journals are reviewed, as are all of the journals published

by the American Physical Society—for instance, "Physical Review Letters"—the journals published by the American Physical Society, the "Journal of the American Chemical Society," and several other journals in that family.

A journal that is peer reviewed is an authentic journal. One that receives papers that are just accepted by an editor is a sort of second rate operation.

Now, each paper submitted to "Science," is reviewed by at least two reviewers. We receive approximately 5,000 manuscripts for review a year, so that involves obtaining about 10,000 reviews.

Senator NELSON. How many?

Mr. RINGLE. About 10,000 reviews for 5,000 papers.

We maintain an active file of approximately 8,000 scientists who review papers for us. This file changes. Some people are discarded as reviewers. Additional reviewers are added every year.

Basically, what we want to find out by peer review is "Are the findings reported supported by the evidence in the paper?" In other words, is the paper technically sound?

Now, besides that, to select from all of these papers that we receive, we want to find out if the findings are significant. Does it make a real advance in the field? Has the author given adequate and fair reference to the related work of others? Are his conclusions supported by the evidence in this paper and other published evidence?

That basically is what the peer review system is.

Senator NELSON. Thank you.

Mr. SCHERAGO. The tremendous strides in science and medicine of the last 100 years would not have been possible without strict adherence to peer review and the use of society journals as a means of communicating peer reviewed information to other scientists.

I would like to emphasize that once a piece of scientific work is published in a peer review journal, it becomes forever a part of the archives of science. Consequently, peer review or society journals are often referred to as archival or scholarly journals. Most archival journals are published by nonprofit medical or scientific societies. This is mainly because commercial publishing firms have found that it is very difficult to make a profit with peer review journals.

I think that this committee should know that peer review journals as a group are in serious financial difficulty, so much so, in fact, that more and more meetings are being held by society journal editors to discuss the problem. One such symposium took place at the annual meeting of the American Association for the Advancement of Science, the largest scientific society in the world, in February of this year.

In a paper delivered to this meeting, Robert Day, managing editor of the publications of the American Society for Microbiology, made this statement, and I quote:

> But will the current trend of rising costs continue? If they do, the scientific journal as we know it today, that is, a package of research papers which is distributed each month directly into the hands of many of the scientists who are peers of the authors and into virtually all of the departments and laboratories involved with similar research will no longer be endangered; it will be extinct.

Mr. Day is not alone in his concern. Virtually every peer review journal has seen its number of scientific pages dwindling to half their former numbers.

Dr. Leland Stoddert, treasurer of the International Academy of Pathologists, said in a recent paper:

Let me speak clearly about the importance of editorial review and the publication of sound, critically reviewed and edited papers in scientific journals. The demands of editorial review sharpen the work of scientists and refine their conclusions. It would be an unhappy day if the edited journal disappeared from the scientific world for economic reasons because scientific standards would not be maintained.

I might add here that the National Institutes of Health has tried to set up currently a special committee to deal with the problem of dissemination of medical information and technology, and that this committee would concentrate on such problems as the failure to disseminate research findings of potential value as rapidly or as effectively as they might.

Senator NELSON. Where are you now?

Mr. SCHERAGO. That is not in the text, sir. We just discovered that.

Most societies have increased membership fees to the point where fewer and fewer scientists can afford them. Mr. Day says that the subscription price for the "Journal of Bacteriology" has tripled since 1968, and by 1985 will triple again. Most society officials agree that they have reached the point where no further reduction in scientific papers and increases in membership dues and subscriptions can be made.

Let me dwell a minute here on the current state of scientific research.

Each year this country spends almost $18 billion on scientific research. A substantial portion of those research funds are supplied by the Federal Government. The National Institutes of Health alone spends almost $2 billion in grants and intramural research.

Senator NELSON. Two billion dollars?

Mr. SCHERAGO. Two billion dollars.

This colossal investment in research activity has in recent years produced an avalanche of new important scientific and medical information.

Dr. Donald S. Frederickson, Director of the National Institutes of Health, said in a speech at the recent meeting of the American Association for the Advancement of Science, "Biomedical knowledge, like all scientific knowledge, has been accumulating at an exponential rate, as reflected in the output of scientific literature. One sampling of biomedical publications suggests an average annual increase in scientific papers of between 4 percent and 5 percent for each year, from 1965 to 1978," and that is only in the biomedical field.

Not all papers which are delivered before a society are published in peer review journals. Some authorities estimate that less than 60 percent of scientific papers ever appear in established scientific or medical journals. It is ironic to think that much of the productive research generated by this enormous expenditure in research dollars is never seen by the scientists and doctors who could best utilize it.

At this time I would like to turn the witness chair over to Mr. Ormes of "Science," who will give you some information on how many papers are published and what is refused.

Senator NELSON. Thank you.

Would you please pull the microphone up closer?

Mr. ORMES. As you heard from Mr. Ringle, "Science" has to review 5,000 or 6,000 papers every year, and we have to get 8,000 to 10,000 reviewers for those papers.

Senator NELSON. How many of the 5,000 to 6,000 are printed annually?

Mr. ORMES. That is what I am going to mention here.

In 1975, we received a total of 5,000 manuscripts, and we printed 1,200. That is at a rate of about 25 percent of what we receive that is accepted.

The number is changed somewhat. Back in 1971, it was 6,000 manuscripts, and we published 1,400. The decline in the number published represents efforts to meet inflation and paper costs, postage costs, and other factors that affect the amount that we can handle.

Mr. SCHERAGO. Bob, would you say those figures are representative of other scientific journals?

Mr. ORMES. I do not know if they are really representative of others. This is what we have done. Nearly everybody has had financial difficulties, but I do not know specifically.

Mr. SCHERAGO. Four factors have been at work during recent history, which have created this problem.

The first of these is the tremendous increases in the number of scientific papers competing for the available pages in scientific journals.

The second is the rapidly spiraling costs of journal production. The cost for printing a page of material in the average journal has increased 30 percent in the last 2 years. Postage, too, has increased substantially. Increases in labor and salaries due to inflation are well-known facts.

Most societies have sought to fight these spiraling costs by increasing membership dues. This in turn has lead to a downturn in association members, which not only keeps the net increase in society revenue small, but decreases the number of people exposed to valuable scientific information.

Reduction in scientific papers published is also an unsatisfactory solution. All things considered, attempts at cost reduction and increases in subscriptions and dues will not solve the problem.

The third factor, and by far the most critical, is the decrease, or lack of advertising revenue in peer review journals. Societies have traditionally subsidized a good portion of their publication costs with paid advertising from firms selling products used by doctors and scientists. However, these advertisers are never allowed to influence the scientific content. This is because the control of the scientific materials published is in the hands of reviewers who did not participate in the revenue from advertising. True peer review journals have steadfastly refused to let advertisers influence their scientific content. This policy had led advertisers to seek other means of communicating with their customers which would allow them greater input.

The business trade press, recognizing this need, has provided that service in the form of controlled circulation magazines, which are often called throwaways by doctors and scientists. Controlled circulation nonpeer review magazines constitute a serious financial problem for peer review journals. Furthermore, the scientific articles in them do not undergo a stringent review process, as do scholarly journals. Consequently they add no new information to the scientific or medical archives.

Each year such publications attract sizeable amounts of advertising revenue from peer review journals. Last year, as a group, 10 publications distributed to the research and laboratory field alone collectively billed over $7 million in advertising revenue, money that could have gone to publish peer review scientific material, had those ads appeared in scholarly journals.

At this point it might be helpful to look at the various types of nonpeer reviewed controlled circulation journals. Essentially there are three types.

The first are product tabloids. These publications publish as their sole nonadvertising content, product descriptions supplied by advertisers, which are essentially free ads. In general, these publications are newspaper size and it is often accepted in the trade that one must advertise in a tabloid in order to get articles published about one's product.

The second type are clinical or research-type journals. These have the appearance of scholarly journals, but do not utilize any accepted review process for their scientific content. It is not unknown for these journals to allow an advertiser to write an article or to accept an article from an individual designated by the advertiser.

Three, news publications—these contain news releases from industry, reviews or abstracts of articles appearing in peer review journals, interviews with scientists who give scientific meetings, and staff written material prepared by the publication's own news staff.

It is often possible for a scientist or a doctor to obtain publicity in such a magazine about scientific theories or drugs which are held in disrepute by most scientists. In this manner, an unscrupulous scientist or doctor may circumvent the traditional peer review process.

Scholarly publications have great difficulty competing effectively in the advertising marketplace with throwaway journals because they are not willing to make the compromises with established scientific practice necessary to interest advertisers. To do so would mean that they would no longer be peer review journals.

Better to preserve the few that survive under the old system than to have no communication system for authentic scientific material.

Let us look now at what throwaways do for advertisers that learned journals cannot.

First of all, they usually send all copies of their magazines to the place where scientists and doctors work. Advertisers feel that professionals read on their jobs more than they do at home. For the most part, scholarly scientific and medical journals are sent to home addresses at the request of the subscribers. This would seem to indicate that advertisers are wrong about where scientists and doctors read professional journals.

On the other hand, advertising managers often ask their salesmen what publications they see on their prospect's desk. Obviously a salesman sees fewer scholarly journals on customer's desks because the doctor receives them at home. Since throwaway publishers send their magazines to laboratories and doctors' offices, most professionals receive at least 6, and some as many as 12, of these kinds of journals.

Another reason that learned journals cannot compete with throwaways is that no peer review journal will allow an advertiser or prospect to influence its scientific content. Furthermore, learned journals often print adverse reference to advertisers' products or present views which are unpopular with groups of advertisers. In no instance will an authentic scholarly journal ever agree to run articles or product descriptions in exchange for advertising.

Advertisers dislike intensely the journal practice of grouping ads in the front and back of scholarly journals. They prefer to see their ads mixed in with articles because they believe they will receive more attention there. Learned journals bunch ads together in the front and back in order to keep from continuing articles. Editors of peer review journals resist mixing ads with articles because they feel it implies advertisers' influence. In general, advertisers group publications in the field into bunches and interspersed, depending on whether ads are grouped. Most society journals are bunched, and all throwaways are interspersed.

Another prime reason for the popularity of throwaways with advertisers is that it is easier to understand the articles in them. In general, nonscientists do not believe that scientists or doctors would read articles written in scholarly style. Advertisers see them as dull and uninteresting.

One other advantage throwaways enjoy is that society journals usually have drab and uncolorful formats, while throwaways make ample use of expensive graphics, color and artwork to make their journals more attractive. So, it is easy to see that in the classic sense of providing the customer with what he wants, throwaways have done a much better job of serving the advertiser.

Scholarly journals have concentrated, on the other hand, on giving the scientific and medical community what it needs.

It is interesting to note that in virtually every case where throwaways are competing with society journals for advertising, the society journal was in existence long before the throwaway. Usually it was the scholarly journals' volume of advertising which accumulated because there were no other journals in the field that attracted the throwaway in the first place. History has shown that every time a controlled circulation publication enters a field served by a learned journal, it drains off a substantial portion of its advertising. This often produces disastrous results. One scholarly chemical journal has lost over 40 percent of its advertising revenue to two throwaways in the field.

It is common practice in the journal field to make scientists pay to have their papers published in a scientific journal. This is especially true in the case of journals having little or no advertising revenue. It is an interesting paradox that some scientists are paying to have their papers published while buying products from firms who support that journal's throwaway competition.

For the last 10 years business publishers have lobbied intensely to force societies to pay tax on their advertising revenue. In 1969, the Internal Revenue Service established new guidelines which have resulted in many societies having to pay taxes on advertising revenue. Thus, the society uses money to pay taxes that otherwise would go to publish more scientific information. The paradox here is somewhat ludicrous. On the one hand the Government creates a nonprofit status for scientific societies so that continued scientific excellence will be assured, and then takes away a substantial portion of its money in taxes.

The business publishers have insisted that the tax-free status of societies constitutes unfair competition. They say this even though the society was there first; and, as we have seen, it is very difficult for a scholarly journal to compete affectively against a throwaway.

In Dr. Crout's testimony, he listed for you 28 publications which have circulations of 70,000 or more. Of these publications, only two employ the peer review system.

I have here a list of these same publications, which is available, indicating the total advertising billings of these publications for the year 1975. These 26 throwaway publications billed over $60 million collectively.

Senator NELSON. This is for advertising?

Mr. SCHERAGO. This is for advertising.

Also, you may be interested in knowing that of all publications serving the medical field, the total billings are about $106 million.

Senator NELSON. What do you mean by all publications serving the medical field?

Mr. SCHERAGO. Controlled and peer review.

Senator NELSON. And when you say medical, you do not mean all scientific?

Mr. SCHERAGO. I do not mean all scientific. In other words, publications circulated primarily to doctors, practicing doctors.

Senator NELSON. The total advertising is what?

Mr. SCHERAGO. About $110 million.

Senator NELSON. And of that $110 million, $60 million is in the so-called throwaways?

Mr. SCHERAGO. No; more than that. Sixty million dollars is in the journals, that Dr. Crout listed. These are journals that have circulations of over 70,000. I do not have figures on what percentage of the $60 million goes into peer review, but it is a small percentage of the total.

In fairness to the people who buy advertising, it is important to mention here the auditing services which evaluate the readership of medical publications. These firms are somewhat similar to the television rating systems used to evaluate the audience for TV programs. These auditing services are unbiased, independent research organizations, who continuously monitor the readership and distribution of journals distributed to doctors.

One of these services audits primarily whether and how well doctors read the material in the magazines and journals they receive. The other measures the number of doctors in a given field who receive each journal, and to some degree also measures readership.

Throwaway nonpeer reviewed publications often receive high scores on these audits, frequently better than the scholarly journal in the field. Advertising buyers place great emphasis on these audits and the magazine with consistenly low scores has little or no chance of survival.

Some firms use these audits as their sole basis for selecting the journals in which they advertise. It is obvious that doctors do read these publications. Throwaways have an advantage in those audits which measure coverage of a specific field of medicine, because they send their magazine free to all the doctors in that specific field who are known.

Society publications, because they are essentially paid for through society dues, seldom show up as well, because no society can claim as members all of the doctors in a given specialty. Thus, advertisers feel that controlled publications provide them with better coverage of their market.

In the scientific or diagnostic laboratory field there are no such audits. This is primarily because the total advertising dollars spent in these types of publications is much smaller and audit services do not find it lucrative enough to study them.

However, because the scientific and diagnostic laboratory constitutes the ultimate buyer of an advertiser's product, many advertisers evaluate these publications on the basis of their response to advertising.

The throwaways always are sent to laboratories, rather than homes, as are the society journals. Thus throwaways also claim more complete coverage of a specific field than a society journal because of their controlled free distribution.

Throwaway publications in the scientific and laboratory fields almost always draw more response for advertisers than do scholarly journals. They can also eliminate subscribers who advertisers feel are not likely to buy their products, such as students and nonmanagement personnel. It remains for the societies to educate these people.

Mr. Chairman, I hope that the facts that I have presented here today will arouse some concern on the part of this committee for the plight of the scientific societies and their journals. If science is to survive, you must find some way to help.

Here are some ways that I feel this committee might be helpful.

One: I respectfully submit that the IRS regulation requiring scientific societies to pay taxes on their advertising revenues is contrary to the public interest and should be repealed.

Two: I suggest that this committee might meet with representatives from industry with the purpose of discussing ways in which a portion of the money now spent in advertising and throwaways might be rechanneled into peer review journals. I think it only fair to mention here that there are already many companies who recognize the importance of peer review journals and set aside a portion of their ad budgets to support them. Unfortunately, there are not enough.

If this committee should decide to propose legislation with respect to advertising in this field, I sincerely hope it will not be in the form of eliminating all advertising. To do so would injure the peer review

journals as well as the throwaways. Rather I would suggest some form of licensing of the editorial in journals which propose to publish scientific or medical articles in scholarly form.

Senator NELSON. You mention that the tax code provisions require associations to pay tax on their advertising. Would you explain that? Do you mean the nonprofit scientific journals?

Mr. SCHERAGO. Yes, sir.

A 501(c)(3) society which is scientific and educational has to pay tax on the advertising revenue that it receives; considering only the costs of publishing advertising, and including some costs of editorial, and anything in excess of that they have to pay tax on. It is not audited as a whole picture business operation.

Senator NELSON. Well, what costs are the scientific journals entitled to write off against the income from advertising?

Mr. SCHERAGO. The cost of printing the ads; the costs of sales; and some editorial costs, I believe.

Is that correct?

Mr. ORMES. The formula for taxation says that the gross advertising revenue minus gross advertising costs is maximum taxable revenue. Then, against that can be set off the editorial costs to the extent that they exceed circulation revenue.

The difficulty is in determining the circulation revenue because there is an elaborate formula for calculating what proportion of society dues must be allocated to the magazine in order to determine the total circulation revenue, including nonmember subscriptions, and other such revenues.

Senator NELSON. I still do not quite follow that.

The implication is that there is a profit made by——

Mr. ORMES. The indication is that if there is a profit made, then the advertising tax must be paid on it.

Senator NELSON. And in determining whether there is a profit, you are saying that you are not entitled to write off all business costs, publication costs, circulation costs?

Mr. ORMES. You are entitled to offset all publication costs connected with—you have to separate the editorial costs of the publication from the advertising costs of the publication, including the printing and any other costs, and you make calculations: One where advertising costs are measured against advertising revenue; the other one where editorial costs are measured against editorial or circulation revenue; and to the extent that advertising net income exceeds editorial costs are measured against editorial or circulation revenue; and to the extent that advertising net income exceeds editorial net costs, you pay tax.

It is a complex formula.

Senator NELSON. You pay a tax to the extent that editorial net costs——

Mr. ORMES. Exceed advertising net revenue, or are subtracted from advertising net revenue. I beg your pardon.

Senator NELSON. I would have to see a more detailed breakdown to see what the impact of that is. How much difference does that make, for example, to "Science" magazine?

Mr. ORMES. We paid a tax of $85,000 for last year, on gross advertising revenue of about $2.2 million.

Senator NELSON. If you had not paid that tax, would the money have gone into a reserve, or what?

Mr. ORMES. Well, other things being equal, that money would have gone into more pages of text. We cannot know as we operate during the year exactly how we are going to come out. But other things being equal, the amount of text we publish is determined by and large by the amount of revenue we have to pay for it.

Mr. SCHERAGO. Mr. Chairman, let me say a word here.

Sometimes societies publish more than one journal, and not all of these journals carry advertising, so that the tax money a society pays on one journal might have gone to publish scientific information in their other journals which do not carry much, if any, advertising.

Senator NELSON. So, if it is a corporation publishing three journals and two of them lose money and one of them makes money, you cannot use the profit from one to subsidize the others? You have to pay the tax first?

Mr. SCHERAGO. Yes, sir.

It is my understanding that that is the case. And that also applies to any other societal activities which they are conducting. Advertising revenue cannot be used to offset the cost of a meeting from which comes a good deal of the information published in society journals.

Senator NELSON. I see.

Did you have any questions, Mr. Gordon?

Mr. GORDON. Yes, thank you.

I just want to get this clear.

At the bottom of page 7 I think you implied, did you not, that the throwaways do allow an actual or prospective advertiser to influence their editorial and scientific content?

Mr. SCHERAGO. It is possible, and sometimes it has happened.

Mr. GORDON. You also implied that this type of publication does not generally print unfavorable references to advertisers' products or present views which are unpopular views for the advertisers.

Is that also correct?

Mr. SCHERAGO. It would be extremely poor business to do so.

Mr. GORDON. So that is why they do not do it?

Mr. SCHERAGO. That's right.

Mr. GORDON. Just one more point.

You also said that advertising content for scholarly journals varies from zero up to about 30 percent, and occasionally up to 40 percent.

Is this not also a rather dangerous situation if you are dependent on advertising to the extent of 40 percent?

Mr. SCHERAGO. Yes, that is true. That is one of the problems.

But Mr. Ormes can answer that question better than I. In general it is considered poor practice for a journal to run less than 60 percent editorial to 40 percent advertising.

Is that not true, Bob?

Mr. ORMES. I think that is true.

We try to run 75 percent text, and we make every effort to make sure that the distinction, the independence of the advertising content from the editorial content, is total. The decision of an advertiser to place an ad has nothing whatever to do with the decision of the editor

to print an article. They are handling that with different staffs and from different places. The effort is made to keep them totally separate.

Mr. SCHERAGO. Let me just say a word about the question that you asked relative to that.

Most of the business publishers who got into this business have lots of other publications in the trade area, that is, in skiing, restaurants, things like that. It is not considered unethical or out of the ordinary for advertisers to obtain editorial coverage in those journals, either by the publishing industry itself, or by the people who receive those publications. That is because the importance of accuracy is not as great as it is in the scientific or medical area. But these publishers pretty much see all advertising objectives as a trade area.

What has really happened is that they have made the scientific and medical field a trade area by their method of publishing. So, it depends on how you look at it as to whether or not it is bad publishing practice.

In other words, it is accepted in some areas, and, of course, in the scientific area it cannot be because unless you are assured that the material in there is accurate, there is no way that science can continue.

Mr. GORDON. What disturbs me is that a firm, a business firm, has to make money. If it advertises, you have to please the advertiser. So, if you are dependent to a large extent on advertising, how is it possible to be independent?

Mr. SCHERAGO. There are many commercial publishers who print and publish peer review journals. It is not a question of where the money comes from. It is a question of who controls the editorial. It is possible to place the control of that editorial in the hands of people who are not on the publication staff, who do not share in the revenue, and who do not have that incentive.

Mr. GORDON. You are saying that the old problem of "he who pays the piper calls the tune" does not apply?

Mr. SCHERAGO. Not in this case; not necessarily.

I am not saying that the opportunity for bribery, which is what we are talking about, is not always there. It is. But in the case of the societies, there are so many safeguards set up in peer review that it would be pretty difficult for that to happen. There is an editorial board which selects in general what types of articles go into the publication. So, you would have to get to them. That is usually—what—12 or 13 people? Then you would have to get to the reviewers which—again, I am not saying it could not happen. But I think it is much more unlikely that it would happen with the control of the editorial external from the publication.

Mr. GORDON. Well, look what happened to the New York Times.

Mr. SCHERAGO. You would give me an exception.

Mr. GORDON. Do you recall what happened to "The New York Times" as a result of printing something unfavorable to the industry?

As a result of publishing an article unfavorable to the drug industry, they lost $500,000 in advertising.

Senator NELSON. Their magazine only did. "The New York Times" did not.

Mr. GORDON. The New York Times Corporation did.

Senator NELSON. It was a publication owned by "The New York Times." "The New York Times" did not lose the advertising.

Mr. SCHERAGO. But even if that is true, "The New York Times" is not a peer review publication.

Mr. GORDON. You are confusing me.

Senator NELSON. "The New York Times" is the owner of "Modern Medicine." They ran a series of articles that you may be familiar with that was critical of the drug industry. Then the magazine owned by "The New York Times" lost advertising. That is a good, clear case of the drug advertiser putting economic pressure upon a publication owned by a paper that was critical of their business. I think that is rather a common practice.

Mr. SCHERAGO. I am sure it is.

Often many publishing operations are owned by conglomerates that have other activities, even some who do Government contract work. You know, there are all kinds of ways you can apply pressure. It does not necessarily have to be with the person or division of that company that does something that an advertiser does not like. Pressure, as you point out, can be applied through the magazine to some other publication.

Senator NELSON. But in the case of a peer review journal, such as "Science" or others, you have a standing panel of scientists who have been selected for their expertise in various and particular disciplines.

Mr. SCHERAGO. Right.

Senator NELSON. And articles are submitted to "Science," and are then peer reviewed by an independent scientist not associated in any way with the magazine, and not receiving——

Mr. SCHERAGO. True.

Senator NELSON. And then they review it, and whatever commentary they have comes back to the editorial board of the magazine.

Is that it?

Mr. SCHERAGO. Right.

Senator NELSON. And who is the editorial board? Are they employees of "Science?"

Mr. ORMES. No. They are advisors to the editor.

Senator NELSON. They are advisors to the editor?

Mr. ORMES. Advisors to the editor; personal advisors to the editor.

Senator NELSON. What is the nature of their expertise, their qualifications?

Mr. ORMES. To extend his knowledge.

Senator NELSON. Who are they? How are they selected—is their selection based upon some scientific qualifications?

Mr. ORMES. Oh, yes—scientific qualifications and variety of discipline and personal knowledge.

