tal where there is a reporting system of extraordinary quality. It has been made easy to follow by providing staff physicians with reporting cards attached to the patients' charts.

Dr. Leighton Cluff, professor of medicine at Johns Hopkins, and three Public Health Service epidemiologists made daily inquiries of doctors and nurses about drug reactions in a 120-bed medical service. They found that those supposed to fill out the cards failed so often that fewer cards were filled out for reactions in the entire hospital than the survey found had actually occurred in a 10 per cent sample of the hospital.

ENTHUSIASTS TROUBLED

If the 10,000 adverse reactions are a shaky foundation for judgments on safety, so are the uncontrolled studies upon which so much reliance has been placed to date. The studies have troubled even such exuberant boosters of the pills as Dr. Joseph Goldzieher ("I can think of no condition in which these pills would not be safe to take").

Citing the "deficiencies in published trials" in an article in the Medical Journal of Australia last June, he said that "much of the current discussion of the incidence of side effects is an exercise in futility."

In the British Medical Journal, Dr. Geoffrey Rivett said he had found no circulatory disorders in between 50 and 100 patients on the pills, even though some of them had a history of such afflictions.

"But such figures prove nothing," he said. "It would be a great help if an authoritative body would carry out" a valid trial. (See accompanying box.)

The FDA's Wright committee did not carry out a valid trial. Its mission was to determine if the incidence of thromboembolic phenomena—clots in the bloodways—is significantly higher in women on the pills than in women in the normal population 15 to 45 years old.

The committee found it impossible to get solid, usable data out of cases of nonfatal clots in Enovid users as recorded in the files of FDA and the manufacturer.

For that reason, the committee could shed no light on the incidence of a condition that is nonfatal but can cause lifelong disability.

The committee concentrated on fatalities, for which the data were more complete. Even so, the consultants labored under terrific handicaps.

The rate of side effects is the product of a fraction. The numerator is the estimated number of persons in whom adverse effects have been reported. The denominator is the population estimated to have taken the drug being studied.

If for any reason the numerator is too small or the denominator too large, or if both flaws exist, the incidence is understated.

To determine the incidence in the normal female population, the committee divided the population believed to be at risk—the denominator—into the number of cases of fatal lung clots as reported in death certificates for 1962.

Death certificates—the numerator—were all that the committee had to go by. But the reliability of these certificates varies greatly.

Unless there is an autopsy—and postmortems are held in only 20 to 30 per cent of all deaths—there is, if the cause of death is not obvious, no audit of the cause given in the certificate. Lung clots are often not obvious.

For women who had taken Enovid (which in this respect is believed to be no more or no less safe than other oral contraceptives), the committee's numerator again had to be what was available: the number of deaths reported to FDA and by the manufacturer, G. D. Searle & Co.

For its denominator, the committee used the number of women assumed to have been using Enovid during 1962. Precisely what that figure was, nobody—the company included—could possibly know.

This was dramatically illustrated last Oct. 16 in the British Medical Journal by Dr. Arnold Klopper. "An inquiry to leading companies in this country and in the United States . . . produced estimates varying from five million to 20 million women all over the world taking these compounds daily," he said.

But if a mere 10 per cent fewer patients took Enovid than the Wright committee calculated, Science magazine has said, "the death rate . . . would come very close to statistical significance for all ages; and if 50 per cent fewer people took it, the rates would be very significantly greater."

The often neglected facts are that the Wright committee, sharply aware of the limitations imposed by the information it had to work with:

Concluded only that the available data showed no significant increase in the risk of fatal lung clots in Enovid users.

Cautioned that "any firm reliance on the risks as calculated is tempered by the assumptions made."

Made one, and only one, recommendation: that carefully planned, controlled studies be started.

Although the potential consequences may be immense, FDA has not acted to implement this recommendation in the 27 months since the Wright committee made it. Until the recommendation is carried out, the uncertainties about hazards will not be stilled.

Nor will the uncertainties be dispelled by what Dr. Irwin C. Winter, Searle's vice president for medical affairs, said a year ago was "undoubtedly . . . the most comprehensive large-scale study in the oral contraceptive field."