Senator NELSON. So, they are not employees, but are advisors to the editor?

[Mr. Ormes nods affirmatively.]

Senator NELSON. And they review the article plus the commentary of the two peers who reviewed it. Is that correct?

Mr. ORMES. This happens in many journals. At "Science," the editorial board does not participate in the reviewing process. It is just the peer reviewers who do the reviewing. The editorial board are advisors to the editor on coverage of subjects that ought to be in the magazine.

Senator NELSON. So, of the 5,000 articles that are submitted, the editorial board advises as to what mix, what variety of scientific articles ought to be included?

Mr. ORMES. They would provide advice on that, yes.

Senator NELSON. The members of your peer review group are independent; they review independently of each other, is that correct?

Mr. ORMES. Yes, sir.

Senator NELSON. And what is the standard by which you measure their peer review? On what grounds? If they say it is mediocre, or not well done, or not soundly based, does the editor then automatically reject?

Mr. SCHERAGO. John?

Mr. RINGLE. That's right.

If both peer reviewers say this article is not up to acceptable scientific standards, we would reject it. If they were split in their opinion, we would seek another opinion, or try to decide on some basis. If the negative reviewer seemed to have very good reasons why he thought this was not up to standard, we would likely reject it, since we have to reject about 80 percent of all material we receive anyway.

Senator NELSON. Well, are most or all of the articles that appear endorsed by the two peer reviewers?

Mr. RINGLE. Yes, sir.

[Mr. Ormes nods affirmatively.]

Mr. RINGLE. Almost all of them.

Senator NELSON. Do you have any more questions, Mr. Gordon?

Mr. GORDON. No, sir.

Mr. SCHERAGO. Senator, just one other thing in that respect.

I really do not feel that, except for tabloids, there is a great deal of exchanging articles for advertising. I think that if there is any influence, it comes from the types of articles that a magazine accepts because obviously it has to publish the kind of editorial that will attract advertisers, that is, the direction that it takes and the fields that it covers. So, in that sense, I think there is more influence than there is in the actual trade, although that does happen.

Senator NELSON. I did not understand your point.

Mr. SCHERAGO. The point is, the direction of editorial content can also be influenced by advertisers as well as the content of a specific article.

Senator NELSON. In a nonpeer review?

Mr. SCHERAGO. In a nonpeer review.

Senator NELSON. Thank you very much, gentlemen. I appreciate your taking the time to come.

Our next witness is Dr. Jack Kelly, chairman of the board, and Dr. Leslie Huffman, Jr., speaker of the Congress of Delegates, American Academy of Family Physicians.

Senator Laxalt was here and intended to introduce Dr. Kelly, but had to leave prior to your appearance. I am sure you saw him this morning. He regrets he could not be here to introduce you.

Go ahead, please.

Would you identify your associates so that the record will be accurate?

STATEMENT OF JOHN C. KELLY, M.D., CHAIRMAN OF THE BOARD, AMERICAN ACADEMY OF FAMILY PHYSICIANS, KANSAS CITY, MO., ACCOMPANIED BY DR. B. LESLIE HUFFMAN, JR., SPEAKER OF CONGRESS OF DELEGATES; AND DR. WILLIAM HUNTER, MEMBER OF THE BOARD, AMERICAN ACADEMY OF FAMILY PHYSICIANS

Dr. KELLY. Thank you.

I am Dr. John Kelly of Reno, Nev. I am currently chairman of the board of the American Academy of Family Physicians.

To my left is Dr. Leslie Huffman, who is speaker of the House of Delegates of the Congress of the Academy of Family Physicians, and from Grand Rapids, Ohio. To my right is Dr. William Hunter from Clemson, S.C., who is the chairman of the Legislation and Governmental Affairs Commission for the academy.

Rather than belabor the Senator with reading my testimony, I would like to have the opportunity of basically outlining it and giving some dialog and comments as we go along. Please feel free to interrupt me for questions as you see fit.

Senator NELSON. Fine.

Your statement will be printed in full in the record. You may present it however you desire.[1]

Dr. KELLY. Thank you, sir.

One of the most important things relative to family medicine and to medicine in general is the educational experience. I would like to comment on the educational experience of our annual meeting.

The American Academy of Family Physicians has an annual meeting that draws approximately 5,000 physicians a year. This meeting is a multifaceted meeting, and at this point in time I would like to ask Dr. Huffman to comment on the different types of educational experience available at that meeting.

Dr. HUFFMAN. Mr. Chairman, in order to give you some idea of the perspective with which we are dealing, the annual Scientific Assembly of the American Academy has 10 major elements.

Senator NELSON. Ten major what?

Dr. HUFFMAN. Ten major elements. In fact, sometimes we affectionately refer to it as the 10-ring circus because we have such a variety of things that are offered to our members. These include 518 clinical seminars; 12 continuing education courses; 14 live teaching demonstrations; 14 dialog programs; 10 programed instructions; 10 taping and strapping demonstrations; 10 fractures demonstrators; 100 scientific exhibits; 16 lectures; and 185 technical exhibits.

Dr. KELLY. Sir, our request at this particular point in time was to be limiting our testimony to prepared comments relative to scientific exhibits and delineation of same.

The American Academy recognizes two types of scientific exhibits—commercial and purely scientific. To distinguish between the two is a task that is somewhat direct and simple. The primary purpose of a scientific exhibit is to provide information to phy-

[1] See prepared statement and supplemental information of Dr. Kelly beginning at page 14226.

sicians through the dissemination of research material. It is awarded in our academy on the basis of relevance to family practice, legibility, and scientific accuracy associated with ethical content. This is in opposition to the commercial exhibit, which is a mechanism for soliciting support for our annual meeting and which is paid for.

Our scientific exhibits we accept no remuneration directly for, and also the scientific exhibits are unsolicited, whereas we do solicit the commercial exhibits. Scientific exhibits, in general, are picked because of their relevance to family practice, and they are picked because of content. If they fail to meet these, we through our committee, or our subcommittee of our scientific assembly, suggest changes in the format, but not in the basic content of the material, to meet a format of application which we have. This is attached in the testimony as exhibit A.

The second point that you requested us to respond to is sponsorship of our scientific exhibits. This sponsorship can vary. It varies from private industry, universities, armed forces. As mentioned by Dr. Crout in his discussion of the 28th, also from pharmaceutical firms. The figure that Dr. Crout cited in his earlier testimony, of 80 percent of scientific exhibits being sponsored by drug firms upon our review, appears to be reasonable.

The third point that you asked us to address is who prepares the scientific exhibits. This is a multifaceted approach also. The individual exhibitor may prepare his own exhibit. In the 1975 academy meeting, the scientific assembly's excellence award was won by an individual who prepared and printed his own material on a poster board situation. Or, the preparation of the exhibit can also come from individuals, such as universities, in concert with the exhibitor, or in some instances pharmaceutical firms supplying economic support for the researcher and then assisting in the development of the format.

The other modality is, of course, the commercial exhibiting companies which prepare the exhibit on a protocol based on the desires based on the particular exhibitor and physician.

You asked relative to the editorial review, we have a subcommittee that reviews all scientific requests. As previously stated, we asked them to adopt to our format, without changing the content. If they cannot adopt to the format as established by the academy, we recommend that they not attend.

We have rejected because of this very fact. We have had some problems in the past, and this year we are in the process of working a review situation prior to the opening of the exhibits with the PMA, and this is outlined in our testimony.

I must stress at this point in time that the protocal relative to this will be the protocol established by the academy, and not the protocol established by the Pharmaceutical Manufacturers Association.

Mr. GORDON. May I ask a question at this point?

Dr. KELLY. Yes, sir.

Mr. GORDON. What is the function of the PMA? I am not sure I get that.

Dr. KELLY. Well, relative to our testimony, the PMA has been asked to critique the scientific exhibits prior to opening our Con-

gress as far as content to protocol, relative to the criteria that we have set up, and those criteria are included in our format. This is an unbiased third-party situation, hoping teh lack of bias comes from the broad base from which the PMA springs.

Mr. GORDON. So the PMA is really performing the review process?

Dr. KELLY. No; the PMA in concert with the Academy Scientific Assembly Committee is doing the review.

Mr. GORDON. Then you regard the PMA as an unbiased reviewer, is that it?

Dr. KELLY. Well, if you had a group representing multiple facets of any industry, and one had a chance to be one up, I think that the leveling of an allover inclusive look would tend to make that oneupmanship a little bit less.

Senator NELSON. I am still puzzled as to how you could accept the Pharmaceutical Manufacturers Association as an objective reviewer of any scientific matter affecting drugs, since they are owned by, controlled by, paid for by, hired by, et cetera, by the pharmaceutical manufacturers.

I think it is obvious, don't you, from the beginning, that in any event nothing critical of the drug industry or any method, any advertising, any promotion that they do would ever appear in any educational format in which they participate, is that not correct?

Dr. KELLY. I would agree with that, except for one simple fact—the criteria being established are our criteria, and not the pharmaceutical manufacturers criteria. The academy sets the protocol. They have been asked to observe and comment on that protocol; but the protocol is ours and not the PMA's.

Senator NELSON. Well, I do not know what the protocol is.

Dr. KELLY. The protocol for review, sir, is in part of the exhibits that we have attached.

Senator NELSON. I see.

All I know is that the AMA had a protocol for advertising in their journals. It read very well and was very specific—we had hearings on it—except they violated it continuously and finally decided to throw out the protocol so that they could continue to accept advertising which, if they had adhered to their protocol of standards, they should have totally rejected.

Dr. KELLY. That may be true, sir. But we are not discussing advertising at this point in time. We are discussing the relevance of scientific exhibits, which are specificially based on the Academy's protocol, prohibited in advertising. This is one of the reasons for the PMA's involvement.

Senator NELSON. All right.

Go ahead.

Dr. KELLY. The fifth point that you asked us to address is the convention and the dependency on drug support. I would like to have Les give us some basic numbers on that.

Dr. HUFFMAN. Actually, of the nine elements of the annual meeting, which I outlined to you previously, it is interesting that only three of these elements have funding in part or supported in part by educational grants from pharmaceutical firms. The remaining elements are dependent upon registration fees which are charged for the seminars; registration fees are charged for the continuing

educational courses; and then we have a registration fee for the whole, or general admission registration fee, which handles our administrative costs or underwrites the remaining elements of the program from the general fund.

The three particular portions of this that do have some pharmaceutical industry import in the form of educational grants are entirely organized by the committee on scientific programs. They are given a completely free rein, with no strings attached, as far as what these programs will include.

For example, I tried to be very critical and go through and see if there were any real points where I could say that a company's products had been favored by one of these. In the most critical review that I could come up with, I could not find but maybe one out of thirteen different presentations in one of these segments that would even be related to a product of that company. So, I think the committee has been very diligent in trying to maintain their own independence in putting on what they feel is best for the annual meeting in selecting both the topics and the speakers, regardless of whether or not the support has come from the pharmaceutical companies.

Senator NELSON. How much support do the pharmaceutical companies give to these three exhibits?

What would the total be?

Dr. KELLY. May I answer that?

An example—in 1975, the total income was $475,463.

Senator NELSON. The total income for what?

Dr. KELLY. For the annual assembly. The total expenses were $579,031. Expenses exceed income by $103,568. Of this income, $247,000, or over 50 percent was from the sale of technical exhibit space.

Senator NELSON. The sale of what?

Dr. KELLY. The sale of technical exhibit space. The pharmaceutical firms paid for that.

Senator NELSON. Two hundred and what was it?

Dr. KELLY. $247,000, or over 50 percent of the total cost.

Senator NELSON. Was paid for exhibition space?

Dr. KELLY. By the pharmaceutical firms. Yes, sir.

Senator NELSON. And then did I understand that in three of the elements there were contributions by the pharmaceutical firms in addition to the payment for advertising, the exhibit space?

Dr. HUFFMAN. Yes, sir.

Those were educational grants.

Senator NELSON. What did they total?

Dr. HUFFMAN. The total was $5,000. No, sir, I am sorry. I am on the wrong line.

It was $1,700. There was a $1,700 income for dialogue and live teaching.

Senator NELSON. That was for the three elements that you mentioned, where there was some contribution by the company?

Dr. HUFFMAN. That is correct.

Senator NELSON. Please go ahead.

Dr. KELLY. That basically covers what we came to tell you, sir. Did you have anything else?

Senator NELSON. I did not have a chance, because I just got your testimony this morning, to go all the way through it.

Did you cover all of the major points within your prepared text?

Dr. KELLY. Yes, sir.

Senator NELSON. All right.

Thank you very much, gentlemen, for taking the time to come. I do appreciate it.

Mr. Gordon has some questions.

Mr. GORDON. The previous witness, Mr. Scherago, stated that early in the history of organized sciences it became apparent that a system of assuring the authenticity of a scientific work appearing in society journals was essential; that to protect themselves scientists established the peer review doctrine. In its simplest form this doctrine says that no piece of scientific research can be considered valid unless it has been reviewed by at least two recognized authorities in the field of science involved. Furthermore these reviewers can have no financial or academic involvement in the work reviewed, and in most cases are to remain unknown to the performer of the work.

Do you follow this peer review procedure for your scientific exhibits?

Dr. KELLY. For the scientific exhibits?

Mr. GORDON. Yes.

Dr. KELLY. The peer review is done by the subcommittee, yes, sir.

Mr. GORDON. That is two independents, as outlined by Mr. Scherago—two independent experts who are not involved at all financially?

Dr. HUFFMAN. Mr. Gordon, with your permission, I would like to answer that.

I happen to have been Chairman of the Committee on Scientific Programs. When we introduced a means of evaluating the scientific exhibits, we did so in a very careful and uniform manner to be conducted by the Committee on Scientific Programs.

The scientific exhibits that we do select in the final analysis are selected based on a standard set of criteria which we established in 1969, and these are reviewed carefully by at least two members of the Committee on Scientific Programs. In many cases the entire committee has seen some of these exhibits and can give their impressions or opinions. But we have at least two reviewers on the committee to complete an evaluation form on every scientific exhibit.

Mr. GORDON. But they are not independent reviewers—they are two people from the committee itself. This is quite different from what Mr. Scherago described as the peer review doctrine.

Dr. HUFFMAN. That is correct.

Actually, peer review for a publication is a different sort of thing, and is another subject. We have peer review there which is outside peer review.

Mr. GORDON. Do you know of any scientific exhibits paid for by the drug firm which was unfavorable to the use of a drug—any drug at all?

Do you recall?

Dr. KELLY. No, sir, I do not.

[Dr. Huffman nods negatively.]

Mr. GORDON. Can you give us any examples of the comparison of efficacy and safety of drugs presented in your exhibits, and would this be included in a commercial or scientific exhibit, and who would sponsor this kind of exhibit?

Dr. HUFFMAN. In commercial exhibits, of course, this information has to be given out at the time that they are talking to a doctor about a drug. They have the standard information on the drugs at the commercial exhibit. Of course that is the commercial approach.

Mr. GORDON. I am talking about scientific exhibits.

Dr. HUFFMAN. Again, the data is reviewed for subjectivity and has to include all of the adverse reactions that occurred, the contraindications, et cetera.

Dr. KELLY. If you have a generic type of material, the entire spectrum of that, whether it is produced by one, two, or four drug companies, is part of the evaluation.

Mr. GORDON. Coming back to this peer review business, you are saying also that the peer review is conducted by the PMA, as well as your committee.

Is that correct?

Dr. HUFFMAN. Actually, we are probably overemphasizing the PMA or the activity of the liaison committee from the PMA. The liaison committee of the PMA is asked to review the exhibits after they have been set up. Now this is long after the peer review, the committee review, has taken place. They are asked to review the exhibits after the setup to be sure that we have not missed a reference to a commercial brand name, or that we have not allowed someone to slip in with something that is really a blatant commercial promotion.

As Dr. Kelly said, we hope that we have safety in numbers by having a number of those companies represented on those committees, and they would be very careful to see to it that no one had violated their protocol. That comes long after the active selection process of the Committee on Scientific Programs.

Mr. GORDON. So, we have a situation where the drug industry sponsors 100 percent of the commercial exhibits, 80 percent of the scientific exhibits, and then the PMA reviews the exhibits to see if they are satisfactory.

Is that it?

Dr. KELLY. That is partially true—100 percent of the commercial exhibits; 80 percent of the scientific exhibits; but the PMA is involved after the peer review has been accomplished by the Academy for ethical content and relevancy to family practice. They are involved in a protocol relationship rather than generic one-upmanship or commercial advantage. That is their involvement.

Senator NELSON. Thank you very much, gentlemen.

Our next witness is Mr. Edward F. Calesa, president of Health Learning Systems Inc., of Bloomfield, N.J.

Mr. Calesa, the committee is very pleased to have you here this morning. Your statement will be printed in full in the record. You may present it however you desire.[1]

[1] See prepared statement of Mr. Calesa beginning at page 14050.

STATEMENT OF EDWARD F. CALESA, PRESIDENT, HEALTH LEARNING SYSTEMS INC., BLOOMFIELD, N.J., ACCOMPANIED BY EDWARD SALTZMAN, EXECUTIVE VICE PRESIDENT, HEALTH LEARNING SYSTEMS INC.

Mr. CALESA. Would you like me to begin, Mr. Chairman?

Senator NELSON. Pardon?

Mr. CALESA. Should I begin?

Senator NELSON. Go ahead.

Mr. CALESA. First of all, let me thank you for inviting me today. This is our very first time here in the Senate building, and we are very excited about it.

I am here with Edward Saltzman, who is executive vice president of the Health Learning Systems. Ed Saltzman and I are pleased to be here to answer your questions about our contribution to medical education.

We contribute through two separate corporations with one common objective—improving the quality and lowering cost of patient care through meaningful education.

The Health Learning Systems Corp. achieves this objective by providing continuing medical education for physicians, interns, nurses, and other allied health professionals; and the HLS Press Corp., through health education directly for the patient.

We will concentrate today on Health Learning Systems.

The primary reason for our existence is to help translate medical research findings from branches of the National Institutes of Health and university-based medical centers to improved patient care. The need is based upon the fact that new research findings reportedly double every 7 to 10 years, and affect numerous aspects of prevention, diagnosis, management, and rehabilitation of disease. More importantly, these findings are not adequately reaching the practicing physician for clinical application with the patient. This concern is well recognized by the Congress in its direction to the National Institutes of Health.

To effect change, there is a need for continuing medical education through improved communication techniques. The need for continuing medical education of practicing physicians is well documented by every major study in medical education. It is further substantiated by the American Medical Association, 9 medical specialty societies, and 14 States, all of which require that members participate in a fixed number of education hours to maintain their membership; 5 States have education requirements to maintain their license in that State; 3 more States will institute relicensure laws by January 1978. All medical specialty boards and subspecialty boards have endorsed recertification examinations.

Mr. GORDON. May I ask a question here?

Mr. CALESA. Sure.

Mr. GORDON. How do you get the scientific information which is developed at NIH and various educational institutions? How do you collect the information you wish to transfer to the practicing physician?

Mr. CALESA. From the medical advisors whom we work with on the various programs we develop. I think we will cover that when we get to the medical advisers.

Did I answer your question?

Mr. GORDON. Not really, but go ahead.

Mr. CALESA. Congress has passed the Bennett amendment to the Social Security Act in October 1972 requiring the establishment of professional standard review organizations, with the primary objective to increase the quality of care through physician education. The problem of malpractice in this country can often be related to this need. The major consequences to society of not adequately fulfilling this need for continuing medical education are increased morbidity and mortality statistics and the extremely high and spiraling cost of health care.

Traditionally this need is being assumed by medical schools and hospitals that provide courses, hospital staff conferences and meetings, traveling medical educators, medical textbooks, scientific journals, and conventions. Problems with these approaches include: Practicing clinicians may not have time to travel and attend courses, particularly those physicians farthest away from the medical centers; the lecturing medical educator may not have adequate teaching tools, and is limited by the amount of time he can devote to this activity; the printed word is often outdated, overused, and not necessarily the best communication medium, particularly for medical subjects. Local meetings can fail to provide national or international perspective.

Upon recognizing this need, Health Learning Systems was organized in 1971 to act as a catalyst in marshaling the resources and disciplines prerequisite to affecting improvement in patient care through education. The disciplines we integrated in our corporation are the following: First and foremost, medicine to provide selection of subjects, physician participants, content control and accuracy; second, education to insure the achievement of learning objectives; third, communications to enhance the speed and accuracy that information could be communicated and provide professionalism and quality in this area; fourth, marketing to find funding for programs and assist in the distribution of completed programs. Integration of these four disciplines is the basis for producing high-quality medical education materials that are up to date, accurate, and professional.

The most important discipline in our organization is medicine. We have developed a medical faculty of more than 400 physicians representing Federal health agencies, medical associations, medical societies, medical boards, medical schools, and teaching hospitals from around the world.

This is spearheaded by our medical director, Dr. Arthur Bernstein, clinical professor of medicine, New Jersey College of Medicine and Dentistry; and Dr. Shervert Frazier, psychiatrist in chief, McLean Hospital and professor of psychiatry Harvard Medical School, a nonpaid member of the board of directors of Health Learning Systems.

Included in our list of experts from the Federal Government with whom we have worked are Dr. Theodore Cooper, Assistant Secretary for Health, Department of Health, Education, and Welfare; Dr. Donald S. Fredrickson, Director, National Institutes of Health; Dr. Robert I. Levy, Director, National Heart and Lung Institute; and Dr. Ronald A. Chez, Chief, Pregnancy Research Branch, National Institute of Child Health and Human Development, National Institutes of Health.

Some of our 400 physician advisors from academic medicine include Dr. James C. Hunt, professor and chairman, department of medicine, Mayo Clinic and Mayo Medical School; Dr. Morton H. Maxwell, clinical professor of medicine, UCLA School of Medicine; Dr. Clark H. Millikan, professor of neurology, Mayo Clinic and Mayo Medical School; Dr. Edward J. Quilligan professor and chairman, department of obstetrics and gynecology, University of Southern California School of Medicine; Dr. Michael E. DeBakey, president, Baylor College of Medicine, Texas Medical Center; and Harold D. Itskovitz, professor of medicine, Medical College of Wisconsin.

Mr. GORDON. Mr. Calesa, would you please describe how all of this works?

You say you have developed a medical faculty of more than 400 physicians. Are they on your payroll? Do you compensate them for their time? What precisely do they do?

Mr. CALESA. Whenever we are producing or developing a program, we call upon people who are leaders in a particular field of medicine, and for the time which they directly work for us we compensate them. They are not full-time employees. None of them are full-time employees of Health Learning Systems Corp.

Dr. Frazier is on the board of directors of Health Learning Systems, but he is not compensated for his participation on the board. He is the third member of the board of directors along with Mr. Saltzman and myself.

Mr. GORDON. You say that you work with Government people. As an example you mentioned Dr. Levy, Director of the National Heart and Lung Institute. I understand he edited one of your programs?

Mr. CALESA. Yes.

Mr. SALTZMAN. He edited a number of them.

Mr. CALESA. He, along with Dr. Cooper, edited one of our programs, the program on hypertension.

Dr. Levy has edited more than one of our programs.

Mr. SALTZMAN. To answer your question, Mr. Gordon, about compensation for people like Dr. Cooper and Dr. Levy, they have never been compensated at all, including their travel expenses.

Mr. CALESA. The physicians in academic medicine who we work with, the leaders, they are compensated for their time; but Federal Government employees are not. They work with us on a voluntary basis.

Mr. GORDON. You compensate them directly, not the sponsor of the program, is that correct?

Mr. CALESA. Yes; we compensate them directly.

Mr. SALTZMAN. We receive a grant from the company, and we compensate the physician from this.

Mr. CALESA. Should I continue?

[Senator Nelson nods affirmatively.]

Mr. CALESA. We have collaborated and worked cooperatively with the National Board of Medical Examiners and representatives associated with the American Board of Internal Medicine, American Board of Family Practice, National Institutes of Health, American Board of Psychiatry and Neurology, American Fertility Society,

Epilepsy Foundation of America, American Heart Association, National Kidney Foundation, and many others.

It is this working relationship we have with medicine that is the basis for us to produce highly credible education programs funded and distributed by industry which are beneficial to the participants in medical schools, physicians in private practice, and patients. It is the integrity, reputation, and knowledge of this group that provides the peer review and controls over the educational materials.

The critical questions we faced were first how to fund and how to distribute the programs that we could develop. We considered three alternatives.

The first was for us to raise capital, develop programs at our own expense, and sell completed programs to physicians in practice. We rejected this alternative because our studies indicated physicians would not pay for the programs, and we had no system of distribution. Second, we considered proposals to appropriate Federal Government agencies. We rejected this idea because of restrictions in Federal health care spending, the time involved in getting proposals written and approved, and most importantly, the inability of the Federal Government to provide adequate distribution. The approach we settled on was to utilize the resources of industry. They have the financial resources, the responsibility to good medical practice, and the distribution outlets to insure awareness and usage of completed programs.

Mr. GORDON. What are these distribution outlets that you are talking about?

Mr. CALESA. I am talking about primarily the fact that they have distribution outlets through their sales representatives, through journal and mail promotional avenues which physicians in practice have come to accept and expect from pharmaceutical manufacturers, and thus have the ability to reach directly into the private practice of physicians' offices. This is something for which they have a unique situation—a situation unique to the pharmaceutical industry.

Mr. GORDON. I guess the principal way is the detail men who bring it to the doctors' offices, is that correct?

Mr. CALESA. Yes, sir, that is correct—not exclusively—but you said principally.

Mr. GORDON. That is exactly what I said.

Mr. CALESA. Why would industry use these resources to support educational programs for physicians? The answer is that pharmaceutical manufacturers develop excellent products that undergo extensive testing before being sold to the public. These products are differentiated by scientifically proven benefits as well as positive and negative side effects.

Each product becomes a potential therapy in the physician's pharmacopeia.

The problem is how to properly and accurately communicate the benefits, side effects, and therapeutic role each product has in the diagnosis and treatment of a patient. In marketing medical products, industry does not sell products to a doctor, but rather fulfills needs that a doctor has in the comprehensive care of his patients. Accepting this statement as dogma, it is an absolute necessity to provide adequate and accurate information which allows the physician to

make informed decisions in selecting methods of diagnosis and treatment for his patients.

A comprehensive continuing medical education program under the rigorous scrutiny of medical peer review, which discusses candidly when drugs should and should not be used and criteria for drug selection, which includes all major drugs in that field as well as nondrug methods, is a way for industry to fulfill its communication responsibility with the physician.

Additional factors are that the manufacturer is trying to upgrade the level of knowledge of the pharmaceutical sales representative, so a better dialog can take place between the physician and the representative. This can be accomplished by exposing the pharmaceutical representative to the same educational materials to which the physician is exposed.

There are other factors as to why the manufacturer will support educational materials, but the most important is that the manufacturer with high-quality products, that have a definite role in the management of patients in a particular therapeutic field, will benefit by providing fair balanced educational material to the practicing physician.

However, since industry was to provide the financial and distribution resources, it was imperative that certain safeguards be built into the educational process to avoid any potential for abuse.

It is our unequivocal contention and therefore policy that these safeguards must be under the control of academic medicine through medical peer review and not regulated either by any Federal agency or interfered with by the pharmaceutical manufacturer.

We have consistently maintained these safeguards in the following way:

First: The educational program is developed and produced by an independent organization, such as Health Learning Systems, rather than by the pharmaceutical manufacturer.

Second: The intention of the program is educational rather than promotional. Specifically, we feel that the educational materials should not be exclusively about drugs, but rather encompass the entire area of diagnosis and management of a particular disease.

Third: The executive editor and editorial board participants in the program be selected independently of the manufacturer providing the grant. We will accept suggestions from the manufacturer regarding participant selection, but only as it relates to providing a fair balanced presentation. All editorial board participant selections must rest with the executive editor of the program.

Fourth: The editorial board participants include a minimum of four independent participants to rule out bias.

Fifth: The editors selected be eminent in their field, be located at leading medical centers and represent the major opinions in that disease area.

Sixth: The content be completely under the control of the editors and not subject to change by the grantor.

Seventh: The program be sponsored by a prestigious medical school, medical school department, health agency, or organization.

Eighth: Educational content peer review be provided by a Federal Government agency and/or medical association active in that field.

Ninth: The content be reviewed for accreditation by all of the leading accrediting organizations in that field.

Tenth: Any discussion of drugs be done in fair balance to all drugs in that field.

Eleventh: Both the indications as well as the side effects of all drugs discussed be highlighted in the program.

Senator NELSON. Do you have any examples? You said the indications for the use of the drug and the side effects of the drug are presented.

Mr. CALESA. Yes; that is what I said. Every one of the programs we establish, educational criteria programs, includes every one of these, and I think that Dr. Crout, when he was here, specifically named our program, "Dialogues in Hypertension," which did exactly this. This is only one of the criteria which we feel are essential.

Senator NELSON. Do you have examples of some drugs for which you presented fully the indications for use and the contraindications and the side effects?

Mr. CALESA. Mr. Chairman, every one of our programs, and I would be happy to send you samples of all of our completed material——

Mr. SALTZMAN. If you are referring to full disclosure, we do not get involved in labeling and therefore we do not include all of the indications for all products and all of the side effects of all products. But the editors who control the content list the indications for all of the drugs in the therapeutic field, as well as the side effects for all drugs discussed and programed in that therapeutic field.

Senator NELSON. Would you send us some examples?

Mr. CALESA. We would be delighted to send you all of our material, sir.

Senator NELSON. Thank you.[1]

Mr. CALESA. Twelfth: Product advertising not be included in the educational material.

Thirteenth: The material conform as closely as possible to approved package inserts for all products.

Fourteenth: All material clearly identify the medical center and association sponsors, the producer, and the manufacturer providing the educational grant.

And finally, that the manufacturer actively participate in the distribution of the program.

When these criteria are met, we have the basis for achieving a common objective of our organization, academic medicine, organized medicine, the pharamecutical industry, and the Congress in providing better patient care through education.

Mr. GORDON. Mr. Calesa, may I interrupt for a moment, please?

From the middle of page 5 to paragraph 3 on page 6, as I read it, what you are saying is that the two primary reasons why the industry sponsors these programs are: (1) they produce drugs and they want to inform the physician about their proper usage; and (2) they wish to improve the detail men's knowledge of the products that they are promoting.

Is that not correct? Is that not what you said?

Mr. CALESA. Yes, sir.

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[1] Material too voluminous to be printed but retained in the committee files.

Mr. GORDON. Now, on page 7, you have used the word "independent" in several places—one, two, three, maybe more places. The previous witness from the Academy of Family Physicians stated, and I am quoting from his statement:

> It is accurate to suggest that drug companies are likely to support those exhibits which are favorable to a particular product of the company. Certainly it would be difficult, if not impossible, to envision a situation in which a drug company would support an exhibit which was unfavorable to a product of that company.

Now, Dr. Crout, Director of the FDA's Bureau of Drugs, and also a medical educator, testified that the educational materials subsidized by the drug industry have a systematic bias and are consistently tilted in the direction of therapeutic enthusiasm. He said that these materials have the appearance of independent scholarly productions, but which are, in fact, an integral part of the drug industry's overall promotional efforts, a more subtle part, of course, than straightforward promotional materials like advertising.

Then he added subsequently "The problem is not that drug industry money corrupts medical experts, but rather that the drug industry sponsor can choose among the many medical authorities on any given topic to support only those whose views already coincide with the interests of the sponsor. This ability of the pharmaceutical industry to select medical authorities that it wishes to support is the basic cause of the biases, as we shall see."

So, the inevitable question is, given your complete or almost complete financial dependence on the drug industry, how can you achieve independence and objectivity—that is one question. Two, who are your sponsors? And three, have your programs condemned the use of a drug marketed by one or more of your sponsors?

Mr. CALESA. OK. There were a lot of things said there. Let me see if I can take that apart piece by piece.

First of all, to answer your question, the peer review system which we have established—the reason we can have objectivity is because we do not have the pharmaceutical manufacturers select the physician participants. That is point No. 1.

Point No. 2, if we establish a multiple number of criteria, which includes review by as many different people, groups, organizations, and societies as we possibly can find, anyone who is willing to review the material that we produce in a field—if we are doing a program on epilepsy, we ask everyone involved in the field of epilepsy to review that particular program.

Mr. GORDON. Well, let's be specific. There has been a lot of talk about the overuse of antibiotics and its consequences. There has been a lot of talk about the overuse of chloramphenicol. There has been a lot of talk about the overuse of clindamycin and lincomycin.

There has been a lot of talk about the overuse of oral hypoglycemic drugs.

Have you had any programs at all which brought this out?

Mr. CALESA. We have produced no programs either in the field of diabetes or infectious disease at this time. We have not been involved in those areas. The areas we have been primarily involved in are the areas of prevention. The areas where we have done the vast amount of our work have been hypertension, hyperlipidemia, obesity.

Mr. GORDON. How about obesity? How about the use of anorectic drugs?

We have had testimony from various experts that they are not much good and that they should not be used.

Have you had any programs along those lines?

Mr. CALESA. We produced a program on the diagnosis and management of obesity which did not even mention drugs, except in one sentence, I believe, which said something to the effect that if drugs are used, then they should only be used on a short-term basis and a very highly critical review should be made by the physician before using any such drugs, and specific criteria were spelled out in that direction. That was like about a one-paragraph statement out of a 30-minute film, along with about a 32-page monograph.

The emphasis of the program that we did on obesity was behavior modification—first diet, then therapy, drugs on a short-term basis if absolutely necessary, and behavior modification to effect permanent weight control.

Mr. GORDON. Do you have a copy of the transcript of that particular program?

Mr. CALESA. Yes; I do. I will send it to you.[1]

Mr. SALTZMAN. Referring to Dr. Crout's statement, you mentioned something about do our programs ever include negatives on the sponsoring client's product or any other product. I think the program for which Dr. Crout gave us some credit, that we developed in conjunction with the National Heart and Lung Institute, I believe Dr. Crout's statement indicated that, if anything, the manufacturer who supported the program's product was put in an extremely negative position.

Mr. CALESA. That program was called, "Dialogues in Hypertension."

I would also like to comment on this. I am not certain that I have gotten in all of the parts and pieces of your original question, of how things are tilted toward therapeutic enthusiasm. I think there was one misconception. I say that in this context. I happen to agree with a great deal of what Dr. Crout had to say. One of the misconceptions is that what we are doing is providing educational programs about drug therapy. We are not.

What we are doing is providing educational programs about the diagnosis and management of a particular disease in a particular therapeutic area. I would say along those lines the emphasis is perhaps, let's say out of a 1-hour educational program, it is perhaps 10 percent, if that much, devoted to drugs. And when we do devote a section to drugs—this is not always true; I no not want to say that—but it is primarily true. When we discuss drugs, we are talking about all drugs in the field.

It may range up to 40 percent; but it is certainly not 100 percent. And we do discuss all alternative methods of therapy, including and starting with nondrug therapy and nondrug methods.

I do not know now if I have gotten through answering all of your questions, except that I would like to go back and say this. If the pharmaceutical manufacturer is going to sponsor educational ma-

[1] Material too voluminous to be printed but retained in the committee files.

terial, and he is going to do it in accordance with the criteria which we have established, what he is doing is providing us with a grant of funds and allowing us the opportunity to produce a fair, balanced, and honest educational program which has been reviewed by as many groups and as many different people and in as many different ways as we possibly can before the educational program is provided to the physician.

Now, I think the very important thing here is who supports these kinds of efforts. I think the answer to that question is the manufacturers with the better products, the high-quality products.

Mr. GORDON. What do you mean by "high quality products?" Is there anyone with a low-quality product on the market?

Mr. CALESA. Let me state it differently.

People who are leaders in a particular therapeutic field, people who have, let's say, the better recognized products.

Mr. GORDON. You are talking about the brand name companies, the trade name companies, are you not?

Mr. CALESA. Yes, sir, I am.

Mr. GORDON. The members of the PMA?

Mr. CALESA. Yes; I am.

Mr. GORDON. OK.

Let's not talk about high-quality products, because according to the Food and Drug Administration, all of the products on the market are high-quality products.

Mr. CALESA. OK, fine.

Did I answer all of your questions?

Should I go on?

Mr. GORDON. I think you have answered them.

Mr. CALESA. It must be pointed out that there is a difference between what I have described as education which does not meet all drug labeling requirements and education which does meet all drug labeling requirements and is considered as advertising.

If all education supported by pharmaceutical manufacturers is to be considered as advertising and thus subject to all drug labeling requirements, serious shortcomings will occur.

First, that automatically means that the pharmaceutical manufacturer will be involved in the selection of physician participants and that they will review, edit, and have final content approval of all content. The reason is that by Federal requirements they must protect themselves against physician participants saying that may be considered accepted medical practice or the individual physician's opinion but deviates from the approved labeling.

The editorial board participants do not accept this infringement by Federal Government authority over what they want to say. In addition, package inserts in the educational material are a tacit endorsement of the manufacturer's products. The effect of drug labeling on education is an infringement on free speech and presupposes that content control cannot be achieved by the medical profession.

The Food and Drug Administration has proposed a series of guidelines to differentiate education from advertising to overcome these problems. As you can see, we agree with all but one of these guidelines and have introduced additional guidelines.

There is one serious difference of opinion. They propose that the intent should not be for ultimate distribution by the pharmaceutical industry. If the manufacturer supporting the program meets all of these criteria, why can't he give it away? He has the distribution channels and can use them to get the program to the doctor. If he paid for the program and has the ability to help get it used correctly, why shouldn't he do this? If he can't do this, why should industry pay for it?

Finally, our opinion is that if the manufacturer is forced to produce educational materials as advertising, we will all lose—the medical educators, medical schools, organized medicine, the pharmaceutical manufacturer, the doctor in practice, and because of these losses the patient and the American public loses.

Mr. GORDON. Sometimes, Mr. Calesa, the line between education and a subtle form of advertising is rather thin. The FDA has to make that determination. Is it a subtle form of advertising, or is it really education?

Mr. CALESA. I think the FDA has spelled out criteria to define how that line should be evaluated, and we, as I just mentioned, are in full agreement with the criteria that they have spelled out, with the exception of one, which is distribution.

So, I accept that problem, and I accept the way they propose to handle that problem.

Mr. GORDON. One thing that puzzles me is why will the doctors not pay for this? Lawyers and economists and other occupations pay for their education. Why would a doctor not want to do that?

Mr. CALESA. Well, they perhaps were spoiled by the industry a number of years ago. But the hospitals will; the hospitals will pay for educational material. They will pay for the hospital staff, and they will pay for the allied health professional. But physicians in private practice will not. According to our studies, the physicians in private practice never had the kinds of demands being placed on them for obtaining continuing medical education, as there are now.

We have produced programs both with and without labeling. Obviously, we favor the former as do all of our medical advisors. As a matter of fact, Dr. Crout, in his appearance before this committee, complimented Health Learning Systems for a program we are producing called, "Dialogues in Hypertension," which is developed in cooperation with the national high blood pressure education program of the National Heart and Lung Institute, the Council for High Blood Pressure Research of the American Heart Association, and the National Kidney Foundation, under an educational grant from Smith Kline and French Laboratories. This program is produced according to the criteria previously discussed.

Dr. Crout then went on to describe a program which we produced under a grant from Marion Laboratories which he said was an example of education that was promotional. In this case it should be pointed out that the program produced met the criteria for drug labeling. It contained the package insert on the films and in the monographs and was edited by the Marion Laboratories' medical and legal departments in accordance with labeling requirements.

It is exactly for this reason that we feel labeling should not be a part of an educational program, assuming the other criteria have

been met. I would like to point out for the record that it was incorrectly stated at these hearings that Health Learning Systems was the producer of a closed-circuit television symposium on diabetes under contract to Pfizer Laboratories.

The question has been raised regarding the extent of industry-sponsored educational material.

We contend at this stage that it is quite small in relationship to their total marketing expenditures. Specifically, from industry-reported sources, the percentage expended for audiovisual presentations was .8 percent in 1972, 1.7 percent in 1973, and 2.1 percent in 1974. This is against a base in 1974 of $909,534,000.

Mr. GORDON. Mr. Calesa, I think that is not a relevant statement. The question is what percentage of the postgraduate educational material is industry sponsoring, not what percentage of its advertising and promotional expenditure constitutes the kind of expenditure that you are talking about.

Mr. CALESA. On the next page I go into that. I was just trying to make a point that the amount of total advertising expenditures against a base of $1 billion is relatively small and insignificant in relation to the total amount of dollars being expended, so that there is not an overwhelming volume of money being poured into this aspect of pharmaceutical marketing. That is the only point I wanted to make.

I said this mainly as a prelude to the next statement that I would like to make, which is that the "Journal of the American Medical Association" publishes an annual report on medical education in the United States. In the most recent publication it listed 4,862 courses from 554 different primary sponsors for the year 1975–1976. The sponsors were medical schools, hospitals, medical societies, and voluntary health agencies, not pharmaceutical companies.

Mr. GORDON. Do you know the percentage, the number of people who are exposed to this type of educational material as contrasted with the university-based medical schools?

Mr. CALESA. I do not have those figures. But I was just going to say that in this issue of "JAMA," whatever facts are available are published in here, and I can send that to you if you wish.

Mr. GORDON. Thank you, but we have that.

Mr. CALESA. I do not know the answer, except for what is in there.

The question has been asked how do we select subjects and physician participants? The answer to that question is that we use our medical faculty of advisors whom we consult with regularly.

In addition to advice from these consultants for selection of subjects, we use the "Forward Plan for Health," published by the Department of Health, Education, and Welfare, and "Health U.S.—1975," Department of Health, Education, and Welfare, and surveys formerly conducted by regional medical programs among physicians. From these sources we select subjects and attempt to obtain funding from the companies who are leaders in the selected field.

Once funded, we approach a medical school, medical school department, or health agency to sponsor the program and determine an appropriate executive editor. The executive editor selects the editorial panel. We make agreements with all of the physicians that editorial content controls rests exclusively with them. They have

final sign-off on the content before we go into production of any of the materials.

When the content is ready to go into production or during the production, we submit the material to as many reviewing medical organizations as possible for accreditation and/or endorsement.

When the education program is completed, we ask the sponsoring agency to write letters and other materials to create awareness of the availability of the educational program. We then give the completed programs to the pharmaceutical manufacturer who distributes the material, making all physicians aware of its availability and use, at no cost to the hospital, medical society, medical school, or physician.

It is the responsibility of the manufacturer to get the materials to the user and assist in making physicians and allied health professionals aware of the program. The only involvement of the grantor is to determine the media and this is based upon their available budget, pay the bills, and assist in the distribution of the program. This is not true where labeling is to be included with the educational material. In this case, the manufacturer is very actively and directly involved in the content of the educational programs.

We have attempted to work very closely with the Food and Drug Administration in developing our educational programs and for the most part, with the exception of distribution noted previously, we agree with all of their criteria for program development.

Based on what we have described today, we feel that high quality medical education programs can be developed effectively to meet the ultimate needs of the patient. If the Government were the primary source of funding for continuing medical education, Health Learning Systems would attempt to be the producer and would take the exact same approach in producing programs as we currently take if XYZ pharmaceutical manufacturer were providing the grant.

We have had the opportunity to observe dramatic results with our programs. We have received numerous letters of praise from Government officials, from academic medicine, and most importantly, our learners, the practicing physicians, who have participated in and been exposed to the programs we have produced.

On a recent closed-circuit television program which we produced, attended by over 11,000 physicians and allied health professionals, we asked the audience to evaluate the program content. With 1,993 responses, the results were: Met my expectations—99 percent; provided important information—97 percent; provided help for better patient care—97 percent; rated speakers excellent to good—100 percent.

On the closed-circuit television program produced by Health Learning Systems on hypertension which was the basis for producing "Dialogues in Hypertension" for which we were complimented by Dr. Crout, I would like to quote a letter dated January 7, 1974, from Dr. Theodore Cooper, then Director of the National Heart and Lung Institute, to Mr. Robert F. Doe, president of Smith Kline and French Laboratories:

As you are undoubtedly aware, one of the principles of the National High Blood Pressure Education Program is that by combining the resources, and by cooperating with each other, the private sector and the Federal Government

can make very significant accomplishments in this critical public health area. If you have no objections, we would like to use the development of this symposium as an example of this principle in action.

As one of the primary companies involved in the communications program toward physicians on hypertension, we have seen from a 1974 study from the National Heart and Lung Institute called "Hypertension Detection and Followup Study" that initial visits to doctors increased 38 percent for hypertension and hypertensive heart disease since 1971. The number of people with hypertension not aware of their disease decreased from 50 percent to 29 percent, and in a separate study of 760 clinicians published in the May 1975, issue of "Medical Opinion," it revealed that the number of physicians who take blood pressure readings increased in 5 years from 50 percent to 90 percent, that 73 percent of physicians routinely use laboratory tests for hypertensive patients, and that the number of patients now talking about hypertension with their physician increased from 9 percent 5 years ago to 36 percent today.

We are pleased to say at this time we are working with the National Board of Medical Examiners to produce a national self-assessment on hypertension for physicians under an educational grant from Smith Kline and French Laboratories. This is an outgrowth of our "Dialogues in Hypertension" program.

Every day we receive letters on one or more of our programs from physicians in practice who thank us for our contribution to their patient care needs. We are young and this industry is young. We have made mistakes. We have not always been able to include all the Food and Drug Administration criteria described in this statement in every one of our programs.

We are concerned, dedicated, and proud to be part of an effort where we have seen visible signs that in some small way we have contributed to an improvement in the quality of health care in this country and abroad.

Thank you for allowing me to share this with you.

Senator NELSON. Thank you very much.

Without personally commenting on the quality of the programs, since I have not seen them I am not qualified to judge them anyway, is it not true, nevertheless, that the drug companies are: (1) Involved obviously, because their interest is in promoting the sales of their products; (2) does not this type of system in which they distribute the programs and materials to the hospitals and the physicians themselves gives them a formalized relationship with the institutions, with the medical schools, if they use the materials, hospitals, teaching hospitals, other hospitals, give them a formalized institutional standing which strengthens their position in order better to promote the business that they are engaged in?

Is that not true?

Mr. CALESA. Well, Mr. Chairman, I do not think that it gives them a feeling of association with that particular university. I do think it gives them a better stature. I do think it gives them, let's say from an institutional advertising point of view, greater stature than someone else might have by virtue of the fact that they have sponsored a program that a multiple number of people are involved in.

But I have to go back again to the most fundamental issue, and

that is, if we are developing a program which includes in its criteria a total number of directional inputs and content control from all of the major factors in the medical community involved in that particular field of medicine, and then providing that, handed out by the pharmaceutical representative, what we have done is we have controlled the content and the quality of the type of story, the dialogue between the representative and the physician to the greatest extent that we possibly can—that is what we do, and that is what we attempt to do.

Senator NELSON. Well, that is the purpose of the hearing. But I think it really raises the fundamental question of whether drug companies, promotors of drug products, should be allowed by hospitals and physicians to intrude into the education business in any fashion whatsoever since everybody knows their bias.

In other words, would it not be much better if they were just out of this business totally, and if all of the postmedical education were in the hands of the scientific community and the medical schools, since, it seems to me, there is no way to avoid the interjection of substantial bias and/or ban prestige and benefit to the promotor of the sale of drugs?

Mr. CALESA. Well, Mr. Chairman, again I have to say that by virtue of the fact that we address ourselves in every case to direct sponsorship by a medical school or a medical school department, we are, in fact, doing exactly what you are saying, which is keeping control of the course within the medical school and the medical universities.

What we are doing, and what we happen to believe in very strongly, is a spirit of cooperation, and that spirit of cooperation asks that all of us provide the resources that we have, that they can contribute most effectively, and what the pharmaceutical manufacturer is contributing, based on the criteria we have outlined here today, are fundamentally financial resources and distribution resources.

Senator NELSON. I understand that.

Since I do not know, let's assume that your programs or anybody else's programs paid for by the drug companies are of the highest scientific quality. Let us assume that.

That probably is even worse, as a matter of fact. If they were of low quality, it might be ultimately beneficial to the medical profession because the reputation of the company would not be enhanced.

What you really have is you produce a high-quality program. So, there is this wonderful company doing these wonderful things. However, in the promotion of their drugs elsewhere, in the medical journals and in the throwaways, none of that criteria is followed, except that which is forcibly imposed upon them by the FDA; so, they have the prestige now because they did something very high quality on hypertension.

Now comes their promotion of drugs in that field, or in any one of a dozen others. The physician already has subtly been co-opted by the company because if they produce such a good program on hypertension or something else, what they are saying over here in their advertising and promotion must be of the same quality.