He referred to a study undertaken by Searle in cooperation with 38 Planned Parenthood Federation clinics. An initial check of a group of 5000 women, he reported, showed an incidence of inflammatory clots among pill users comparable to the minimum rate known in the normal female population.

But the usefulness of the study was frankly conceded to be limited even by Dr. Winter when he said that there was not "an adequate control group" and that "adequate statistics" on the normal incidence of thrombophlebitis "were not available."

A SIGNIFICANT YEAR

A further criticism was made by Dr. Herbert Ratner of the Stritch School of Medicine of Loyola University in Chicago, who dealt in an interview with acknowledgements by Dr. Winter that the 5000 women were limited to those who, before entering the study, had been on the pills for at least two years.

This means that the study excluded those women who had started on the pills but dropped out because of side effects—serious or otherwise—or for other reasons in the first 12 months of use.

And this initial period, Dr. Ratner said, is the one in which most side effects occur. Therefore, he said, any conclusions drawn from data on the selected group that was able to enter the study are open to question.

Today's concern is most intense not about nausea and other such effects associated with pill-induced pseudo-pregnancy, but about afflictions involving the circulatory system: fatal clots, disabling clots, eye damage. There are, however, other concerns, including a feared possible relation between pill use over several years and cancer.

Although his warnings about such a possible relation have been hotly and widely challenged, Dr. Roy Hertz, former chief endocrinologist of the National Cancer Institute, said in an interview that the estrogenic substances used in the pills are known to induce a wide variety of tumors in numerous species of animals.

"It is, therefore, imperative that their generalized distribution to women of child-bearing age for protracted perids of time be preceded by appropriately comprehensive epidemiologic studies to ascertain whether such effects are to be anticipated in man," he said.

"To date, no statistically adequate studies sustained for a sufficiently long period of time have been reported," Dr. Hertz said, but some are being organized at the National Institute of Child Health and Human Development, of which he is now scientific director.

He said that these studies will get follow-up data for prolonged periods of time on users of various methods of contraception so as to ascertain the comparative effects.

These studies are recognized as appropriate for dealing with the questions about a possible serious adverse reaction that, if it would appear at all, would not be expected to manifest itself until after many years of pill use. But such studies will not be directed primarily to answering questions about possible adverse circulatory effects that most commonly would appear in the initial months of use.

UNDERCURRENT OF UNEASE

A gap almost as wide as that between Dr. Hertz and his challengers, who say flatly that the pills pose no cancer danger, exists over another possibility: that the pills, under certain rare circumstances involving failure of the user to follow instructions, can masculinize a female fetus.

In cases involving other major afflictions—including heart, liver, kidney and, in teen-agers, bone-closure diseases—those who believe the pills safe when carefully and properly used are challenged occasionally, but thus far rarely by solid, meaningful data.

Here, too, however, there is an under-current of unease. The pills have not been used long enough—it is only eight years since Enovid was marketed, chiefly for menstrual disorders—for anyone to speak with complete certainty about the effects of continuous use from adolescence to menopause.

Dr. McCain, the Emory University obstetrician, has reported that between May, 1954, and October, 1965, he found "disturbingly numerous" complications in 41 patients on the pills.

"The psychiatric complications seem to me to carry the most serious potential," he told a group of colleagues at the District IV meeting of the American College of Obstetricians and Gynecologists last Oct. 21 in Norfolk.

Of the 41 patients, he said, three "have told me that they were desperately afraid that they were going to kill themselves"—two of them after they had been on the drugs less than two weeks, the third after about four months. "The suicidal fears have disappeared in all three patients since omitting the contraceptive pills," he reported.

These patients are " the only ones I have ever had that have told me so dramatically of their fear of suicide," he said, adding that "it is disturbing to wonder how many women on the contraceptive pills have committed suicide and/or homicide."

Dr. McCain said that some colleagues have told him of pill users who have become almost euphoric. In either case—depression or euphoria—study of the psychiatric effects is needed, he said.

In this area as in others, the uncertainties about the relative safety of the pills can no longer be brushed aside. FDA's new Advisory Committee on Obstetrics and Gynecology acknowledged this after its first meeting.