I am not so naive as not to understand that. Neither are you; nor are they. That is their purpose—to infiltrate the whole educational system in order to promote the sale of drugs, at which they have been tremendously successful.

There are some of the finest clinicians in this country testifying that we probably use 4 or 5 times, and some of them have said 10 times, as many drugs as in the interest of the health of the patient. They have already co-opted a good part of the medical profession in terms of their selling them the idea that you ought to prescribe a drug for everything else. How would anybody explain that in some careful studies done by physicians themselves, they find that 95 percent of the doctors are prescribing something for a common cold, and of those, 65 percent is an antibiotic. Since a cold is a viral infection, the target organism is not affected by an antibiotic. Every witness we have had has testified that there is no way to justify the prescribing of an antibiotic for the common cold. Then why were they prescribed? Because the company was very good at selling.

This, it seems to me, is another subtle technique for enhancing their prestige in order to make more acceptable their promotion of their products in other forms and media, through detail men, through advertising in the magazines. Isn't that clearly what is going on?

Mr. CALESA. Well, I would take some exception to that, Mr. Chairman. I would say the following.

First of all, at several hearings here, one of the things I keep reading about in the pink sheet is that pharmaceutical manufacturers are being encouraged to educate and to inform, rather than to promote. I think what we are trying to do is to be the implementer or the catalyst of that kind of approach. I think by virtue of the fact that we can comprehensively package educational material in a therapeutic field, and provide it in a fair and balanced format, and provide it both to the sales representative as well as to the physician, you now have the basis for a better dialog, so that many of the problems that you are describing are not going to occur.

What do you do without it? You just maintain the same basic system that you have expressed concerns about in the past.

What we are trying to do is to step forward. We are trying to say, OK, perhaps there were problems with what took place in the past. Let's now do something about it, and that is what we are attempting to do.

Senator NELSON. I am not commenting on the quality of the work that your group does at all. The tragedy, I think, is that there is a vacuum here. There has been a failure on the part of the medical profession, the medical schools, to provide the continuing education of the physician in an adequate way. So, along comes the drug companies and they say let's jump into the vacuum, which is what they have done. They do not belong there. That is for the medical schools. That is for the scientific community, and in my judgment not for the drug company.

I am not quarreling about your organization and its work at all. I think the great sadness is that there is a vacuum for which apparently some need is supplied by the wrong people. That is all. They are perfectly fine people. They do not belong in the drug education business. That is for the scientific community.

Mr. CALESA. I agree with you, and that is exactly the approach that we take. We keep them out only to the extent that they are providing the funding and the distribution.

I agree with you. I think they do not belong there.

Senator NELSON. But that is the real subtlety of it. They gain great prestige by promoting education, and they gain access, and they gain reputation, which enhances their credibility, of course, in terms of selling the products, which is what they are in the business of doing. That is clear enough.

Mr. CALESA. Yes; that is the business they are in. There is no question about that.

Senator NELSON. Fine.

Thank you very much, everyone.

We appreciate your taking the time to come.

We will be hearing next from some medical educators on this whole problem.

Thank you.

Mr. CALESA. Thank you.

[Whereupon, at 11:55 a.m., the subcommittee recessed, to reconvene upon the call of the Chair.]

APPENDIX

MATERIAL SUPPLIED FOR THE RECORD BY THE SUBCOMMITTEE ON MONOPOLY

[September 17, 1975]

STATEMENT OF COMMITTEE ON SCIENTIFIC EXHIBITS IN REGARD TO PHARMACEUTICAL SUPPORT OF SCIENTIFIC EXHIBITS

The scientific exhibit is an established and efficient method of continuing medical education that brings new information from the research scientist and revised correlations of old information from the academic community for the attention of the practicing physician. A scientific exhibit is designed to emphasize a few points and not to be an in depth presentation of any subject. Because exhibits that contain too much information seldom attract a large audience, it is necessary that the amount of information on any exhibit be limited.

By reviewing scientific exhibits, physicians are able to learn more in less time about a wider variety of subjects than by any other educational method. The depth of the education is regulated by the interest and perceived needs of the physician. Those who wish a superficial knowledge of the advances in specialities other than their own, may take a quick walk through the entire exhibit. Those who wish to learn more about a subject may spend considerable time asking questions of the exhibitor. This informal discussion between the exhibitor and the practitioner is a valuable learning experience for both and not infrequently leads to further correspondence between the two. The scientific exhibit has been one of the main attractions of the American Medical Association meetings for the past seventy-five years and this educational method should be preserved.

Recently, the Food and Drug Administration has ruled that those exhibits which have been sponsored by pharmaceutical companies should be considered to be promotional rather than educational even though no trade names and no names of a pharmaceutical company are used. The fact that the exhibitor has tabulated the data and is responsible for the editorial content of the exhibit, does not keep those exhibits from being promotional. If an exhibit is designated as promotional it must conform to the Standards of approved labeling. This means that unapproved indications and unapproved dose schedules cannot be used. All data in regard to comparative efficacy and safety must be based upon controlled clinical trials and not upon clinical experience. By this definition, approximately 80 percent of the scientific exhibits at the AMA meeting are promotional and probably half of these are in non-compliance with the regulations for the labeling of pharmaceutical products as set forth in the federal register.

If these proposed FDA regulations are complied with, few pharmaceutical companies will be willing to sponsor scientific exhibits. The scientific exhibit will degenerate into a collection of homemade displays prepared by a few physicians who feel strong enough about a given subject to spend several thousand dollars of their money. Past experience has shown that few of these unsponsored exhibits are worthwhile. Strict interpretation and enforcement of the proposed rules would seriously retard medical communication. It is recommended that the AMA should take a strong stand in attempting to persuade the FDA to adopt more reasonable and permissive attitudes toward the scientific exhibit.

A knowledge of the logistics and the costs involved are necessary before anyone can formulate reasonable regulations for scientific exhibits. Presenting a scientific exhibit involves the following steps:

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1. COLLECTION OF SCIENTIFIC DATA

Usually the exhibit serves as a method of presenting the conclusions of research that the exhibitor has worked on for several years. If the data is old and has been published, reprints can be reviewed before exhibits are accepted. However, this is impossible with new data and the exhibit committee is forced to rely upon the abstract, the reputation of the exhibitor and the reputation of the institution from which he comes. The support for this research may have come from a pharmaceutical company but often it has come from several sources. Exhibits which serve as a review of a particular disease may have data that comes from several sources and not the research of the exhibitors.

2. DESIGN OF THE EXHIBIT

Exhibitors sometimes design their own exhibits but professional help is usually needed to have an exhibit that effectively conveys the message of the exhibitor.

3. EDITING OF COPY

Each exhibitor decides what is to go in his exhibit and has complete editorial responsibility for the text of both the exhibit and the brochure. Before an exhibit is made, it is customary to have the proposed copy reviewed by several people. If a pharmaceutical product or medical device is mentioned, it is especially helpful for the manufacturer to review the copy for accuracy, legality and clarity of presentation. This review of copy does not imply that the exhibitor has delegated editorial control or responsibility for the exhibit to anyone else. If this review did not exist, exhibitors might make what they believe to be honest statements about a product but which are more extravagant than the company would make. This editorial review helps to prevent errors and should be continued.

4. EXHIBIT CONSTRUCTION

A few exhibits are constructed at home with cardboard, wrapping paper and crayons, but these seldom receive enough attention to justify the time and effort of the exhibitor. Therefore, most exhibitors use professional exhibit makers to construct a free-standing, self-contained exhibit that will attract the attention of physicians.

5. SHIPMENT, SETUP, DISMOUNTING AND STORAGE

In most convention halls it is necessary for the exhibitor to hire members of the Teamsters Union to transport the exhibit to the designated space, union carpenters to set up the exhibit, and union elecricians to screw in the bulbs and plug in the cords. Union personnel are also required to dismantle an exhibit. This is not only expensive but requires considerable experience and time on the part of the exhibitor to see that it is properly done. Many pharmaceutical companies have experts in this field who can do the job more efficiently than the average physician.

6. BROCHURES

Physicians wish a summary of many exhibits to review at leisure. If the material has previously been published, reprints may be used but the lag time between competition of a project and the publication in a medical journal usually makes this impossible. Some brochures are simply photographs of the exhibit, but most are more carefully prepared by an artistic and innovative printer. Pharmaceutical companies often obtain extra copies of those brochures that are favorable to their products and use this in their sales promotion. Brochures that contain material that has a substantial disagreement with the package insert cannot be used. Consequently it is desirable for the pharmaceutical companies to review the brochure before it is published.

7. PERSONNEL STAFFING THE EXHIBIT

For a meeting as large as the AMA it is necessary to have two physicians in attendance in order to keep the exhibit staffed at all times. In some cases, other

professional personnel such as nurses and technicians may be used instead of/or in addition to the physicians. An unattended exhibit loses much of its teaching value. Unless the personnel staffing an exhibit are adequately compensated, only the most dedicated will stand there all day.

8. ESTIMATED COST OF PREPARING AN EXHIBIT FOR THE AMA

1. Collection of data—$100 to $100,000.
2. Design of Exhibit—$200 to $1,000.
3. Editing of Copy—$100 to $1,000.
4. Construction of Exhibit—$3,000 to $30,000.
5. Shipping and Setup—$400 to $1,200.
6. Preparation of brochures—$300 to $3,000.
7. Expenses of personnel—$600 to $3,000.
8. Total cost for exhibit (except No. 1)—$5,000 to $40,000.

Few physicians or scientific investigators can afford to have an exhibit unless they receive financial support. In the past, large clinics and medical centers supported exhibits as part of their public relations and professional education programs. The source of these funds has been severely reduced lately. Some exhibits have been supported by professional societies and lay health organizations, but too often these organizations are more interested in recruiting members and raising funds than in educating physicians. Support from the federal government through National Institutes of Health, Armed Forces Institute of Pathology, the Food and Drug Administration and the military forces has helped in the past, but this has recently been greatly reduced. Approximately half of the federally supported exhibits have had good scientific value, but the other half have been ineffectively presented propaganda designed to enlist the physicians' support for a specific government program. The only other source of financing exhibits has been pharmaceutical companies. Either directly or indirectly this pays about eighty percent of the cost of the scientific exhibits. If ill-conceived federal regulations eliminate this support the scientific exhibit will disappear. Not only will the medical profession lose this most efficient single method of medical education but many of our great medical conventions will disappear. The AMA and most of the state medical societies would cease to have large scientific programs and would settle for a business meeting of the House of Delegates. Continuing Medical Education would then consist of the free standing papers in the specialty societies and the planned courses and symposiums put on by various groups. No longer would there be one place where physicians from all different specialties could meet and freely exchange knowledge.

Some pharmaceutical companies do have altruistic medical directors who are willing to support a purely educational exhibit but the financial directors who approve the expenditure of funds must be assured of getting their money's worth. Corporate identity is possible in the "sponsored teaching exhibits", but is not now possible in the scientific exhibits. Product identity in the scientific exhibits is possible, but is obscured by the use of generic terms throughout the body of the exhibit. Using a scientific exhibit for promotional purposes is contrary to the spirit of the regulations of the AMA. However, the AMA cannot be responsible for anything that happens to an exhibit or to the brochures after the meeting. In this highly competitive society few pharmaceutical companies can afford to support a purely educational exhibit and very few would be willing to support an exhibit under the proposed FDA rules.

There is a gray area of promotional exhibits that lies between the truly scientific exhibits and the known commercial exhibits. It has been the policy of the AMA exhibit committee to guard against promotional abuse in the scientific exhibit. We think that we have done a good job in the past and hope to continue. However, the rigid implementation of the rules proposed by the Food and Drug Administration would retard medical communication and not improve patient care. It is recommended that representatives of the AMA meet with the Food and Drug Administration to consider ways of modifying the severity of these rules.

JAMES M. MOSS, M.D.

The University of Vermont
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BURLINGTON, VERMONT 05401

April 8, 1974

Alan B. Lisook, M.D.
FDA Bureau of Drugs
Washington, D.C. 20000

Dear Doctor Lisook:

Having read of your excellent investigation of experimental trials of therapy, especially in cooperation with drug manufacturing concerns, I thought I should address this letter to you, though it may be more appropriate to call to the attention of the Commissioner of the FDA what I have to report. Would you be good enough to let me have your reaction to this matter and, if appropriate, pass the information along to whatever other person in the organization you think it best review the matter.

Enclosed are copies of an initial letter from Modern Medicine Publications soliciting my participation in a Forum and also of subsequent correspondence between us. As you can see from the initial letter, dated July 31, 1972, I was asked to submit a statement concerning the management of migraine. I believe three other authorities around the country were also asked to contribute.

The initial manuscript which I submitted was returned with some deletions to which I objected because of the initial assurance in the soliciting letter than any point of view was acceptable. I was struck by the fact that my emphasis on the lack of specific value of a brand name shotgun preparation (Fiorinal) had been deleted. Also deleted was the statement, "The criteria for distinguishing purely muscle contraction headaches from vascular headaches are tenuous and vague", a statement directly counter to the manufacturer's (Sandoz) claim of specificity of their drug for "tension headache". Because of my insistence, the Editor agreed to a compromise version which left my opinion intact. Elsewhere in the manuscript I state, "No drug to date, whether by controlled or impressionistic trials of therapy, has been shown to be predictably or permanently effective in eliminating attacks in the majority of cases". Further on, I state, "none has been shown to be more effective than conscientiously and sympathetically applied psychotherapy. Once the migraine personality becomes well known to the physician and he develops increasing skill in dealing with it, including assistance to the patient in modifying his attitudes, habits of living, patterns of emotional reaction, and/or environmental stress, the results are as good as with prescribing anything that comes out of a bottle. Common sense psychotherapy is every doctor's business, but the cost in time and energy for carrying out the only truly effective approach to the prevention of recurrent headaches causes it to be almost universally neglected in favor of pharmacotherapy alone -- an easier way out but less successful. This is not to say that agents counteracting emotional tension and promoting relaxation are not often useful accessories."

A later statement was, "That drugs with possible preventive vaso-constrictor action regularly administered (methysergide, inderal)* are useful once status migrainus sets in has not yet been established." (* Sansert, Propranolol).

In the first paragraph of the manuscript I originally had some rather strong statements suggesting mismanagement of headache based on faulty conceptions of mechanism, which might assuage the physician's conscience but dupe the patient and the fact that patients often improved temporarily and non-specifically in response to any management, which protracted the unintentional charlatanry. I later spontaneously realized this language was too strong and deleted it, substituting entirely innocuous language.

This all took place before an abrupt and unexpected letter of rejection from a Miss Sylvia Covet, Editorial Director, in a position apparently to supersede the decisions of Dr. John H. Rosenow, the Senior Medical Editor, with whom I had been corresponding. Just two days prior to receiving her letter, we had a long distance telephone call from the Editorial offices requesting a different photograph, since the one sent was too dark for reproduction. About this time I also learned of the pressure Sandoz was under to substantiate its claims for Fiorinal by the FDA and also Sandoz's solicitation of investigators for alleged sound experimental trials of therapy utilizing this drug with the very inviting proposition of payment of $200 for each subject so investigated. I have enclosed copies of my remonstrance to Editor Covet and her replies. Nevertheless, in view of the specific provisions in the initial solicitation to the effect that any stated opinion would be acceptable, the hours of time and of effort I devoted to the project, my nationally known insistence on integrity in experimentation, especially trials of therapy, the cavalier and discourteous and disrespectful action taken by Editor Covet, I frankly was outraged and strongly suspicious of spoken or unspoken collusion between Modern Medicine and Sandoz. Whether I am correct about the latter or not, there is no question that the initial promise was not held to and the agreement not kept. Therefore, I would like to see this matter pursued further if it is within the province of the FDA to do so. As I indicated in the letter to Miss Covet, this sort of bias on drugs indulged in by a magazine that subsists entirely on advertising revenues and distributes its issues free to physicians all over the country should perhaps come as much under the scrutiny of the FDA as do the manufacturers and pseudo-scientific clinicians who carry out their experimental trials of therapy.

If you would like further indications of my experience with problems of headache, previous experimental work with H. G. Wolff at Cornell over many years, and published papers of mine in connection with aspects of experimental trials of therapy in other areas, I should be glad to supply them. I would be glad to send you a copy of the first version of the manuscript, but my request to the Editor to return copies of the revised manuscripts which I sent have never been complied with.

Since I visit Washington from time to time in connection with my collaborative work with Dr. Sever in the NINDS, I would be happy to stop at your office for further discussion of this matter if you deemed it of any use.

Sincerely yours,

George A. Schumacher, M.D.
Professor of Neurology

GAS/sam
Enclosures - 8

The University of Vermont
DEPARTMENT OF NEUROLOGY, DEGOESBRIAND UNIT
MEDICAL CENTER HOSPITAL OF VERMONT
BURLINGTON, VERMONT 05401

July 1, 1974

Dr. Alexander M. Schmidt
Director, Bureau of Drugs
Food and Drug Administration
5600 Fischer Lane
Rockville, Maryland 20852

Dear Doctor Schmidt:

On April 8th, I sent a letter to Dr. Alan B. Lisook summarizing a situation which I thought constituted unethical action in drug promotion, or at least in suppressing criticism of a manufacturer's product, by one of the so-called "throw-away" journals, namely, Modern Medicine, distributed free to hundreds of thousands of physicians and supported financially solely by advertisements.

The Editors of this publication solicited a manuscript from me on the treatment of migraine, an area in which I have had considerable experience and originally did research work when still associated with Dr. Harold G. Wolff at Cornell Medical School in New York years ago.

The essay was solicited without promise or expectation by me of any compensation, and I was happy to provide what I thought was a statement based on sound scientific opinion. I enclose a copy of the original letter of solicitation.

In my treatment of the subject, I frankly minimized the value of certain drugs, particularly Fiorinal, cast doubt on the entity, "tension headache" for which it had been promoted for years as an almost specific remedy and in general suggested that the reliance on a variety of drugs instead of other more time consuming and more effective approaches represented simply an easy way out for the doctor. It was only after I had submitted the manuscript that I learned to my surprise that Fiorinal was being subjected to critical investigation by the FDA and that Sandoz was under some compunction to prove its allegedly specific value, and providing handsome financial grants to physicians to carry out allegedly controlled experimental trials of therapy (this after the drug had been on the market for 20 or more years).

My manuscript was initially modified by the Editor, deleting some of my critical comments about the drug approach to headache treatment and especially omitting the statement that, "The mystique of the therapeutic specificity of Fiorinal for tension headache needs to be dispelled with the realization that it is merely APC combined with barbiturate". Because of my strenuous objections to this deletion, it was re-instated and I subsequently softened some of the harsher criticism I made of the usual approach to the treatment of headache.

Nevertheless, at the point of publication, when a picture had been solicited and sent in, there was a sudden and unexpected rejection of the manuscript by the top Editor, Miss Sylvia Covet, apparently in a superior position to the Editor with whom I had been corresponding. The explanation was simply (after six months and three revisions), "Your comments do not meet the criteria established for this series".

I forwarded additional material, including copies of correspondence and a copy of my manuscript, to Dr. Lisook because of my awareness of his interest in sleuthing the way in which drug houses get physicians to carry out trials of therapy with their drugs without adequate scientific control and suggested that this might be a matter for the FDA to investigate, that is, the possible unethical bias of magazines of this sort in their attempt at control of what authors say in relation to therapeutic approaches or drugs that might run counter to the interests of the pharmaceutical firms on whose advertisements they depend financially. I have had no response from Dr. Lisook, but am sufficiently concerned about the matter to want to press it and hence at this time am writing to you about it and expect that you will find time to let me have your reaction to it.

Sincerely yours,

George A. Schumacher

George A. Schumacher, M.D.
Professor of Neurology

GAS/sam
cc: Dr. Alan B. Lisook
Enclosure

April 12, 1973

Miss Sylvia Covet
Editorial Director
Modern Medicine Publications
4015 West 65th Street
Minneapolis, Minnesota 55435

Dear Miss Covet:

I regret that your letter of March 26, 1973 provides neither adequate explanation nor justification of your abrupt action in rejecting the manuscript on headache. It was rather evasive and did not truly respond to the facts I had pointed out in my previous letter which I still feel represent the essential truth of the matter.

It has become apparent now that even a journal, such as Modern Medicine, as well as drug manufacturers themselves, can have a biasing influence upon readers in connection with sound scientific appraisal of treatments or medications because of ulterior motivation. In view of this, I believe the FDA should bring a journal such as yours under its scrutiny as well as drug manufacturers and it is my intention to bring this matter to the notice of the FDA in complete detail. To reject the manuscript because it was too "incendiary" is a ludicrous comment in view of the strong differences of opinion that sometimes exist between critical scientists. It is an especially weak excuse after the wording of the initial solicitation of a paper from me by your Executive Medical Editor, stating specifically that the statement might contain "a scorching condemnation or a paean of praise". This action of yours is really quite a turnabout and could be explained only by the following relevant facts,

Sandoz now has full-page ads for Fiorinal on the back covers of the issues of the Archives of Neurology. The FDA, however, and rightly, has expressed some concern about the claims of the manufacturer for this drug. I have had the same criticism for twenty or more years. Plus, this situation provides one plain reason why you editorially deleted the comment in my manuscript indicating the non-specificity of this shot-gun preparation and raising the question about the validity even of a headache syndrome for which it is allegedly specific.

Your action is further more understandable in view of the decision by Sandoz, following the FDA's scrutiny, to recruit physicians in the headache field around the country to carry out therapeutic trials of the drug (paying the physician $200 for each patient included in this study) after the drug has been on the market for twenty years. This also tends to explain why Modern Medicine has decided to publish a Forum on the medical treatment of migraine. It would seem that it may have been suggested by Sandoz, probably

in consultation with and the approval of Dr. Arnold Friedman who put Fiorinal on the market, enabling Sandoz to make millions. It is obvious that both Dr. Friedman, professionally, and Sandoz, financially, have a large stake in what appears in the Forum, in view of the coming evaluation by the FDA.

Though you may have had other reviewers, I suspect that the dampers were put on the publication of my views by Dr. Friedman. I cannot conceive of any other clinical scientist in the headache field objecting to any aspect of the content of my statement. I have been practicing these principles and teaching them to students and physicians for thirty-five years with reasonable evidence of success. To request the opinions of four different physicians (whom I presume were sound clinical scientists with recognized research and clinical experience in the field) and then to turn the views of one down because of the negative comments of a reviewer with whose opinions my views did not coincide, is a grossly dishonest action.

The matter is sufficiently important to me so that I shall attempt to have it further publicized. I am submitting my statement on the management of migraine which you solicited and then rejected to whatever reputable neurologic journal might accept it, accompanied by a letter to the editor for publication describing the sequence of events in this case. I will speak personally to the Editor-in-Chief of one of the journals who is a friend and whose esteem and respect I have always had.

Though I doubt you will be interested, I am enclosing three mimeographed handouts, prepared by me, for medical students, physicians, and patients on the subject of headache. One is an outline of headache mechanisms and appropriate therapies derived from the work of Dr. Harold G. Wolff with whom I worked and carried out research for many years at Cornell before coming here. Another is a reprint of a published panel on headache to which I contributed extensively held in New York several years ago. The third is a pamphlet for patients discussing the headache problem and its treatment in comprehensive, yet simple and lucid form. Although it may appear a bit conceited to you, I am sure that if you take the trouble to read these, you will understand why I believe that your journal and the physicians who read it, as well as the vast army of headache sufferers, are the losers, not I, by your fundamentally dishonest decision to exclude my manuscript on a last minute basis from the Forum to which you invited its contribution.

Yours truly,

George A. Schumacher, M.D.
Professor of Neurology

GAS/sam

Enclosures - 3

MODERN MEDICINE PUBLICATIONS 4015 WEST 65TH STREET • MINNEAPOLIS, MINN. 55435 • (612) 927-4471

February 13, 1973

George A. Schumacher, M.D.
The University of Vermont
Department of Neurology
Medical Center Hospital of Vermont
Burlington, Vermont 05401

Dear Dr. Schumacher:

I am enclosing a revised copy of your remarks for the Forum on headache. We have incorporated the changes you suggest and are using the "compromise" paragraph three that you submitted in your letter of February 5th. On some of the changes our people made, there was perhaps a too-zealous insistence on our particular style and conceptions of grammar. On many of these, it seems to me, there is room for honest difference of opinion, and we are therefore using your versions. In some of the changes that we made in your paragraph three, I think we were just plain wrong.

Thank you for your interest and concern. Your contribution will make this Forum stimulating, interesting and worthwhile. I'd appreciate it if you could return the approval form as soon as possible.

Sincerely,

John H. Rosenow, M.D.
Senior Medical Editor

JHR:lbs

Enclosures

THE MANAGEMENT OF MIGRAINE

Significant progress in the management of what H. G. Wolff termed "man's most prevalent distress" is unlikely until presumably authoritative writers and the vast majority of practicing physicians abandon unproved and unscientific concepts, reliance on anecdotal experience, and semantic misnomers. Notions of such alleged entities as "histaminic cephalgia", "allergic headache", "sinus headache" (excluding acute suppurative inflamation), "eye-strain headache" and a host of others persist in common medical parlance for ordinary vascular headache (HA) and continue to provide convenient handles for (mis)management which assuage the physician's conscience and dupe the patient. The fact that the patient often improves -- temporarily -- protracts this unintentional charlatanry.

Though all the links in the chain of pathogenesis remain yet to be ascertained, for practical purposes recurrent (HA's)unassociated with demonstrable intracranial, extracranial, or paracranial disease should be considered as owing to cranial artery distension, with or without components of sustained cranial muscle contraction. The criteria for distinguishing purely muscle contraction HA's from vascular HA's are tenuous and vague. If "tension" HA's exist, they form but a small fraction of the vast army of vascular HA (migraine) sufferers, constituting 10% of the world's population.

For HA's of moderate intensity a nap, with or without aspirin or APC, often suffices. Strong black coffee and aspirin(with or without barbiturate) is effective in a few subjects. The mystique of the therapeutic specificity of "Fiorinal" for "tension" HA needs to be disspelled with the realization that it is merely APC combined with barbiturate. When HA is too severe to respond to simple analgesics, caffeine, and/or sedatives, more intensive pharmacotherapy directed toward cranial vasoconstriction is indicated.

Ergotamine tartrate (Gynergen) is the best agent, most predictably effective intramuscularly or intravenously, but also, in perhaps 2/3 of subjects, orally (sublingual or ingested) rectally, or inhaled via spray atomizer. Its combination in proprietary preparations with caffeine (also a cranial vasoconstrictor) for oral or rectal administration appears to enhance its effect. In isolated failures there is little choice but to fall back on potent narcotic analgesics such as meperidine (Demerol) or codeine. The necessity for several hours or a day's rest following relief from a headache is usually neglected by the physician or ignored by the patient.

Though the availability of reasonably predictable relief from a nagging headache or an acute "splitting" hemicrania is reassuring knowledge to the patient, the most desired aspect of management most certainly is prevention of recurrent attacks. No drug to date, whether by controlled or impressionistic trials of therapy, has been shown to be predictably or permanently effective in eliminating attacks in a majority of cases. An advantage over placebos has been demonstrated in some agents, including methysergide (Sansert); rarely with preventively administrated ergotamine tartrate (alone or in combination with barbiturate sedative and other questionable agents, in cautiously planned regimens); inderal (Propranolol), and opipramol (Insidon), but the reliability of these imperfect trials of therapy and experience to date have not yet been adequate to warrant their routine use with confidence by the physician.

None has been shown to be more effective than conscientiously and sympathetically applied psychotherapy. Once the migraine personality becomes well known to the physician and he develops increasing skill in dealing with it, including assistance to the patient in modifying his attitudes, habits of living, patterns of emotional reaction, and/or environmental stress, the results are as good as with prescribing anything that comes out of a bottle.

Common sense psychotherapy is every doctor's business, but the cost in time and energy for carrying out the only truly effective approach to the prevention of recurrent headaches causes it to be almost universally neglected in favor of pharmacotherapy alone -- an easier way out but less successful. This is not to say that agents counteracting emotional tension and promoting relaxation are not often useful accessories. Indeed, in the vascular headache crisis, known as "status migranus", where headaches have reached an unremitting, daily frequency lasting weeks, or even months, the almost certain fact of an underlying depressive illness is too often unrecognized by the physician. The primacy of this basic problem, the headache then being a psychophysiologic epiphenomenon, must be dealt with by continued reassurance, at times investigating and dealing with psychodynamics, almost always by separation of the patient from his usual environment, and the judicious application of antidepressants. Cranial vasoconstrictors at such times are often useless, though if a headache fluctuates, waxes and wanes, ergotamine during a new exacerbation may be helpful. Other than this, encouraging the patient simply to endure the pain, providing occasional relief by a narcotic, and predicting with absolute confidence that the attack will ultimately end, is all that can be offered in status migrainus. That drugs with possible preventive vasoconstrictor action regularly administered (methysergide, inderal) are useful once status sets in has not yet been established.

George A. Schumacher, M.D.

Professor of Neurology
University of Vermont college of Medicine
Burlington, Vermont

MODERN MEDICINE PUBLICATIONS 4015 WEST 65TH STREET • MINNEAPOLIS, MINNESOTA 55435 • (612) 927-7011

July 31, 1972

George A. Schumacher, M.D.
College of Medicine
Dept. Neurology, University of Vermont
Burlington, Vermont 05401

Dear Dr. Schumacher:

The editors would like to have you take part in a Forum based on an abstract published in MODERN MEDICINE. I am enclosing a copy of the abstract. The question for discussion is "What are the best prophylactic and therapeutic medications for the treatment of migraine?" Your views will be read with interest by thousands of readers. (More than 200,000 physicians regularly receive MODERN MEDICINE.)

Essays are to be about 300 words long and should reach us in about a month to allow time for editing and submission of the edited copy to you for approval. We suggest an informal style, without extensive documentation or multiple literature citations. Would you also please send us a recent photograph of yourself that we can print along with your remarks? The picture will, of course, be returned.

We have been queried as to how these essays should be oriented in relation to the abstract cited. If you believe it merits a scorching condemnation or a paean of praise - fine. You may prefer to use the abstract and question as a springboard for a more general discussion of your opinions and experience. That's fine, too. In each Forum, we solicit statements by persons who have contributed significantly in the field to which the abstract relates, and who represent various points of view. In this way, our readers get a spectrum of reaction to problems about which there is room for honest difference among men of experience, ability and integrity.

This should be a lively, informative Forum. I look forward to hearing from you.

Sincerely yours,

John H. Rosenow, M.D.
Executive Medical Editor

JHR:lbs

Physicians Radio Network

15 Columbus Circle
New York, NY, 10023
(212) 541-8384

December 30, 1975

Dear Doctor

You may have heard your colleagues talking about a new medical news service operating at no cost to physicians.

The service is called the Physicians Radio Network (PRN) and is now broadcasting in Chicago providing 24-hour, 7-day-a-week coverage of clinical, socio-economic and political news affecting the practice of medicine as well as local reports prepared by the Chicago Medical Society. The broadcasts are "closed circuit" and can be heard only by those who have a special PRN radio.

The radio and all programming are free, supported entirely by pharmaceutical advertising. You need only fill out and return the enclosed form and your radio will be shipped without charge. The instrument itself is compact, attractive and fits nicely on a bookshelf or desk.

PRN seeks to bring important medical news to you quickly and at your convenience. Major stories are repeated hourly throughout the day; bulletins are broadcast at once. For instance on December 9th, PRN listeners heard a report on the use of antacids to reduce the complications of gastric aspiration in obstetric patients; a report from the Maryland Institute of Emergency Medicine on the development of a new delayed-action shock syndrome -- hepatic insufficiency; a report from Wales that an allergic reaction similar to bronchial asthma may account for some forms of proctitis; and from Washington, organized labor's reaction to the AMA's National Health Insurance proposals. These are four of the twenty-four medical news items offered that day. From time to time, postgraduate course programs are also offered which permit you to take part in accredited continuing medical education.

Already, more than 1,500 Chicago doctors have their free radio receivers at their homes or offices. Five hundred additional receivers are now available for distribution. If you would like to receive one, please return the enclosed card promptly. Later replies will be filled in the order received. It will take approximately 12 months to supply all Chicago physicians with radios.

Please fill out and return the enclosed card now. If you have any questions, please call us collect at (212) 541-8384.

Sincerely,

Thomas F. Bird
Director, Broadcast Services

UNIVERSITY OF MIAMI
MIAMI, FLORIDA 33152

DEPARTMENT OF PHARMACOLOGY
SCHOOL OF MEDICINE
P.O. BOX 520875, BISCAYNE ANNEX

TELEPHONE (305) 547-6643

October 29, 1974

Quentin Young, M. D.
Cook County Hospital
1825 W. Harrison
Chicago, Illinois 60612

Dear Dr. Young:

Keeping up with the growing body of knowledge that has such profound influence on medical practice today is a problem with which we are all familiar. In no area of medicine is the change more constant or the need more acutely apparent than in Clinical Pharmacology. But just recognizing the problem isn't enough. Where can we go for consistent, current information on appropriate drug therapy?

In an attempt to expand our already-established sources of drug information, an innovative program has been developed at the University of Miami School of Medicine. It was designed to increase the benefit potential of an existing resource for continuing information on drug therapy to the practicing physician--the informed pharmaceutical representative. By extending his role in a way that permits greater functioning in the capacity of an active member of the health care team, he has more opportunity to work with you in answering some of the questions that arise daily concerning drug utilization.

Roche Laboratories is cooperating in a Pharmaceutical Consultant Program--the first of its kind--in which pharmaceutical representatives work side by side with physicians and other health care professionals in a clinical environment. Your Roche representative, Mr. Rook, was one of forty recently selected to participate in this program at the University of Miami School of Medicine. Here are some of the things this program included: Assigned to an intern with whom he shared two weeks of clinical experience, he was actively involved in morning rounds, attending rounds, elective conferences, post mortem examinations, 24-hour duty shifts "on call" for admissions and emergencies, and 20 hours of Clinical Pharmacology seminars. It was a unique opportunity for exposure to multiple aspects of clinical medicine in an academic setting, and this was possible from a distinctive vantage point--at the patients' bedsides.

After completing this program, the Roche Pharmaceutical Consultant can be expected to have a more in-depth understanding of the pharmacologic action of a variety of therapeutic agents which encompass not only Roche products but those of other pharmaceutical companies as well. In addition, he has the advantage of being actively involved in patient care in a dynamic new way.

This program has the endorsement of the University of Miami Medical School and the Department of Pharmacology and has been presented to the National Academy of Sciences/National Research Council Drug Research Board. As the program progresses, we anticipate the endorsement of the American Society for Pharmacology and Experimental Therapeutics (ASPET). You will also be reading about this program in forthcoming issues of professional journals.

At the moment, we are in the process of assessing the program. The results of our study, along with the quantifying data obtained, should provide the necessary information to permit our proceeding on a broader scale. We would appreciate any comments you might like to provide regarding the Roche Pharmaceutical Consultant Program. With your cooperation, I believe we can help meet an essential need of practicing physicians everywhere.

Very truly yours,

Roger F. Palmer

Roger F. Palmer, M. D.
Professor and Chairman
Department of Pharmacology
Professor of Medicine and Chief
Division of Clinical Pharmacology
Department of Medicine
University of Miami School of Medicine

Cook County Hospital
1825 West Harrison St., Chicago, Illinois 60612 (312) 633-6000

December 13, 1974

Roger F. Palmer, M.D.
Professor and Chairman
Department of Pharmacology
Professor of Medicine and Chief,
Division of Clinical Pharmacology
Department of Medicine
University of Miami School of Medicine

Dear Dr. Palmer:

I have your letter of October 29, 1974 and am sorry for the delay in responding to it.

Here at Cook County Hospital we have taken a diametrically opposed position to the one you have developed. Increasingly distressed by the inappropriate function of the "detail man," we have finally found it necessary to eliminate their activities on our campus (see memo attached).

Our position is that the responsibility for the training of medical students and house officers, not to mention the continuing education of attending physicians, is our own and in no way can be prudently vested in representatives of commercial agencies.

The Executive Medical Staff reached this firm conclusion unanimously upon review of our extensive negative experience with the army of drug salesmen which occupied our institution.

While it may be that these merchants individually are personable and intelligent people, their motivation is not suitable for achieving the most objective, safe, and economical application of pharmacology in the clinical setting. That motivation, of course, is to maximize the sales and the profits of the drug companies which they

represent. It is just such practices that have resulted in unnecessary cost to the entire public, as well as unmeasured inappropriate and excessive use of drugs in our health care system.

Sincerely yours,

Quentin D. Young

Quentin D. Young, M.D.
Chairman, Department of Medicine

QDY:nm
Copies: National Academy of Sciences/
National Research Council Drug Research Board
The Medical Letter
The American Society for Pharmacology and Experimental Therapeutics
Health Research Group

Cook County Hospital
1825 West Harrison St., Chicago, Illinois 60612 (312) 633-6000

October 17, 1974

TO: All Department, Division, and Section Heads

FROM: Mr. William J. Silverman
Director

SUBJECT: Policy Regarding Vendors and Salesmen of Pharmaceuticals

On the recommendation of the Drug and Formulary Committee, affirmed by unanimous vote of the Executive Medical Staff of Cook County Hospital, effective immediately, vendors, salesmen, and detail men representing medical and surgical supply houses and pharmaceutical companies, will not be allowed on or in hospital premises including Karl Meyer Hall except by appointment with the Purchasing Department or the Pharmacy Department. Special arrangements for exceptions to this rule may be made only with the approval of the Purchasing Department, the Pharmacy Department, or this office.

WJS/gw
cc: James G. Haughton, M.D.
Department Heads, HHGC

UNIVERSITY OF MINNESOTA
TWIN CITIES

College of Pharmacy
318 Harvard Street S.E.
Minneapolis, Minnesota 55414

February 5, 1976

Jere E. Goyan, Ph.D.
School of Pharmacy
University of California
San Francisco, CA 94143

Dear Dean Goyan:

It is unfortunate that a letter such as this is necessary, but we believe it is long overdue that the students and faculty of your institution should seriously question the continued existence of a pharmacy publication.

Enclosed you will find a copy of the latest issue of Action in Pharmacy. We are confident that you are aware of this type of publication.

The publication presents as facts to the pharmacy students, opinions of its editors and authors who remain anonymous from their articles. It does not fully cite purported references and attempts to manipulate the students into a more "pro-industry" position. It simply is an example of irresponsible journalism.

Not surprisingly, Action in Pharmacy is entirely paid for by Parke, Davis and Company. At one time, it was sponsored by the National Pharmaceutical Council, who ceased funding it two years ago. Is this the type of "educational service" which Parke, Davis and Company should be providing to College of Pharmacy and their students? We believe the answer is a resounding NO!

We hope that you will examine the current enclosed issue, paying special attention to the discussion of formularies, the rational health insurance "information", and to the review of the Wharton School of Business study (page 4).

In many cases this publication is the major source of contemporary pharmacy "information" that your students receive. We are aware of one Dean who refuses to distribute this irresponsible publication. We would further hope that you would take the time to examine this entire situation with the best interests of your students in mind.

Sincerely,

Albert I. Wertheimer, Ph.D. Associate Professor, Director	Peter A. Parish, M.D. Hill Visiting Professor	Dale B. Christensen, M.S. Graduate Fellow
Richard Hammel, M.S. Graduate Assistant	J. Lyle Bootman, B.S. Graduate Fellow	Fred R. Curtiss, B.S. Graduate Assistant
Michael Ira Smith, B.S. Graduate Fellow	Helene Framm, B.S. Research Assistant	Andy Stergachis, B.S. Research Assistant

Enclosure

IN PHARMACY
VOL. 8, Number 5 JANUARY, 1976

The AACP - SAPhA - COS Split

It is no secret that the quality of education provided by pharmacy schools has shown a marked improvement in recent years. Part of this improvement can be attributed to the federal funds received by the schools under The Health Manpower Act of 1971. Federal funds have become an integral part of pharmacy education and according to the American Association of Colleges of Pharmacy (AACP) account for 26 percent of the various schools' budgets. A major portion of these funds have been used to develop clinical pharmacy programs in various schools.

The Senate Subcommittee on Health heard testimony from AACP asking for continuation of federal money to support and expand pharmacy education. However, the Student American Pharmaceutical Association (SAPhA) vehemently opposed any further funding in its present form in their testimony before the same Subcommittee. The Council of Students (COS) disagreed with SAPhA's testimony in a written communication to Senator Kennedy — the chairman of the subcommittee. In essence, pharmacy went before the Subcommittee divided.

The facts of the matter are simple. Pharmacy schools need federal help to maintain the quality of education now being provided to pharmacy students. Existing legislation demands that the standards of pharmacy education in general and clinical pharmacy in particular be upgraded. It is ironic that SAPhA should oppose the continuation of those very funds which are responsible for upgrading educational standards. The SAPhA's testimony tends to indicate that even with the withdrawal of federal capitation funds, the schools will somehow find alternate sources of funding to maintain high quality education. We fail to recognize the wisdom of this statement.

Another part of SAPhA's testimony which baffles us is its contention that if federal funds are to be given, these should be spent to meet the needs on a case-by-case basis. We question the rationale of this approach since it is neither practical nor democratic. SAPhA's testimony, at least to us, shows the influence of APhA on the public statements of SAPhA.

(See AACP, page 2)

One of the journals that we receive each month is Private Practice published by the Congress of County Medical Societies. It largely speaks to the interests of the local practitioners and sometimes is controversial and certainly critical of many of the federal programs that are being proposed.

There are many instances, when you must agree with the conclusions they reach and while we have never had the opportunity of meeting Francis A. Davis, MD, publisher of this journal, many of the articles he and his colleagues publish relate to the tragedy that could occur in the United States in the area of socialized medicine.

Their December issue points out the fact that the Department of HEW has recently estimated that the Kennedy-Corman style NHI bill would cost the taxpayers 113 billion dollars the first year.

Dr. Davis says that with the total working population of 81 million people that the program at a 150 billion per year, which probably is more realistic to **its actual cost, would average out at a $1,851 per year for every person working.**

He also makes note of the fact that with Medicare and Medicaid as guides you would have every reason to expect the cost to **rise** rather **rapidly within five years and** probably **reach about $3,000 for every working person.**

As you will note in another article in this journal we have made mention of the status of the national debt, the importance that it has to us at this point in history. It would certainly appear to us that Dr. Davis has pointed out a basic flaw in any thinking that projects governmental medicine on any wide scale.

It may be simplistic to say so, but to

Third party payers including the Medicaid programs of various states have been attempting to curtail the utilization of drugs by adopting either an open, semi-open or closed formulary. A formulary is a list of drugs which are authorized for prescribing and dispensing. **It has been argued that since most formularies represent a collective judgment of several experts, this system should encourage rational primary purpose of a formulary is to control costs of drugs dispensed to the beneficiaries of the programs.**

It is noteworthy that in the past, several third party payers had considered formularies as a useful tool in limiting the drug costs. However, a recent study proves the point that a closed formulary might not curtail drug cost after all. The recent research of

The Report of the Study Commission on Pharmacy was presented in Washington, D.C. on December 5 and was the result of two years of work. The reactions were mixed but many did express disappointment with the report. Part of this disappointment probably stems from the fact that the report did not come forth as a blueprint of how to change pharmacy or that clinical pharmacy was not the answer to pharmacy's problems. Pharmacists for the Future, the title of the report, is a futuristic view of the practice of pharmacy. It offers concepts, findings and recommendations and **should be read by everyone associated with pharmacy.**

While we cannot reproduce the entire report, it is available from the American Association of Colleges of Pharmacy. One of the areas we would like to acquaint you with is the "clinical scientists" for pharmacy and pharmacy education.

The commission states that "pharmacy education is in a most difficult situation. Many roles or tasks have been suggested for pharmacists but they have not been scientifically analyzed as to the competencies involved. **It is difficult, if not impossible, to identify with precision the relevant science basic to a competency which has not been clearly defined and evaluated".**

What is needed, according to the report, **is a clinical scientist - one who is expert at the patient's bedside and equally competent in the laboratory.** This person would be able to discern that portion of his science which is relevant to the care of the patient. He would then be able to assist his colleagues "in making the choice of those parts of his scientific discipline which must be given the highest priority within the curriculum".

Therefore the commission recommended:

1. **"That serious efforts be made by all colleges of pharmacy to provide members of the faculties effective opportunities to practice pharmacy in some role to the end that they may be more conscious of the essential relationship of knowledge and skill and, further, serve as role models for their students.**
2. **That . the research efforts of pharmacy faculty members be directed as much as possible to the solution of problems of pharmacy practice.**
3. **That a concerted effort be made to organize and finance a program to appropriately educate and train a small number [c. 100] of 'clinical scientists' for pharmacy and pharmacy education."**

These "clinical scientists" could be of great benefit to pharmacy in helping the other health professions see the benefits of pharmacy. Medicine has its "clinical scientists" but we only have a handful and it could be that our "clinical scientists" might even be called upon to assist in the education and training of the other health professionals.

This is a great opportunity for pharmacy and we would hope that some of you would begin looking into this and seek education so that you could help fulfill this need.

The United States declares bankruptcy! Impossible you say. Whoever heard of such a thing. Well, how about New York City? The "Big Apple" is in serious difficulty and the Federal government had to help out. But who will offer assistance to the Federal government when it faces this problem.

The gentlemen we have placed in Washington have mismanaged the nation's finances to a fare-thee-well. It was **Lyndon Johnson who became the first president to propose a $100 billion budget and now the budget gap is approaching $100 billion.** The gross public debt is $548 billion and seven years ago it was $358 billion. It is easy to see that we have spent almost $200 billion more than we could raise in taxes.

Tax reforms, spending cuts and a balanced budget are needed. It can be anticipated that many political platforms will be built around these themes.

There will be reductions in welfare and social programs and we may see less interest in Congress about National Health Insurance programs. Our experience with **Medicare** has told us that it **will cost over double what was expected** and **NHI could increase the government's consumption of our GNP from 37 percent to about 45.** Medicaid programs in many states are nearing bankruptcy and pharmacy fees for drugs are being cut.

The New York lesson seems fairly clear. You cannot keep spending more than you make.

Drs. Smith and Garner of the University of Mississippi demonstrates that the "savings" from a closed formulary used by Mississippi for two classes of widely used drugs is indeed questionable. **It is probable, according to these researchers, that either the physicians are prescribing another formulary drug of a questionable therapeutic value for a given condition or they are leaving it up to the patient to pay from his pocket for the drug not included in the formulary. But the costs of drug therapy are not lowered.**

Another study published in the December 1975 issue of Pharmacy Times comes to nearly the same conclusions. Here the dispensing patterns for most commonly used drugs were analyzed and several differences were observed under different types of third party programs. There is a marked shift in the dispensing of several important drugs under the formulary system, although the economic impact of this shift has not been studied.

We are of the opinion that the formulary system has more disadvantages than benefits. It interferes with the prescribing freedom of the physician, is inflexible and becomes rapidly outdated. Whether it encourages rational use of drugs is still open to question and from the limited evidence we have, formularies do not result in savings to the third parties. Administratively, these might, in some cases, simplify the reimbursement mechanism but **our emphasis should be on serving the patient's needs first.**

More comprehensive studies are needed in this area before drug formularies become an accepted tool in the hands of the third parties. **It may end up that the only function the formularies serve is to interfere with the practice of medicine without any monetary benefit.**

patient care®

16 THORNDAL CIRCLE
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Dear Sir:

J. Richard Crout, MD, director of the Bureau of Drugs of the FDA, recently testified before the Senate subcommittee on monopoly chaired by Senator Gaylord Nelson on the issue of pharmaceutical industry "dominance" over continuing medical education.

Enclosed is a preprint of an editorial challenging Dr. Crout's testimony, which will appear in the August 1, 1976 issue of Patient Care, a controlled circulation publication received by approximately 100,000 primary physicians twenty-one times a year.

Because of your membership on a congressional committee involved with matters of health, we felt you would want this editorial called to your attention. Although we properly can speak only for Patient Care, we believe -- and we hope you do, too -- that the issues raised by Dr. Crout in his testimony deserve a balanced review. For this reason, we would welcome any comments you may have.

Sincerely,

Lewis A. Miller
Editor-in-Chief

Is the pharmaceutical industry subverting CME?