Whether the committee will attempt to remedy this situation by recommending a proposal for a rigorously controlled investigation, such as that in the box with this story, "may well be its single most crucial decision," says the scientist who made the proposal.

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[From This Week Magazine, July 12, 1964, p. 13]

BIRTH-CONTROL PILLS—HAVE THEY SIDE-EFFECTS?—AN AUTHORITATIVE ANSWER TO A QUESTION MANY WOMEN ARE ASKING

(By Edwin J. DeCosta, M.D., Attending Obstetrician and Gynecologist, Passarant Memorial Hospital, Chicago)

"But doctor, are they really safe?" No wonder that after the thalidomide tragedy many patients worry about the possible harm from taking the new birth-control pills. And there have been a few medical reports—plus many rumors—of dangerous side effects. Without considering the controversial social or religious aspects of birth control, let us take a look at the medical facts about this important discovery.

First, no other method of birth control is as simple. The small hormone pills are taken at bedtime for 20 days each month. Apparently they work by suggesting to the body's master gland, the pituitary, that the woman is already pregnant, so the pituitary doesn't instruct the ovaries to produce an egg that month. When the patient stops taking pills after 20 days the lining of the uterus is sloughed and bleeding follows. Then the pills are started again for the next cycle. This simple method approaches 100 per cent effectiveness.

But . . . and there is always a but . . . there may also be undesirable effects when the pills are used. Generally, these effects are not serious—only nuisances similar to those experienced by some women during early pregnancy. They may become, for reasons we can't explain, bloated or nauseated, have

fullness and soreness of the breasts, suffer from headaches or even changes in their personality. Some women also gain weight rapidly, some have disturbance of their menstrual flow. Rarely, the menses do not return for some time after the pills are discontinued—which, of course, makes the patient fear she is pregnant.

Fortunately, in most instances these complaints disappear within a couple of months, as in pregnancy. But not always. At times, the weight gain, bleeding and personality changes maybe sufficiently disconcerting to warrant discontinuance of the pills.

But these are just nuisance factors. What about the reports of more serious problems? I have heard oral contraceptives accused of masculinizing female babies if taken inadvertently during early pregnancy, of interfering with future fertility, of causing uterine fibroids or even cancer. Most of these charges are palpable nonsence—there is no evidence to support any of them. Indeed, many patients report getting both physical and psychological benefits from the pills.

DANGER—LEG CLOTS

There is, however, one other widely reported problem connected with oral contraceptives. From time to time women taking them have developed blood clots (thrombosis) in the veins of their pelvis or legs. This can be serious—even fatal—but studies do not indicate that pills cause the clots. Thrombosis also occurs in men, and in women who are not taking contraceptive pills.

I am reminded of a recent medical meeting where a doctor reported several instances of leg clots occurring in patients taking the pills. Another doctor promptly rose. His patient too had been given a prescription for the pills, and had developed leg clots. But she had forgotten to have the prescription filled!

Do I myself prescribe the pills? I do, whenever I think they are indicated. But to avoid even the most remote risk, I would not prescribe them to women who have had blood clots, varicose veins, heart or kidney disease, or malignancy.

To sum up, my own answer to anxious patients is yes, there is good reason to believe that oral contraceptives are safe for normal women under their physicians' supervision.

# APPENDIX V

## WRIGHT COMMITTEE REPORTS ON ENOVID

### REPORT ON ENOVID BY THE AD HOC COMMITTEE FOR THE EVALUATION OF A POSSIBLE ETIOLOGIC RELATION WITH THROMBOEMBOLIC CONDITIONS

SUBMITTED TO THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, AUGUST 4, 1963

For centuries man has been interested in mechanisms and factors affecting the normal menstrual cycle, as well as those believed to be effective in either increasing of decreasing fertility. The artifacts of many civilizations attest to this. Therefore it should arouse no surprise that when a preparation which suppresses ovulation became available in tablet form it should be rapidly accepted and widely used. Such a tablet consisting of norethynodrel with ethinylestradiol 3-methyl ether (Enovid) has now been used by well over 1.5 million women for either contraception or for the treatment of disturbances of gynecologic endocrinology. It is believed that this substance acts by inhibiting the synthesis of gonadotropin by the anterior pituitary gland and in this manner suppresses ovulation in a high percentage of users.