Editor's Corner

EXPRESS STOP

Unworthy attack: The head of the FDA Bureau of Drugs has charged that growing influence of drugmakers over postgraduate education threatens the integrity of the profession. Using rhetoric, not facts, he accuses journals such as *Patient Care* of slanting editorial content and, by implication, duping physician readers. We reject his thesis as unreal, undocumented, and uncharacteristic of a government official usually known for fair balance.



Lewis A. Miller
Editor-in-Chief

A respected physician who should know better has used overkill and innuendo in an attack on the pharmaceutical industry, on controlled circulation publications such as *Patient Care,* and—by implication—on physicians who use such journals for continuing medical education.

The attacker is J. Richard Crout, MD, director of the Bureau of Drugs of the FDA, who has enjoyed a reputation as an advocate of fair balance and factual presentation in communications—at least until his aberrant performance before the Senate subcommittee on monopoly.

Dr. Crout's thesis is that the influence of the pharmaceutical industry over the continuing education of physicians is growing rapidly and is a long-term threat to the integrity of the profession. One major form of undue influence, he claims, is exerted through advertising support of controlled circulation journals, which, by his definition, usually "do not have a rigorous review" of editorial content of the type conducted by what he calls the "scholarly medical journals." His cure is to place control of CME materials with the medical schools, and he leaves the door open for Government to help bring this about.

We reject Dr. Crout's thesis as specious, simplistic, and unsupported by evidence. His testimony is short on carefully researched data and long on personal political rhetoric—subtly worded statements of so-called fact that are nothing more than hollow speculation—and negative innuendos. Here are some selected examples:

» "It is reasonable to ask why our profession should be subject to an onslaught of allegedly educational material, not subject to the kind of independent review given the scholarly medical literature, which is financed by the drug industry, and ultimately paid for by our patients."

» "I must wonder whether a journal that subsists wholly on sales of advertising space to the drug industry is able to present a skeptical attitude toward drugs in general or toward specific drugs. . . . For whatever reasons the editorial content of these controlled circulation journals [mailed to physicians without charge] is overwhelmingly optimistic about drug therapy."

» "Usually it is acknowledged [by editors of controlled circulation journals] that whenever material severely adverse to a sponsor is received, that sponsor is given the opportunity to rebut that material before it goes into the journal."

» "The problem is that the industry sponsor can choose from among the many medical authorities on any given topic to support only those whose views already coincide with those of the sponsor. This ability . . . is the basic cause of the biases."

» "There can be no doubt that scholarly medical journals should contain new information about drugs and should not be limited to the contents of approved package inserts. The issue here is whether such an article in a controlled circulation journal presents, in the guise of a scientific paper, promotional information which otherwise could not be legally published as drug advertising or drug labeling . . . . The Federal Food, Drug, and Cosmetic

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Act poses no threat to . . . the voice of any medical opinion on drugs, providing industry funding of that communication is not involved."

It is about as frustrating to respond intelligently to these cleverly worded statements as it is to come to grips with a bowl of Jello. The anecdotal evidence that Dr. Crout occasionally provides is exactly the sort of material he so rightly rejects when presented in support of drug claims. We find it inconceivable that, without more substantiation, Dr. Crout would charge the pharmaceutical industry with attempted subversion of CME, medical journals, and the medical profession.

We do not believe that the influence of the pharmaceutical industry on continuing medical education is a threat to the integrity of the profession. We do believe that such influence exists, just as we believe that influence on continuing medical education exists from Government sources such as PSRO, NIH, and FDA. Wherever money or politics provides power, pressure and influence are bound to exist. Pharmaceutical advertising supports all of the major medical journals and many of the minor ones. Directly or indirectly, pharmaceutical advertisers in some instances may influence selection and direction of editorial content, a condition that responsible editors abhor and that should be corrected. The frequency with which this occurs is unknown; in fact, Dr. Crout did not give a single documented instance. On the whole, industry support of medical journals has been beneficial rather than detrimental to the profession; without it, many valuable publications would die or become sere and insubstantial.

Dr. Crout's attitude toward the medical profession is condescending if not outright condemnatory. "I do not consider my colleagues to be pawns of the communications industry," he says at one point. Yet the wording of his statements implies that the typical practitioner has no more brains than a turkey. Is it really possible that physician readers are permitting themselves to be corrupted and duped by jellyfish editors who quiver in response to a frown or a finger pointed by a pharmaceutical advertiser? We infer from his words that a doctor reading a controlled circulation journal could not discriminate between factual and biased information on unapproved uses of drugs. He confuses the issue by further suggesting that the reader would be magically protected from distortion and harm if he were to read such information in scholarly medical journals. These innuendos insult both readers and editors.

Which are the "scholarly" medical journals? Of journals with greater than 70,000 circulation, he names only two, *JAMA* and the *New England Journal of Medicine*. Both are substantially dependent on pharmaceutical advertising as a source of revenue, yet in Dr. Crout's cloudy vision, the editors of such scholarly journals would be immune from the kinds of advertiser pressure that supposedly affect those of us who have fallen from grace, the editors of controlled circulation journals. Speaking for *Patient Care's* editors, we find this comparison invidious and repugnant. We, like the editors of *JAMA* and the *New England Journal*, have a responsibility to our readers and their patients, a responsibility faithfully executed for nearly 10 years with credibility and acceptance by practitioners and academicians.

Every article in *Patient Care* is researched with the help of not one but several consultants. It is reviewed by still other consultants and by a panel of reader representatives (true peer review). It is published with a fair and clear expression of both majority and minority opinions. Our review practices are independent and rigorous, subject to no single influence, but responsive to the plurality of influences that are a part of our free society, most particularly to the influence of our readers' needs.

For the record, we must also state that *Patient Care* articles have been skeptical "toward drugs in general or toward specific drugs" when warranted in the opinion of our consultants; and we can document this statement with references.* *Patient Care* editors do not give advertisers the opportunity to rebut material adverse to their products as a matter of policy, though we are not afraid to recognize that a manufacturer is a knowledgeable resource about his drug. Nor does *Patient Care* permit its advertisers to select its medical authorities; what is more, we have not been asked to do so.

In fairness to Dr. Crout, at no point did his testimony level such charges specifically at *Patient Care*. In fact, he singled out a *Patient Care* article on oral hypoglycemic agents** as discussing the implications of the University Group Diabetes Program study "in a balanced way, ultimately taking a middle of the road position."

This minor compliment notwithstanding, Dr. Crout's broad based attack on the drug industry and on controlled circulation medical journals is undeserved and uncharacteristic of him. We choose to treat it as a momentary aberration caused by Potomac Fever; we take his word that he is not campaigning for FDA regulation of the editorial policies of journals whose financial support comes from pharmaceutical advertising. But on the outside chance that his testimony was a trial balloon for such regulation, we are putting this response on the record and encourage you to write to him*** with your reactions (copy us if you will).—LAM

*"Sorting out options with specific antibiotics," November 1, 1973, page 43. "Propranolol for which angina patients?" March 15, 1974, page 92. "Sympathomimetics—Controlling perfusion in cardiogenic shock," June 15, 1974, page 20. "First things first in drug interactions," December 1, 1974, page 171. "Meeting first challenges in stroke," April 1, 1976, page 24. "Choosing diuretics for optimal results," June 15, 1976, page 22.

**See "Oral hypoglycemics? Yes, No, Maybe." *Patient Care*, February 15, 1976, page 102.

***J. Richard Crout, MD, Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20204.

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The Journal of Medical Consultation

July 27, 1976

Senator Gaylord Nelson
Chairman
Select Committee on Small Business
Senate Office Buildings
424 Russell
Washington, D.C. 20510

Dear Senator Nelson:

As the publisher of CONSULTANT magazine, owned by Cliggott Publishing Company of Greenwich, Conn., I would like to respond to the statement made by Earl J. Scherago before the Subcommittee on Monopoly of the Senate Select Committee on Small Business on May 24, 1976. Copies of this letter are being sent to the other members of your committee, Mr. Scherago and Dr. J. Richard Crout of the FDA who also made some critical remarks in a statement before your committee in April.

CONSULTANT is a controlled circulation monthly publication which reaches approximately 143,000 private practicing physicians. Controlled circulation assures that the physicians who receive the journal will find it of greatest value to them. Articles can be directed exclusively to this clearly defined circulation. CONSULTANT has been published continuously since 1961 and contains entirely original, clinical articles.

Mr. Scherago states that for 20 years he has been a publisher's representative involved in the solicitation of advertising in journals published by non-profit societies. Since he claims he is active solely in advertising sales, I assume he has little or no direct contact with the editorial phase of the publication he represents. It is difficult to see how Mr. Scherago would have sufficient knowledge of the procedure of article development used by CONSULTANT or many of the other controlled circulation journals he criticizes.

Mr. Scherago goes to considerable lengths to define the doctrines of Peer Review and its importance in establishing authenticity for scientific work. "In its simplest form this doctrine says that no piece of scientific research can be considered valid unless it has been reviewed by at least two recongnized authorities in the field of science involved", declares Mr. Scherago. He goes on to imply that Society Journals are Peer Review publications while controlled circulation journals are not. This impression is entirely false. Society Journals do not enjoy exclusivity in this procedure. CONSULTANT magazine is a Peer Review Journal. We have always employed a Peer Review technique despite Mr. Scherago's puzzling remark, "that is because commercial publishing firms have found that it is very difficult to make a profit with Peer Review Journals." Our present masthead lists 47 eminent physicians in 25 medical disciplines who make up the CONSULTANT Advisory Board. Members of this advisory board together with specialists in many disciplines, execute our Peer Review procedure.

Since a number of controlled circulation journals enjoy Peer Review why can't the "Scholarly" publications compete effectively in the market place with these journals?

Mr. Scherago would have you believe that Scholarly Journals "aren't willing to make the compromise with established scientific practice which advertisers demand." This is a totally false, misleading statement without substantiation which infers that an advertiser can influence the editorial content of our magazine. All of the articles in CONSULTANT are written by invitation of our editorial staff. Leading clinicians are asked to write on a subject of current importance to the practicing physician. The paper will be edited for form and style, but is entirely the authors' views and he must approve the final manuscript. Advertisers simply have no say in any articles which appear in the publication whether the opinions expressed are popular or unpopular. CONSULTANT does not run product descriptions in its pages and never has nor will it publish articles in exchange for advertising. The doctors who read medical journals are not easily fooled. Any hint of advertiser influence or the slightest departure from complete objectivity in editorial presentation would result in a disastrous loss of confidence in the journal by the reader.

We have indicated that CONSULTANT and other fine clinical journals utilize the vital Peer Review system. They also publish without compromise to author or advertiser. Why, then, has it been so difficult for Scholarly journals to compete? Mr. Scherago reported that Peer Review Journals as a group were in serious financial difficulty. He quotes from a paper delivered in February, 1976 by Robert Day, Managing Editor of the publications of the American Society for Microbiology at the annual meeting of the American Association for the Advancement of Science to emphasize the problem of continously rising publishing costs. These rising costs are certainly not the exclusive concern of Peer Review Journals. All publishers, Peer Review or not, realize that the only way to maintain the quality and quantity of their article pages in the face of rising costs is to improve efficiency and increase revenues. The key to increasing advertising pages is to provide evidence to advertisers that the physicians who receive your publication actually read it and find the information it contains of value to them. Many pharmaceutical companies conduct their own readership studies and, in addition, there are syndicated readership reports available.

I suggest that the major problem facing Mr. Scherago and many Peer Review Journals is that they are not competing successfully for the physicians attention. This is unfortunate as there is an important place among journals for both the scholarly publication and those of the controlled circulation type. When medical publications present authoritative important and useful information in an attractive and readable format they will achieve satisfactory readership levels among the physicians in their circulation. Establishing a publication chronologically first in a field is not, of itself, sufficient reason for success. Many Peer Review Journals should be examining their publications to discover why they are not attaining acceptable readership levels and should be making whatever changes are necessary to achieve improved readership. If the problem is not with readership perhaps the Peer Review Journals should evaluate the quality of their sales representation.

The controlled circulation publications are healthy when many society journals are not because they are

providing the kind of information and continuing medical education that the practicing physician needs. Controlled circulation journals perform a vital service in the dissemination of important, timely developments in medicine to the doctors of this country. To verify this you need only go out and talk with the physicians who are providing the day to day care of the American people.

We have written you because as a small, independent medical publishing firm we are gravely concerned about any developments which might lead to legislation or regulations inhibiting a free medical press. In an effort to balance the inaccuracies and mis-statements in Mr. Scherago's testimony I respectfully request that my letter become a part of the record of your hearings.

Very truly yours,

John M. O'Brien
Publisher

JMO'B:nam

PREPARED STATEMENTS

STATEMENT BY
EDWARD F. CALESA, PRESIDENT, HEALTH LEARNING SYSTEMS INC.
1455 BROAD STREET, BLOOMFIELD, NEW JERSEY 07003
BEFORE SUBCOMMITTEE ON MONOPOLY
SENATE SMALL BUSINESS COMMITTEE
MAY 24, 1976

Edward Saltzman and I are pleased to be here to answer your question about our contribution to medical education. We contribute through two separate corporations with one common objective -- improving the quality and cost of patient care through meaningful education. The Health Learning Systems corporation achieves this objective by providing continuing medical education for physicians, interns, nurses, and other allied health professionals; and the HLS Press corporation, through health education directly for the patient. We will concentrate today on Health Learning Systems.

The primary reason for our existence is to help translate medical research findings from branches of the National Institutes of Health and university based medical centers to improved patient care. The need is based upon the fact that new research findings reportedly double every seven to ten years, and affect numerous aspects of prevention, diagnosis, management, and rehabilitation of disease. More importantly, these findings are not adequately reaching the practicing physician for clinical application with the patient. This concern is well recognized by the Congress in its direction to the National Institutes of Health.

To effect change, there is a need for continuing medical education through improved communication techniques. The need for continuing medical educa-

tion of practicing physicians is well documented by every major study in medical education. It is further substantiated by the American Medical Association, nine medical specialty societies, and fourteen states all of whom require that members participate in a fixed number of education hours to maintain their membership. Five states have education requirements to maintain their license in that state. Three more states will institute relicensure laws by January, 1978. All medical specialty boards and subspecialty boards have endorsed recertification examinations.

Congress has passed the Bennett Amendment to the Social Security Act in October of 1972 requiring the establishment of Professional Standard Review Organizations, with the primary objective to increase the quality of care through physician education. The problem of malpractice in this country can often be related to this need. The major consequences to society of not adequately fulfilling this need for continuing medical education are increased morbidity and mortality statistics and the extremely high and spiraling cost of health care.

Traditionally this need is being met by medical schools and hospitals that provide courses, hospital staff conferences and meetings, traveling medical educators, medical textbooks, scientific journals, and conventions. Problems with these approaches are that practicing clinicians may not have time to travel and attend courses, particularly those physicians farthest away from the medical centers, the lecturing medical educator may not have adequate teaching tools, he is limited by the amount of time he can devote to this activity, the printed word is often outdated, overused, and not necessarily the best communication medium particularly for medical subjects.

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Local meetings fail to provide national or international perspective.

Upon recognizing this need, Health Learning Systems was organized to act as a catalyst in marshalling the resources and disciplines prerequisite to affecting improvement in patient care through education. The disciplines we integrated in our corporation are the following: First and foremost, medicine to provide selection of subjects, physician participants, content control and accuracy. Second, education to insure the achievement of learning objectives. Third, communications to enhance the speed and accuracy that information could be communicated and provide professionalism and quality in this area. Fourth, marketing to find funding for programs and assist in the distribution of completed programs. Integration of these four disciplines is the basis for producing high quality medical education materials that are up to date, accurate, and professional.

The most important discipline in our organization is medicine. We have developed a medical faculty of more than 400 physicians representing Federal health agencies, medical associations, medical societies, medical boards, medical schools and teaching hospitals from around the world. This is spearheaded by our Medical Director, Doctor Arthur Bernstein, Clinical Professor of Medicine, New Jersey College of Medicine and Dentistry; and Doctor Shervert Frazier, Psychiatrist in Chief, McLean Hospital and Professor of Psychiatry, Harvard Medical School, a member of the Board of Directors of Health Learning Systems. Included in our list of experts from the Federal Government with whom we have worked are Doctor Theodore Cooper, Assistant Secretary for Health, Department of Health, Education, and Welfare; Doctor Donald S. Fredrickson, Director, National Institutes of

Health; Doctor Robert I. Levy, Director, National Heart and Lung Institute; and Doctor Ronald A. Chez, Chief, Pregnancy Research Branch, National Institute of Child Health and Human Development, National Institutes of Health.

Some of our 400 physician advisors from academic medicine include Doctor James C. Hunt, Professor and Chairman, Department of Medicine, Mayo Clinic and Mayo Medical School; Doctor Morton H. Maxwell, Clinical Professor of Medicine, UCLA School of Medicine; Doctor Clark H. Millikan, Professor of Neurology, Mayo Clinic and Mayo Medical School; Doctor Edward J. Quilligan, Professor and Chairman, Department of Obstetrics and Gynecology, University of Southern California School of Medicine; Doctor Michael E. DeBakey, President, Baylor College of Medicine, Texas Medical Center; and Doctor Harold D. Itskovitz, Professor of Medicine, Medical College of Wisconsin.

We have worked with the National Board of Medical Examiners, and representatives associated with the American Board of Internal Medicine, American Board of Family Practice, National Institutes of Health, Board of Psychiatry and Neurology, American Fertility Society, Epilepsy Foundation of America, American Heart Association, National Kidney Foundation, and many others.

It is this working relationship we have with medicine that is the basis for us to produce highly credible education programs funded and distributed by industry which are beneficial to the participants in medical schools, physicians in private practice, and patients. It is the integrity, reputation, and knowledge of this group that provides the peer review and controls over the educational materials.

The critical questions we faced were first how to fund and how to distribute the programs that we could develop. Three alternatives were considered. The first was for us to raise capital, develop programs at our own expense, and sell completed programs to physicians in practice. We rejected this alternative because our studies indicated physicians would not pay for the programs, and we had no system of distribution. Second, we considered proposals to appropriate Federal Government agencies. We rejected this idea because of restrictions in Federal health care spending, the time involved in getting proposals written and approved, and most importantly, the inability of the Federal Government to provide adequate distribution. The approach we settled on was to utilize the resources of industry. They have the financial resources, the responsibility to good medical practice, and the distribution outlets to insure awareness and usage of completed programs.

Why would industry use these resources to support educational programs for physicians? The answer is that pharmaceutical manufacturers develop excellent products that undergo extensive testing before being sold to the public. These products are differentiated by scientifically proven benefits as well as side effects. Each product becomes a potential tool in the physician's armamentarium. The problem is how to properly and accurately communicate the benefits, side effects, and therapeutic role each product has in the diagnosis and treatment of a patient. In marketing products, industry does not sell products to a doctor, but rather fulfills needs that a doctor has in the comprehensive care of his patients. Accepting this statement as dogma, it is an absolute necessity to provide adequate and accurate information which allows the physician to make informed decisions in selecting methods of diagnosis and treatment

for his patients.

A comprehensive continuing medical education program under the severe scrutiny of medical peer review, which discusses candidly when drugs should and should not be used and criteria for drug selection which includes all major drugs in that field as well as non-drug methods, is a way for industry to fulfill its communication responsibility with the physician.

Additional factors are that the manufacturer is trying to upgrade the level of knowledge of the pharmaceutical sales representative, so a better dialogue can take place between the physician and the representative. This can be accomplished by exposing the pharmaceutical representative to the same educational material that the physician is exposed to.

There are other factors as to why the manufacturer will support educational materials, but the most important is that the manufacturer with high quality products, that have a definite role in the management of patients in a particular therapeutic field, will benefit by providing fair balanced educational material to the practicing physician.

However, since industry was to provide the financial and distribution resources, it was imperative that certain safeguards be built into the educational process to avoid any potential for abuse. It is our unequivocal contention that these safeguards must be under the control of academic medicine through medical peer review and not regulated by any Federal agency or interferred with by the pharmaceutical manufacturer.

We define these safeguards as follows: First, that the educational programs be developed and produced by an independent organization such as Health Learning Systems rather than by the pharmaceutical manufacturer. Second, that the intention of the program is educational rather than promotional. Specifically, we feel that the educational materials should not be exclusively about drugs but rather encompass the entire area of diagnosis and management of a particular disease. Third, that the executive editor and editorial board participants in the program be selected independently of the manufacturer providing the grant. We will accept suggestions from the manufacturer regarding participant selection, but only as it relates to providing a fair balanced presentation. All editorial board participant selections must rest with the executive editor of the program. Fourth, that the editorial board participants include a minimum of four independent participants to rule out bias. Fifth, that the editors selected be eminent in their field, be located at leading medical centers and represent the major opinions in that disease area. Sixth, that the content be completely under the control of the editors and not subject to change by the grantor. Seventh, that the program be sponsored by a prestigious medical school department, health agency, or organization. Eighth, that educational content peer review be provided by a Federal Government agency and/or medical association active in that field. Nineth, that the content be reviewed for accreditation by all of the leading accrediting organizations in that field. Tenth, that any discussion of drugs be done in fair balance to all drugs in that field. Eleventh, that both the indications as well as the side effects of all drugs discussed be highlighted in the program. Twelfth, that product advertising not be included in the educational material. Thirteenth, that the material conform as closely as possible to approved package inserts for all products.

Fourteenth, that all material clearly identify the medical center and association sponsors, the producer, and the manufacturer providing the educational grant. And finally, that the manufacturer actively participate in the distribution of the program.

If these criteria are met, we have the basis for achieving a common objective of our organization, academic medicine, organized medicine, the pharmaceutical industry, and the Congress in providing better patient care through education. The most important result is decreased morbidity and mortality for the patient and a reduction in health care costs brought about by knowledge in the diagnostic evaluation, laboratory procedures and management alternatives. The medical academic community and Federal health agencies should be praised for their contribution, and the pharmaceutical industry should be encouraged and praised for its support.

It must be pointed out that there is a difference between what I have described as education which does not meet all drug labeling requirements and education which does meet all drug labeling requirements and is considered as advertising.

If all education supported by pharmaceutical manufacturers is to be considered as advertising and thus subject to all drug labeling requirements, serious shortcomings will occur. First, that automatically means that the pharmaceutical manufacturer will be involved in the selection of physician participants and that they will review, edit, and have final approval of all content. The reason is that they must protect themselves against physician participants saying anything that may be considered accepted medical practice or the individual physician's opinion but deviates from the approved labeling. The

editorial board participants do not accept this infringement by Federal Government authority over what they want to say. In addition, package inserts in the educational material are a tacit endorsement of the manufacturer's products. The effect of drug labeling on education is an infringement on free speech and presupposes that content control cannot be achieved by the medical profession.

The Food and Drug Administration has proposed a series of guidelines to differentiate education from advertising to overcome these problems. As you can see, we agree with these guidelines and have introduced additional guidelines. There is one serious difference of opinion. They propose that the intent should not be for ultimate distribution by the pharmaceutical industry. If the manufacturer supporting the program meets all of these criteria, why can't he give it away? He has the distribution channels and can use them effectively to get the program to the doctor. If he paid for the program and has the ability to help get it used correctly, why shouldn't he do this? If he can't do this, why should he pay for it? Finally, our opinion is that if the manufacturer is forced to produce educational materials as advertising with labeling, we will all lose -- the medical educators, medical schools, organized medicine, the pharmaceutical manufacturer, the doctor in practice, and the patient.

We have produced programs both with and without labeling. Obviously, we favor the former as do all of our medical advisors. As a matter of fact, Doctor Crout, in his appearance before this Committee, complimented Health Learning Systems for a program we are producing called "Dialogues in Hypertension," which is developed in cooperation with the National High

Blood Pressure Education Program of the National Heart and Lung Institute, the Council for High Blood Pressure Research of the American Heart Association, and the National Kidney Foundation, under an educational grant from Smith Kline & French Laboratories. This program is produced according to the criteria previously discussed.

Doctor Crout then went on to describe a program we produced under a grant from Marion Laboratories which he said was an example of education that was promotional. In this case it should be pointed out that the program produced met the criteria for drug labeling. It contained the package insert on the films and in the monographs and was edited by the Marion Laboratories' Medical and Legal Departments in accordance with labeling requirements. It is exactly for this reason that we feel labeling should not be a part of an educational program, assuming the other criteria have been met. I would like to point out for the record that it was incorrectly stated at these hearings that Health Learning Systems was the producer of a closed-circuit television symposium on diabetes under contract to Pfizer Laboratories. We were not the producer, nor did we participate in any way in this program.

The question has been raised regarding the extent of industry-sponsored educational material. We contend at this stage that it is quite small in relationship to their total marketing expenditures. Specifically, from indsutry-supported sources, the percentage expended for audiovisual presentations was 0.8% in 1972, 1.7% in 1973, and 2.1% in 1974. The expenditure for conventions and exhibits was 1.4% in 1972, 1.7% in 1973, and 1.7% in 1974. This is against a base in 1974 of $909,534,000.

The Journal of the American Medical Association publishes an annual report on medical education in the United States. In the most recent publication it listed 4,862 courses from 554 different primary sponsors for 1975 to 1976. The sponsors were medical schools, hospitals, medical societies, and voluntary health agencies, not pharmaceutical companies. Generally, this list which is a projection for the coming year is half the actual number of courses that will be given.

The question has been asked how do we select subjects and physician participants? The answer to that question is that we use our Medical Faculty of Advisors whom we consult with regularly.

In addition to advice from these consultants for selection of subjects, we use the Forward Plan for Health published by the Department of Health, Education, and Welfare and Health U.S..- 1975, Department of Health, Education, and Welfare, and surveys formerly conducted by Regional Medical Programs amongst physicians. From these sources we select subjects and attempt to obtain funding from the companies who are leaders in the selected field.

Once funded, we approach a medical school, medical school department, or health agency to sponsor the program and determine an appropriate executive editor. The executive editor selects the editorial panel. We make agreements with all of the physicians that editorial content control rests exclusively with them. They have final sign-off on the content before we go into production of any of the materials.

When the content is ready to go into production or during the production, we submit the material to as many reviewing medical organizations as possible for accreditation and/or endorsement. When the education program is completed, we ask the sponsoring agency to write letters and other materials to create awareness of the availability of the educational program. We then give the completed programs to the pharmaceutical manufacturer who distributes the material, making all physicians aware of its availability and use, at no cost to the hospital, medical society, medical school, or physician. It is the responsibility of the manufacturer to get the materials to the user and assist in making physicians and allied health professionals aware of the program. The only involvement of the grantor is to determine the media and this is based upon their available budget, pay the bills, and assist in the distribution of the program. This is not true where labeling is to be included with the educational material. In this case, the manufacturer is very actively and directly involved in the content of the educational programs.

We have attempted to work very closely with the Food and Drug Administration in developing our educational programs and for the most part, with the exception of distribution noted previously, we agree with all of their criteria for program development. Based on what we have described today, we feel that high quality medical education programs can be developed effectively to meet the ultimate needs of the patient. If the Government were the primary source of funding for continuing medical education, Health Learning Systems would attempt to be the producer and would take the exact same approach in producing programs as we currently take if xyz pharmaceutical manufacturer were providing the funding.

We have had the opportunity to observe dramatic results with our programs. We have received numerous letters of praise from Government officials, from academic medicine, and from practicing physicians who have participated in and been exposed to the programs we have produced.

On a recent closed-circuit television program which we produced, attended by 11,000 physicians and allied health professionals, we asked the audience to evaluate the program content. With 1,993 responses, the results were:

- Met my expectations - 99%
- Provided important information - 97%
- Provided help for better patient care - 97%
- Rated speakers excellent to good - 100%

On the closed-circuit television program produced by Health Learning Systems on hypertension which was the basis for producing "Dialogues in Hypertension" for which we were complimented by Doctor Crout, I would like to quote a letter dated January 7, 1974 from Doctor Theordore Cooper, then Director of the National Heart and Lung Institute to Mr. Robert F. Dee, President of Smith Kline & French Laboratories -- "As you are undoubtedly aware, one of the principles of the National High Blood Pressure Education Program is that by combining the resources, and by cooperating with each other, the private sector and the Federal Government can make very significant accomplishments in this critical public health area. If you have no objections, we would like to use the development of this symposium as an example of this principle in action." As one of the primary companies involved in the communications program toward physicians

on hypertension, we have seen from a 1974 study the National Heart and Lung Institute called "Hypertension Detection and Followup Study" that initial visits to doctors increased 38% for hypertension and hypertensive heart disease. The number of people with hypertension not aware of their disease decreased from 50% to 29%, and in a study of 760 clinicians published in the May, 1975 issue of Medical Opinion, it revealed that the number of physicians who take blood pressure readings increased in five years from 50% to 90%, that 73% of physicians routinely use laboratory tests for hypertensive patients, and that the number of patients now talking about hypertension with their physician increased from 9% five years ago to 36% today.

We are pleased to say at this time we are working with the National Board of Medical Examiners to produce a national self-assessment on hypertension for physicians under an educational grant from Smith Kline & French Laboratories. This is an outgrowth of our "Dialogues in Hypertension" program.

Every day we receive letters on one or more of our programs from physicians in practice who thank us for our contribution to their patient care needs. We are young and this industry is young. We have made mistakes. We have not always been able to include all the Food and Drug Administration criteria described in this statement in every one of our programs. We are concerned and proud to be part of an effort where we have seen visible signs that in some small way we have contributed to an improvement in the quality of health care in this country and abroad.

Thank you for allowing me to share this with you.

STATEMENT

BY

J. RICHARD CROUT, M.D.

DIRECTOR

BUREAU OF DRUGS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE

THE

SUBCOMMITTEE ON MONOPOLY

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

APRIL 28, 1976

Mr. Chairman:

I am delighted to appear today to discuss at your invitation the relationship between the pharmaceutical industry and medical education. This is an important topic and a timely one. There is considerable evidence that the pharmaceutical industry plays a very important, perhaps a dominant, role in the post-graduate education of physicians, dentists, and other health professionals. This role of the pharmaceutical industry in supporting post-graduate medical education has increased rapidly in recent years and, in my opinion, is a problem deserving of national attention.

Let me emphasize from the start that I do not consider this issue to be primarily a problem in drug regulation. While I will draw upon the experience of the Bureau of Drugs in citing a number of examples in this testimony, my remarks will also reflect views developed during two decades of personal experience as a student and a teacher of medicine before coming to the Food and Drug Administration (FDA). I testify today as a concerned physician who believes that the growing influence of the pharmaceutical industry on medical education is a long-term threat to the integrity of my chosen profession.

THE PROCESS OF MEDICAL EDUCATION

Before considering the many ways in which the pharmaceutical industry is involved with the education of physicians, I would like to comment briefly on trends in medical education since the turn of the century.

Today the education of medical students is under the control of universities and customarily consists of a four-year curriculum, at the end of which the student receives his M.D. degree. A century ago, however, there were, in addition to university-based medical schools, a number of private trade schools training physicians. Because of the low professional competence of the graduates of these trade schools, the training of physicians became a national scandal early in the 1900's. After publication of the Flexner report in 1910, medical education came under the full control of universities; thus nearly every physician now in practice in this country was trained at a university as a medical student.

The second great advance in medical education in this century was the development of full-time faculties in medical schools. This has occurred as a result of our national investment in biomedical research and training since World War II. Today's medical student thus graduates with a rich and broad education in medical science after a four-year exposure to university faculties dedicated to teaching, patient care, and medical research. In such an environment professional competence, commitment to scientific principles, high personal standards are emphasized as the physician's primary and necessary attributes.

After graduation from medical school, the modern physician then takes several additional years of training in a medical speciality or in

family medicine. This training typically occurs in medical institutions, including university hospitals, military and Government hospitals, larger private hospitals, and some community hospitals. After such experience many physicians take advanced examinations, known as Board Examinations, to become certified as specialists. At this point the physician is probably as highly trained technically as he will ever be in his life, and he enters the practice of medicine, the product of an extended and expensive educational process.

POST-GRADUATE MEDICAL EDUCATION

From this point on, the physician is in large part left to his own devices to maintain and update his fund of knowledge. He can maintain his university contacts by joining a clinical teaching faculty, an excellent approach to staying abreast of advancing medical knowledge, but an opportunity usually available only to Board-Certified specialists in cities with medical schools. He can also seek out any of a number of short courses sponsored by specialty societies and conducted in medical institutions. He can also read the medical literature, attend medical meetings, and take advantage of a variety of audio-visual presentations, either in the privacy of his car, home, or office, or in staff meetings at his local hospital.

In recent years, several States and specialty societies have recognized the physician's need for continuing education to keep his medical knowledge current and have attempted to encourage greater efforts at self-education. These States and societies have imposed on the physician

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requirements for a specified number of credit hours, usually 150 in three years, to qualify for license renewal or recertification. The American Medical Association grants a Physician's Recognition Award to physicians completing 150 hours of continuing education in three years.

There are aspects of continuing education for physicians that are unique. While other professionals must also maintain their skills and be aware of new developments (e.g., the tax lawyer must be aware of changes in the Tax Code) there is no field I can think of in which "keeping up" is so closely related to learning about new products or new uses of old products. Certainly, there is other information necessary also--e.g., knowledge of newer diagnostic techniques and new insight into disease mechanisms--but a significant portion of what an up-to-the-minute doctor needs to learn about is related to advances in therapeutics, especially drugs and medical devices.

To understand the importance of post-graduate education to the physician's use of drugs, one must appreciate how rapidly information on drugs changes. Ninety percent of prescriptions written today are for drugs which were not even on the market a generation ago. New information about the uses and potential adverse effects of drugs appears almost continuously. Since the professional career of the average physician spans thirty to forty years, it is evident that most of what he learns about new drugs occurs after he completes his formal medical training.

DRUG INDUSTRY'S ROLE IN POST-GRADUATE EDUCATION

It thus is not surprising that the drug industry is vitally interested in the educational materials the practicing physician receives. In view of the great financial resources available to the industry it should also not be surprising that it has come to support a large and growing proportion of such educational materials.

It has long been recognized that the industry-supported detailman is an important and influential source of information on drugs for the practicing physician. Drug labeling and drug advertising, which are closely regulated by FDA, also provide information. It is less well recognized, however, that much of the written and audio-visual teaching material supplied to the physician on all medical subjects throughout his professional career is also supported by the pharmaceutical industry. This includes the vast majority of medical magazines which fill his mailbox, the clinical symposia that discuss specific drugs or general approaches to therapeutics, the audio-visual teaching systems he studies in his spare time, the films and closed circuit TV tapes he sees in his hospital conferences, and even the scientific exhibits and presentations by panels of experts he encounters at medical meetings. This extensive underwriting of post-graduate medical education and communication by the drug industry has occurred primarily in the past decade, and is the problem I want to emphasize in this testimony.

Let me note that while the drug industry has a natural interest in the post-graduate education of physicians, it is not alone in fostering this trend. Pharmaceutical industry financing of such endeavors has been encouraged by medical institutions eager for attractive teaching materials, by respected investigators and clinicians eager to make their work and opinions more widely known, by practicing physicians under increasing pressure to participate in formal training to maintain licensure, and by medical societies facing growing demands to make such training available. These groups are well aware of the vast resources the industry has at its disposal, particularly in comparison with medical institutions and medical societies. Make no mistake, modern educational materials are costly. There has been a growing sophistication in the techniques used to educate people, and the "old" methods--lectures, review articles, textbooks--are perceived by some as dull and tedious. Instead we now have "learning systems" generally involving films or videotapes accompanied by elaborate graphics and self-instruction materials. It may well be true that these newer kinds of materials can be prepared only with special subsidies (assuming their added value as educational instruments is worth the extra money).

There is a cost involved, however, in giving substantial control over that subsidy to the drug industry. That cost is the introduction of systematic bias. Without contending that industry-supported

materials are regularly inaccurate, I believe that these sponsored materials are consistently tilted in the direction of therapeutic enthusiasm. There has been a rapid growth in expensive, slick audio-visual materials, conferences, symposia, and publications which have the appearance of independent, scholarly productions but which are in fact an integral part of the drug industry's overall promotional efforts, a more subtle part, of course, than straightforward promotional materials like advertising.

Let me emphasize that the systematic bias I am describing does not arise because the medical authorities who contribute to these teaching programs present knowingly biased views because of pharmaceutical industry support. The problem is not that drug industry money corrupts medical experts, but rather that the industry sponsor can choose from among the many medical authorities on any given topic to support only those whose views already coincide with the interests of the sponsor. This ability of the pharmaceutical industry to select the medical authorities it wishes to support is the basic cause of the biases we shall see.

In the discussion to follow, I will present a number of examples of medical communication which will illustrate the problem I have been describing. In some cases these merely present a particular

point of view. Other examples will be shown of medical communication which, in my judgment, do not constitute the sort of disinterested, balanced, scholarly products we expect educational materials to be.

I recognize that I have selected these examples to make a particular point. They will show that drug promotion can masquerade as education. I have certainly not attempted to present a full review of all the medical communication sponsored by the drug industry. I am aware of many examples of excellent industry-sponsored materials. Nevertheless, I believe it is inevitable that the educational materials produced by and for an industry with an interest in increasing sales of drugs will, on balance, be biased in a direction intended to promote drug use. The examples presented in this testimony are not atypical and were not difficult to find.

I also believe the growing proportion of medical communication that is supported by the drug industry threatens the integrity of the whole process of post-graduate medical education. I would now like to turn to some examples to illustrate my concerns.

THE MEDICAL LITERATURE

Appendix A is a list of the twenty-eight medical publications having a circulation of seventy thousand or more. The list was compiled from the

March 24, 1976 issue of Standard Rate and Data Service which contains circulation figures for all major publications. Of these twenty-eight publications, only one, The New England Journal of Medicine, is financed to any major extent by subscriptions. Twenty-five of these twenty-eight leading publications are sent to physicians free of charge and are paid for entirely by industry funds. Two other publications, American Medical News and the Journal of the American Medical Association, are financed through a combination of dues paid to the American Medical Association and by pharmaceutical advertising.

Only two of the journals, The New England Journal of Medicine and the Journal of the American Medical Association, are scholarly journals, i.e., journals which primarily print reports of original research submitted by the investigator after review by independent expert reviewers. The remainder are publications which the pharmaceutical and publishing industries call "controlled circulation" publications. They are also known popularly as "throw-aways". They generally do not publish original work and usually do not have a rigorous review of papers of the type conducted by the scholarly journals. They are sent to physicians, not because they are requested, but simply because the physicians' names appear on mailing lists.

Of the twenty-six leading journals which are throw-aways, four concentrate on legal and socioeconomic aspects of medical care. The remaining twenty-two focus on medical treatment. The medical publications sent to the physician thus constitute a literature overwhelmingly supported by the drug industry.

We have brought with us today a number of examples of these journals. Each one consists of a number of drug advertisements plus a number of articles which appear to be independently written.

It is not easy to assess the scientific quality of the controlled circulation journals. Much of it appears, on its face, quite reasonable, tending to be oriented toward review articles and articles dealing with particular clinical problems, e.g., how to diagnose and treat lower back pain. At the same time, however, I must wonder whether a journal that subsists wholly on sales of advertising space to the drug industry is able to present a skeptical attitude toward drugs in general or toward specific drugs.

Editorial Policies

FDA has received complaints from some authors that when they prepare an article unfavorable to drug products the articles are rejected by the controlled circulation journals even when they were solicited by the journal in the first place. The reasons given for rejection are that the article does not meet some unspecified technical standard, but whether or not this is the entire reason is difficult to determine.

Members of our staff have had several meetings with editors of controlled circulation journals asking specifically about editorial policy regarding articles adverse to the product of an advertiser. A common answer is that such articles rarely are received because physicians are more interested in reporting successes than failures and that, furthermore,

successes make more interesting reading than failures. Another common answer is that the journal sells space on the basis of reader interest and to sustain this interest the journal must contain objective articles. Usually, however, it is acknowledged that whenever material severely adverse to a sponsor is received, that sponsor is given the opportunity to rebut that material before it goes into the journal.

In any event, and for whatever reasons, the editorial content of these controlled circulation journals is overwhelmingly optimistic about drug therapy. A recent editorial appeared in the January 1976 issue of Current Prescribing. The article, entitled "The Undermedicated Society," laments that underprescribing and not overprescribing is a major problem in American medicine. The author states, "The family physician's alleged propensity to overprescribe has provoked well-publicized investigations, both Congressional and clinical."

"But what of the other side of the problem - underprescribing? Do doctors sometimes prescribe too little? In interviews with experts in several specialties, Current Prescribing found that the answer is yes. For many conditions, and with a number of drugs, M.D.'s may be giving their patients therapeutic short change." I am submitting a copy of this article for the record.

The editorial position is not without merit, but several questions arise. The editorial writer was not a physician and had to seek advice about matters like under- and overprescribing from physicians. In selecting his consultants could the support of his magazine have affected his choices? Is a journal wholly dependent upon the pharmaceudical industry

for support willing to editorialize on the excessive use of a drug class? Perhaps the answer is yes, but one must wonder.

Information on Unproven Uses of Drugs

The pages of the controlled circulation journals frequently are employed to bring to the physician's attention new uses for a drug product which are not yet approved by the Food and Drug Administration, something the manufacturer is not permitted to do through the usual channels of drug advertising and detailing. A typical example is an article entitled "Migraine...and More, Treatment and Prevention" from the April 1976 issue of Current Prescribing. I will also submit a copy of this article for the record. The American Medical Association grants one full hour of Category I, the highest category of continuing education credit, for study of this article. This article describes unapproved uses for Ayerst's Inderal, Knoll's Octin, Carnrick's Midrin, Merck's Periactin, and Sandoz's Sandomigran. Sandomigran is an investigational drug not marketed in this country. The issue is not whether the article is scientifically correct or whether it is proper to publish such information. There can be no doubt that scholarly medical journals should contain new information about drugs and should not be limited to the contents of approved package inserts. The issue here is whether such an article in a controlled industry circulation journal presents, in the guise of a scientific paper, promotional information which otherwise could not be legally published as drug advertising or drug labeling. The article in question did not pass through the rigorous independent editorial review common to scholarly journals.

Support for Brand Name Drugs

I would point out, in addition, that the editorial policies of these journals are often consistent with the position of the large pharmaceutical manufacturers. For example, in a special supplement of the March 1976 issue of Private Practice, a controlled circulation journal sponsored by the Congress of County Medical Societies, the editors report on a campaign launched with the help of the publishers of Private Practice to fight repeal of Oklahoma's strong anti-substitution law. A copy of this article will be submitted for the record.

Later in an editorial in the April 1976 issue of the same magazine, the editors report on the success of this educational campaign in changing public opinion in regard to drug substitution. The publisher of Private Practice offers to make available, free of charge, the newspaper mats, video and audio tapes and brochure text to any county medical society wishing to mount a similar campaign. A copy of the pertinent section of this editorial is attached as Appendix B.

Let me emphasize that I am not implying, for purposes of this testimony, that these campaigns are improper or not in the public interest. The important question is: Is it likely, or even possible, that a controlled circulation journal dependent upon drug industry support would take another point of view?

I would like to call your attention to one of these publications, the March 1976 issue of Primary Cardiology. It would take a perceptive reader indeed to see the fine print at the bottom of page 5 of this

issue, which says: "USV Pharmaceutical Corporation sponsors PRIMARY CARDIOLOGY^{tm} as a continuing educational service to the practicing physician." A copy of the page on which this quote appears is attached as Appendix C.

The controlled circulation journals represent a large proportion of the total literature reaching physicians, are entirely dependent on the drug industry for support, and appear to be generally enthusiastic about drug therapy. This is not to say they do not provide very useful information. These journals specialize in carefully presented practical discussions designed to help the physician deal with most common problems. These journals are excellent communicators and they must be having some impact. There is no avoiding the question of whether it is desirable that they be financed entirely by an interested party.

In addition to controlled circulation journals supported by the advertising of many pharmaceutical companies, there are a number of publications which appear to be independent but are actually sponsored entirely by a single pharmaceutical company. We have brought with us today several examples of this type of publication, which we will submit for the record. Such house organs are regulated as labeling and cannot be inconsistent with the approved package insert for the drugs discussed. These magazines, however, do not look like drug labeling and their sponsorship is not easy to ascertain.

INDUSTRY-SPONSORED SEMINARS

The drug industry sponsors numerous medical symposia and seminars. These have been discussed in Pills, Profits, and Politics, by Silverman and Lee, as follows: "One customarily practiced device is the drug industry sponsored conference or symposium devoted either to a particular new drug product or to a clinical problem in which the product may seem to have value. The nominal host may be a medical group, a medical school, or a medical or scientific academy. The speakers may include various Americans, although European participants supposedly provide desirable glamour. It is generally considered useful to include a hundred or more physicians in the audience of newspaper, magazine and trade journal writers. The indoctrination of the doctor in the audience is viewed as helpful, but more importance is placed on the accounts filed by the press representatives present and on the formal published proceedings of the conference, which may be used for months as 'scientific' background."

Since the publication of the Silverman and Lee book, the live audience has been extended by the use of closed circuit live television. In January 1976, Pfizer Laboratories, Division of Pfizer, Inc., sponsored such a closed circuit nationally televised seminar on the diagnosis and treatment of diabetes mellitus. The program seminar provided a learned discussion of this disease but attempted to steer clear of the findings of the University Group Diabetes Program (UGDP) and the resulting adverse publicity surrounding oral hypoglycemic drugs, including Pfizer's Diabinese.

Without debating in this testimony the merits of the UGDP Study, it is difficult to imagine how a modern discussion of diabetes treatment fail to emphasize its findings. I am aware of at least one round-table discussion in a controlled circulation journal, Patient Care, which discussed the implications of the study in a balanced way, ultimately taking a middle-of-the-road position which suggested that many physicians who treat diabetes felt the oral hypoglycemic drug should be used more sparingly. This certainly seems a minimum position. The Pfizer symposium, however, largely avoided the whole issue.

Another example is a symposium sponsored by Wyeth Laboratories which was devoted entirely to its product Serax (oxazepam), a benzodiazepine tranquillizer similar to Librium and Valium. The proceedings of this conference were published as a supplement to the May 1975 issue of Diseases of the Nervous System. The special issue did not reveal the symposium's sponsorship, but contains articles which suggest special advantages that the Wyeth product may have over the other benzodiazepine tranquillizers.

I want to emphasize again that medical investigators must be free to write whatever they wish about drugs and to speculate about advantages one drug may have over another. In this case, however, the investigators were selected by the manufacturer to participate in an industry-sponsored meeting, the proceedings of the meeting were published without reference to such sponsorship, and the papers all turn out to be favorable to Serax.

Even if the investigators, who are well-known physicians in their field and investigators of known integrity, are accurate in everything they say, the process through which this supplement to a medical publication was produced is cause for concern.

EDUCATIONAL MATERIALS

The fastest growing areas in continuing medical education today are audio-visual materials and multi-media learning systems.

Radio Broadcasts

The Physician's Radio Network (PRN) broadcasts the latest news of medicine to physicians twenty-four hours a day. I will demonstrate a PRN Radio portion of one of these broadcasts right now. The radios themselves and the programming on them are financed entirely by the sale of advertising time to pharmaceutical manufacturers. Each sixty minutes of programming contains eight minutes of advertising for brand name drugs. Routine listing to PRN is approved for Category 5A Continuing Medical Education Credit by the American Medical Association. Physician's Radio Network is a subsidiary of Visual Information Services, itself a subsidiary of Republic Corporation.

Video Tapes

Visual Information Systems also produces the Network of Continuing Medical Education, a biweekly, hour-long video-tape distributed to hospitals, courtesy of Roche Laboratories, division of Hoffmann-LaRoche, Inc.

Nearly every major pharmaceutical company is engaged in producing materials for continuing education. These materials commonly use formats one associates with disinterested educational efforts--i.e., expert panels and lectures by distinguished physicians. Despite their appearance, and despite the fact that they may be generally accurate, they are often promotional of particular drugs or drug classes and, on the whole, are one-sided. One does not often find in these materials the sort of healthy skepticism of a particular therapy that a journal like the Medical Letter brings to its readers. Typically, one does not see on such panels those physicians who believe oral hypoglycemic agents are dangerous, who believe antianxiety agents and sedatives are overprescribed, or who think that hyperactivity in children is overdiagnosed and overtreated with drugs. The result is a tone of therapeutic optimism, uncritical review of the subject and lack of balance.

I want to illustrate the kinds of materials I am talking about by showing a few examples of industry-sponsored educational materials related to the use of psychoactive drugs.

The first example is a video tape on depression, sponsored by the American Pyschiatric Association and financed by Pfizer Pharmaceuticals. The program is made available to groups of physicians by Pfizer detailmen. Some segments of the program will demonstrate that the tape, while probably reflecting the participants' views fairly, strongly encourages use of antidepressants generally and to some degree Pfizer's product Sinequan specifically.

As you will see, the tape begins by mentioning that there are 4 to 8 million people with depression, and that the tape is sponsored by the American Psychiatric Association and financed by Pfizer.

A series of scenes then suggests that depression is far more pervasive than one might have suspected. First an estimate of 20 million people per year is proposed as a more probable alternative to the 4 to 8 million figure. Depression is broadly defined as "the absence of joy, anhedonia" and various examples illustrate its ravages: the housewife, the underachiever, people with psychosomatic complaints, insomnia, or sexual dysfunction. The increase in recent years of the use of tricyclic antidepressants is noted and is accounted praiseworthy. Finally, the last speaker of the symposium suggests that tricyclic antidepressants are particularly good drugs and indicates certain advantages that Sinequan, Pfizer's tricyclic, has.

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The message is quite clear:

--Depression is everywhere and being underdiagnosed;

--Patients need not be actually depressed--insufficient joy, psychosomatic complaints, or underachieving may be the only signs or symptoms and may be enough to make a diagnosis of depression;

--Sinequan is the best of a good group of drugs, whose use, fortunately for the American public, is finally increasing to high levels;

--The physician should join this welcome trend and use the drugs more.

There is every reason to believe that the physicians participating in the taped discussion are voicing with full personal integrity, their best medical opinions. It is also likely, however, that the drug firm knew what each physician would say before they invited him and thus assured the emergence of a particular point of view in its educational production.

Audio cassette tapes come to physicians in ever-increasing numbers. They are particularly useful to the physician because they allow him to make use of time that ordinarily is lost while driving in his car.

I would like to play for you an excerpt from a February 1976 tape from the American Osteopathic Association Audio Educational Service, sponsored by Abbott Laboratories; the speaker is an osteopathic physician interviewed for this particular program.

Again, a clear message is given: anxiety is everywhere and chemotherapeutic agents are the treatment of choice. The program tells the physician that minor tranquilizers are the preferred drugs and mentions that a once-a-day regimen is best. Abbott's Tranxene SD happens to be the only minor tranquilizer with a once-a-day dosage regimen.

A second excerpt is from a lecture on Stress, Anxiety, and the Cardiovascular System by Han Selye, M.D., Ph.D., D.Sc. In the words imprinted on the audio cassette, the lecture is, "Sponsored as a service to physicians by Pfizer Laboratories Division."

Again without a hard sell, the message is the same: More people need more tranquilizers for longer periods of time. Pfizer Labs manufactures the minor tranquilizer Vistaril and the trade name Vistaril is displayed prominently on both sides of the cassette. Transcripts of the excerpts I have just played are attached as Appendices D and E.

As another example, Roche Laboratories, manufacturer of Librium and Valium, sends out records of heart sounds in various types of heart disease. The records themselves are excellent and I believe quite useful. Each record is jacketed with promotion for Librium and Valium,

interspersed with textual material. The unmistakable impression given is that the presence of heart disease, rather than the presence of anxiety, calls for tranquilizers, despite a fine print disclaimer, "the editorial content of this series is not intended to suggest the use of any specific drug or treatment program."

Pharmaceutical Industry Benefits from Educational Materials

Our experiences with several organizations which planned to produce a large number of educational materials provide some interesting insights. As an example, two years ago, Synapse, a subsidiary of the J. Walter Thompson Company, proposed to produce a series of forty-eight disease oriented video tapes to be sold to physicians under the auspices of the American Academy of Family Physicians. The cost of producing each tape was to be paid by a pharmaceutical manufacturer. The first tape was on urinary tract infections and was to contain commercials for Eli Lilly's cephalosporin antibiotics. The advertising agency expressed considerable dismay when FDA ruled that if the products advertised were intended to treat the disease discussed by the tape, then the entire tape would be considered drug labeling. This meant that the content could not deviate significantly from the labeling in the package insert. Synapse's contention was that no company would sponsor such an educational undertaking unless it could be related to one or more of that company's drugs, and, indeed, the series did not go forward. This contention has been repeated over and over again by media suppliers in discussions with the Agency.

Increasingly, pharmaceutical companies are providing continuing education materials for use at hospital staff meetings. These materials generally are produced by independent companies such as Medcom and Health Learning Systems on contract for pharmaceutical manufacturers.

Examples of Multi-media Presentations

Health Learning Systems, in cooperation with the National High Blood Pressure Education Program, the Council for High Blood Pressure Research of the American Heart Association, and the National Kidney Foundation has produced an excellent series of materials on hypertension. The series, called Dialogues in Hypertension was produced under an educational grant from Smith Kline & French (SKF) Laboratories, manufacturers of Dyazide, a fixed-combination diuretic indicated for hypertension. Let me emphasize that none of the materials produced were favorable to Dyazide specifically and, if anything, deemphasized the product.

In this instance the educational materials, while industry-supported, were under the total control of a Federal-private program of unquestioned independence and prestige which was furthering the widely-accepted goal of assuring that more people with high blood pressure were diagnosed and treated. SKF did no more than pay the bills. The goal of the overall program happened to conincide with the goals of manufacturers of drugs used in treating hypertension and with good medical practice.

In many other cases, however, increased use of medication is not necessarily consistent with good medical practice.

One such example is a learning system on the subject of stroke developed by Health Learning Systems, Inc., and sponsored by Marion Laboratories. The learning system consists of two motion picture films, accompanying work books, tests to be taken by physicians, plus materials used to advertise the learning system to directors of medical education and to hospital medical staffs.

Marion Laboratories markets papaverine hydrochloride in a sustained release oral dosage form named Pavabid. The drug is claimed to be a cerebral vasodilator and to improve circulation to the brain (let me note parenthetically that the usefulness of this drug has not, in our view, been demonstrated).

In the April 5, 1976 issue of the Federal Register, the FDA called for marketers of papaverine to submit evidence of safety, efficacy, and possible "grandfather" status of the drug. The Federal Register statement said that the drug would be removed from the market if such evidence were not submitted.

At a September 1974 meeting of the Western Pharmaceutical Marketing Research Group, held in Chicago, a representative of Health Learning Systems explained why Marion Laboratories was interested in sponsoring a learning system on stroke. Marion's Pavabid already had more than 60 percent of the cerebrovasodilator market and Marion felt that no amount of advertising would increase this percentage very much. It

was also felt, however, that if the total market for cerebrovasodilators could be expanded, Marion Laboratories would get a high percentage of the increased sales. One way to expand the market for cerebrovasodilators was to convince physicians that these drugs were useful in the prevention and treatment of stroke.

The first segment of the learning system made no direct claims for the effectiveness of Pavabid in the treatment or prevention of stroke but simply focused on the transient ischemic attack (TIA), a brief episode of focal neurologic deficit, as an early warning sign of stroke. It then provided prescribing information for Pavabid and a logo of a linegraph superimposed over a longitudinal slice of a brain.

The second part of the learning system discussed the "Diagnosis and Treatment of Cerebral Vascular Insufficiency." The relatively uncommon cases which can be helped by surgical intervention were discussed in a superb presentation by Dr. Michael E. De Bakey, President of the Baylor College of Medicine.

The final segment of the learning system considered vasodilator therapy. The accompanying workbook pointed out that intravenous papaverine, which is not marketed in the United States, is one of the most effective vasodilating drugs and then proceeded, in a leap in logic, to recommend the use of oral papaverine in patients recovering from completed strokes and transient ischemic attacks.

Again, despite the educational format and the appearance of distinguished physicians, the learning system is not a disinterested effort. First of all, it is directly linked to a frankly promotional effort. The linegraph-brain logo that appeared in the film was subsequently reproduced in journal advertisements and promotional labeling for Pavabid. Those promotional efforts are directed, just as the learning system was, at the use of Pavabid in the treatment and prevention of transient ischemic attacks. In addition, although some physicians believe cerebrovasodilators are useful, a great many others disagree. The learning system did not refer to these negative views and a user of the system would necessarily gain a very incomplete view of the current opinion of experts regarding these agents.

Another new continuing education modality is the Medical Telephone Conference System. These "telesessions," sponsored by pharmaceutical firms, enable physicians from around the country to discuss a disease for which the company's product is offered with the guidance of a company representative.

Appendix F is a leaflet intended for pharmacists describing telesessions to be held for Pennwalt's Zaroxolyn. Noteworthy are the statements "A.M.A. Credit" and "Positive Effects on Sales Shown by Previous Participating Companies in Other Therapeutic Categories: Roche - Abbott - Burroughs Wellcome - Smith Kline & French."

While we do not know precisely what fraction of educational materials is industry-sponsored, we believe it is large. The examples provided show clearly that the educational content is commonly promotional in intent.

SCIENTIFIC EXHIBITS

At most medical meetings there are numerous exhibits, some of which are commercial exhibits promoting various drug products, others of which are scientific exhibits describing the work of independent scientists. These latter are usually not bound by the kind of

limits our regulations place on drug labeling or advertising, because they have been considered equivalent to scientific publications. As a result, such scientific exhibits frequently discuss new uses of drugs, drugs not yet approved, and comparative properties of drugs not made in approved labeling.

Recently, Agency action related to the regulation of drug labeling has raised serious questions about these exhibits. In an attempt to define ways in which a drug company could distribute independently prepared educational materials, such as standard textbooks of pharmacology, we suggested guidelines under which such information would not be considered drug labeling. For the most part, these guidelines attempted to assure that such materials were wholly independently developed and edited. We did not feel that materials which discussed products of a single manufacturer or which discussed drugs and were produced with drug company funds could avoid being labeling if a drug company distributed them.

We have discussed these guidelines with representatives of the American Medical Association and the Pharmaceutical Manufacturers Association who indicates that many scientific exhibits depend upon the support of individual pharmarceutical companies whose products are described in the exhibits.

The problem faced by the AMA is detailed as follows in a memorandum written by one of their committee chairmen: "By this definition (meaning sponsored by the manufacturer of the drug), approximately 80 percent of the scientific exhibits at the AMA meeting are promotional and probably half of these are in noncompliance with the regulations for the labeling of pharmaceutical products as set forth in the Federal Register."

Cost of Scientific Exhibits

In the same memorandum, the author estimated that the total cost of a scientific exhibit is $5,000 to $40,000 and concluded: "few physicians or scientific investigators can afford to have an exhibit unless they receive financial support. In the past, large clinics and medical centers supported exhibits as part of their public relations and professional education programs. The source of these funds has been severely reduced lately. Some exhibits have been supported by professional societies and lay health organizations, but too often these organizations are more interested in recruiting members and raising funds than in educating physicians. Support from the Federal Government through National Institutes of Health, Armed Forces Institute of Pathology, the Food and Drug Administration and the military forces has helped in the past, but this has been greatly reduced. The only other source of financing exhibits has been pharmaceutical companies. Either directly or indirectly this pays about 80 percent of the cost of the scientific exhibits.

"Using a scientific exhibit for promotional purposes is contrary to the spirit of the regulations of the AMA. However, the AMA cannot be responsible for anything that happens to an exhibit or to the brochures after the meeting. In this highly competitive society few pharmaceutical companies can afford to support a purely educational exhibit."

Use of Scientific Exhibits to Promote Unapproved Drugs

Appendix G shows, as an example, pages 66 and 67 and 76 and 77 of the official program for the Twenty-seventh Annual Scientific Assembly of the American Academy of Family Physicians (AAFP) held in October 1975. A large percentage of the exhibits are drug related. Appendix H shows pages 138 and 139 of the program of the American College of Physicians' Fifty-seventh Annual Session held in April 1976. In both programs, there is an exhibit by the same physician describing the development of an antihypertensive drug, prazosin hydrochloride.

Let me note that under FDA regulations pharmaceutical manufacturers may not promote their drug products prior to approval for marketing. In this case, although it was not noted in the program, the investigator was a full-time employee of the drug manufacturer which had developed prazosin. Prazosin had not been approved for marketing at the time of either meeting.

In the AAFP program, there are two scientific exhibits on Tolmetin, a drug developed by McNeil Laboratories for treatment of rheumatoid arthritis. At the time of the AAFP meeting, Tolmetin had not been approved for marketing in the United States. In response to the Agency's questions, a representative of the firm stated that the construction of both exhibits was financed by McNeil. The representative went on to state that his company customarily financed such exhibits when its medical monitor was pleased with an investigator's results. He stated that such scientific exhibits were shown at two to four conventions each year and that while attending the convention, each exhibitor received an honorarium of about $250 per day plus reimbursement of all expenses.

Again, let me stress that I have no reason to believe that these industry-supported scientific exhibits represent anything other than the honestly-held beliefs and legitimate findings of the investigators involved. Many contain high-quality work. It is nevertheless a matter of great concern that most of the content of scientific exhibits is to a great degree selected by the drug industry. The exhibits committees of the conventions no doubt can eliminate the more frankly promotional exhibits, but they can do little to alter the fact that an exhibit unsupported by a drug company will usually not be produced and submitted for their review.

ROLE OF REGULATION

Mr. Chairman, let me turn at this point to the possible role of regulation in addressing this overall problem. The FDA is responsible for regulating drug advertising and labeling, and I believe we do that well. On the other hand, we also have a responsibility not to restrict legitimate educational materials which are not under the authority of the Federal Food, Drug, and Cosmetic Act.

I would like to make one point unequivocally clear. Any scientist, physician, or other person can say or write anything he wants about a drug, so long as this effort is not subsidized by the drug industry. The Federal Food, Drug, and Cosmetic Act poses no threat whatsoever to scientific communication and debate on drugs, to the reporting of research on drugs, or to the voicing of any medical opinion on drugs, providing industry funding of that communication is not involved.

Once a drug firm distributes written or audio-visual material about a drug, or in association with one of its drugs, however, that material comes under the labeling provisions of the law. Labeling has been defined quite broadly in the Federal Food, Drug, and Cosmetic Act and by the Courts and includes virtually all printed materials about drugs placed into interstate commerce and supported by a drug firm.

Under present law FDA has regulatory authority over some of the materials I have been using as illustrations. Cassettes which discuss a particular drug, for example, must meet standards for drug labeling and may not promote nonapproved uses of drugs, minimize hazards, or make comparisons not supported by evidence. This still does not, of course, mean that they are neutral educational materials as their formats might suggest.

PROPOSED FDA GUIDELINES

Recently, FDA was asked by a medical society whether a drug company could legally distribute a monograph prepared by the society without including prescribing information. The society objected strongly to the presence of such information because it would, they felt, have suggested that the monograph was promotional or prepared by the drug manufacturer when in fact it was not. In an attempt to define the circumstances in which we would consider informational material disseminated by a drug manufacturer not to be drug labeling, and thus not obliged to contain package insert information or to maintain strict conformance to the content of the approved package insert, we suggested the following five tests:

1. The material has been prepared solely for educational use and not with any intent that it be used for other purposes, e.g., sale to or distribution by the pharmaceutical industry.

2. The material is not promotional in nature taken as a whole, and is in the form of balanced educational materials. For example, the material may not contain any significant emphasis on uses for drug products that are not approved by the Food and Drug Administration as safe and effective, i.e., use for unapproved indications or in derogation of required contraindications and warnings. Although the material may contain occasional references to such uses, such references may not be frequent or be given major consideration or importance.

3. The material has been prepared independently, i.e., the pharmaceutical industry has not participated in the preparation of the material and has not exercised editorial review over the content of any of the material.

4. The material covers a number of different drugs, and does not support use of one particular drug or the drugs of a particular pharmaceutical company.

5. The material is not associated in any way with a promotional campaign for any drug product by the pharmaceutical firm supporting the exhibit. The material may contain reference to support by a pharmaceutical firm.

These tests, let me stress, were intended to permit truly independently prepared educational materials which do not have an overall promotional message to be distributed by drug manufacturers. When we were asked about scientific exhibits, we suggested essentially the same criteria.

We are currently drafting an extensive revision of our drug advertising and labeling regulations, and we expect to include guidelines such as those noted above in these proposed regulations. We are concerned that both the American Medical Association and the Pharmaceutical Manufacturers Association believe that these criteria would virtually eliminate scientific exhibits and industry-sponsored symposia. These regulations could thus have an enormous impact on post-graduate medical communication and we would not take such a step lightly. We expect extensive comment on these regulations and will consider such comments carefully. At the same time, the extensive influence of the drug industry in these educational media is well illustrated by the profound effect our suggested guidelines could have.

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In brief, then, regulation under the Federal Food, Drug, and Cosmetic Act is an important restraint on some promotional efforts sponsored by the drug industry. I would not want to suggest, however, that regulation is the best approach to take for all of the educational materials supported by the drug industry. The idea of the Federal government and Madison Avenue locked in eternal battle over every piece of educational material sent to physicians is not particularly attractive. Neither of these parties should have primary control over educational materials. Such control properly belongs with the profession itself and its medical schools.

AN OVERVIEW

Mr. Chairman, I would like to summarize the problem in broad terms. The technical knowledge required for the optimal practice of medicine is continually advancing at a rapid pace. Because of this, there is need for excellent courses and teaching materials to assist the modern physician in maintaining his professional competence throughout his career. This need is increasingly recognized by specialty societies and State boards of licensure. Thus physicians are coming under increasing pressure to demonstrate in a formal way their participation in various courses, hospital seminars, and other teaching programs.

To fill the need for teaching materials the communications industry has moved aggressively in recent years to produce an enormous variety

of brochures, books, monographs, magazines, controlled circulation journals, closed circuit TV video tapes, movies, audio cassettes, and self-instructional learning systems. Many of these are sent free to physicians, some under the sponsorship of professional organizations. These materials are highly professional from the standpoint of communications technology and obviously expensive to produce.

Outstanding medical authorities commonly are featured, and the scientific content of these communications is often excellent. While some of these communications relate to specific drugs and are readily recognizable as promotional material, many others deal with broad issues in medicine, including the diagnosis and general management of various diseases. Others may describe specific technical advances in a variety of specialty fields. The financial support for all of this activity comes predominantly from the pharmaceutical industry, which in turn obviously passes the cost along to the consumers of drugs.

The proliferation of industry-supported educational materials has increased to the point where they now constitute the bulk of educational information provided to the practicing physician in his practice. The physician, of course, has other opportunities for post-graduate medical education, including a variety of courses conducted by medical schools, scientific meetings, and the medical literature.

The relative impact of these different educational opportunities on physician behavior is not clear. Physicians are trained to think for themselves, to be critical, and to engage in life-long learning. I do not consider my colleagues to be pawns of the communications industry. Nevertheless, it is reasonable to ask why our profession should be subject to an onslaught of allegedly educational material, not subject to the kind of independent review given the scholarly medical literature, which is financed by the drug industry, and ultimately paid for by our patients.

My concern, Mr. Chairman, is with this system, because it places the post-graduate education of an entire profession too much under commercial, non-university influence. I believe it is self-evident that the drug industry would not be supporting this field so heavily if it did not believe such support was beneficial to the sale of drugs.

Let me also emphasize that, while I have used the words "physician" and "drug industry" throughout this testimony, a similar situation applies to other health related professions and industries. The post-graduate education of dentists, veterinarians, and pharmacists is also heavily influenced by the drug industry. Nor is this industry alone in its behavior. My testimony applies equally well to the medical device industry and the diagnostic products industry.

The best solution to this problem is easy to describe in concept, but difficult to envision without major changes in the whole structure of post-graduate medical education. As I have emphasized repeatedly, I

believe that control of the educational process for physicians properly resides with university-based medical schools. The pre-Flexnerian era taught us that medical education should not be entrusted to a commercial trade school environment, and our society should not have to learn that lesson over again. Medical schools are not financially in a position to accept responsibility for the post-graduate education of physicians.

I believe it is important that this problem be discussed openly, and I commend your Subcommittee for undertaking these hearings. If the extent of the problem is as great as I suspect, and if my concerns are confirmed by others, society must entertain innovative solutions, even drastic changes in some of our current behavior.

The possibility of permanent pharmaceutical industry dominance over the total post-graduate education of physicians and other health professionals is too serious for us to ignore.

Mr. Chairman, my colleagues and I will be happy to answer any questions you or the other Subcommittee members might have.

APPENDIX A

Circulation of U.S. Medical Journals With Total Circulation Over Seventy Thousand According To March 24, 1976 Issue of Standard Rate and Data Service

Journal	Free Distribution	Paid Distribution
American Family Physician	108,714	
American Medical News	258,811	2,307
Consultant	142,120	
Current Prescribing	118,168	
Drug Therapy	113,793	
Emergency Medicine	109,974	
Hospital Medicine	178,687	
Hospital Practice	187,134	
Hospital Tribune	100,000	
Infectious Diseases	139,840	
Journal of the American Medical Association	27,579	211,856
Journal of Legal Medicine	125,626	
MD Medical Newsmagazine	181,481	
Medical Aspects of Human Sexuality	161,522	
Medical Challenge	77,749	
Medical Economics	169,624	
Medical Opinion	152,191	
Medical Tribune	150,000	
Medical World News	164,652	
Modern Medicine	170,311	
New England Journal of Medicine	923	158,190
Patient Care	101,145	
Physician's Management	179,386	
Physician and Sportsmedicine	90,533	
Postgraduate Medicine	108,068	
Practical Psychology	104,092	
Private Practice	171,659	
Resident and Staff Physician	95,948	319

EDITORIAL

Anti-Substitution Success / Medical Device Disaster

by Llewellyn H. Rockwell, Jr.

Most of the people who understood drug substitution in Ada and Shawnee, Oklahoma, were for it. Last month in PRIVATE PRACTICE we reported on the unique media campaign waged by county medical societies, with the help of county pharmacists associations and the Congress of County Medical Societies, to change that. "We wanted to see if we could educate our patients in the dangers of drug substitution," said Orange Welborn, MD, an Ada general surgeon, "and motivate them to take action against the substitution bill that was then pending in our state legislature."

"It worked," adds Roy Kelley, a Shawnee surgeon. "It worked splendidly. It turned apathetic patients—and, I might add, doctors—into militant foes of substitution."

The story of the campaign, complete with reproductions of the ads used, was published in the March PRIVATE PRACTICE. The final results are now in.

In January 1976, before the campaign, people in Ada and Shawnee were asked, "Have you heard about the drug-substitution bill that is pending in the Oklahoma Senate?" If they answered yes, they were then asked to explain what it would mean, and whether they were for or against it. In Shawnee, 38% knew, 59% hadn't heard about it, and 3% weren't sure. Of those who knew what it was, 52% were for substitution, 32% were against, and 6% were undecided. "Cheaper drugs will help older people"; "We will get the same drugs for less" were typical responses.

In Ada, 54% knew what substitution was; 45% didn't; one percent wasn't sure. Of that 54%, 43% were for substitution, 38% were against, and 18% were undecided. "The elderly will be helped by generic names"; and "Substitution will be cheaper" were two of the comments.

Combining the two cities, the county medical societies found that 48% had heard about substitution; 51% hadn't. And of that 48%, 46% were for it, 36% against, and 17% were undecided. "Our job," said surgeon Dr. J. B. Wallace of Ada, was to change the percentages of people who had heard of substitution and of those who were against it."

The intensive five-week campaign combined newspaper ads, and TV and radio spots. The campaign ended with the county societies sponsoring a two-hour TV movie, with live breaks for telephoned questions to a panel of doctors and pharmacists.

After the media campaign, the percentage of people in Shawnee who had heard of substitution went from 38 to 57; in Ada, it went from 54 to 89. In Shawnee, the percentage of people who opposed substitution went from 32% to 77%; in Ada, from 38% to 84%.

"Even more important that this exciting change in public opinion," said Dr. Kelley, "was the action we were able to persuade our patients to take. Over 2,400 cards or letters of protest were sent to the state representatives and senators from Shawnee and Ada. After the first week, they were taking notice. After the campaign, they were completely on our side. I believe we have proved that this kind of campaign will work."

The Congress of County Medical Societies, Inc., agrees with Dr. Kelley, and the newspaper mats, video and audio tapes, and brochure text will be made available, free of charge, to any county society wishing to mount a similar campaign. And the CCMS is considering the implementation of similar campaigns against National Health Insurance and the 1962 "efficacy" amendments to the Food and Drug Act, which have caused the alarming fall-off in new drug development.

* * *

What Congress did to the pharmaceutical industry, and indirectly to patients and doctors, with the 1962 amendments, it is

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