It was soon recognized that Enovid produced a variety of side effects, including nausea and vomiting (sufficient to require discontinuation of the treatment in about 25% of the cases) and there have been reports of edema, weight gain, changes in thyroid or adrenal function, thyroiditis or toxicosis, hair loss or growth, dermatitis, cholestatic jaundice, chloasma, toxemia of pregnancy like syndromes and others. Except for nausea and vomiting the proof that these have been a direct result of the use of Envoid is in most instances open to question and is not within the scope of this report.

Beginning in 1961 reports began to appear from numerous sources of thromboembolic conditions, including thrombophlebitis and pulmonary embolism, occurring in women who had taken or were taking Enovid. Some of these patients died. While the index of suspicion was raised it was also recognized by the scientific community that a very large number of young and middle-aged females were involved, that such conditions do occur with and without obvious explanation, and that the coincidental factors involved' in such situations are not necessarily etiological. One solution would have been to scrutimize carefully each case history in detail, select those which appeared to be idiopathic in all other aspects, but who had the common denominator of exposure to Enovid, and compare these with a proper sampling from the population as a whole to determine whether there was evidence of an increase in the incidence of thromboembolism and deaths in the exposed series. Unfortunately the incidence of thromboembolism in the United States in this or any other population group is not known despite efforts in a few areas to obtain such figures. This type of condition is not reportable so that most of the patients which are not hospitalized are never recorded at all or the records remain in the physician's files. Once the attention of the medical profession and the general population was drawn to a possible relationship with Enovid, reporting of all types and severity of thromboembolic conditions in patients who had taken this drug was inevitably accentuated and comparable statistics became even more difficult. The death rate from thromboembolism in females of a comparable age group during the same period was not known, although this was obtained in the course of the present investigation.

In January of 1963 the Commissioner of the Food & Drug Administration, of the Department of Health, Education & Welfare established an ad hoc Com-

mittee to review and analyze this situation and to determine if the use of Enovid resulted in an increase in the incidence of death from thromboembolic conditions. This consitutes a report of the efforts of the Committee to resolve the questions involved. The Committee was composed of representatives with broad interests but especially experienced in the fields of gynecology and obstetrics, vascular diseases, thromboembolism, hematology (especially coagulation), and statistics; and epidemiology.

The Committee has not been unmindful of the complexity of the over-all considerations involved in this area. These incude not only the medical implications but also those involving the biological, psychological, social, philosophical and religious aspects. The relationship of all of these to the population explosion must be of interest to all intelligent citizens. Nevertheless these factors were not permitted at any time to cloud the immediate issues which constituted the commission of the Committee.

Background material was obtained from the Food & Drug Administration and G. D. Searle & Company. The representatives of both organizations were completely co-operative throughout this study. More than 350 case reports of both thromboembolism and death from the files of both sources were reviewed by the members of the Committee together with much additional data. After this it was concluded that because of the impossibility of obtaining solid comparable statistics regarding thromboembolic complications as they occur in the usual population groups, it was essential to concentrate on deaths where the documentation is more complete and valid.

*The coagulation balance*

The possibility of the production of changes in the coagulation balance which might significantly add to the risk of thrombosis or embolism was carefully considered. The pertinent literature on this point was reviewed and special studies designed to answer certain questions were carried out in the laboratories of member of this Committee.

In assuming the responsibility of trying to establish whether the use of Enovid affects blood coagulation adversely to a degree capable of resulting in thromboembolic disease, the Committee, after reviewing the available literature and recent unpublished experiments performed by members of the Sub-committee (attached appendix), accepted the following basic facts:

1. Enovid produces some uterine changes similar to those occurring in pregnancy. Therefore it was essential that the coagulation changes during pregnancy be reviewed. The gravid woman develops significantly increased concentrations of the following plasma clotting components: Factors VII (proconvertin), X (Stuart), VIII (AHF),* IX (PTC), fibrinogen, and platelets. Less definite evidence regarding Factors II (prothrombin) and the fibrinolytic components has been reported. Virtually nothing is known as yet regarding parallel changes in Factors XI (PTA) and XII (Hageman). Factor V (AC-globulin) is unaffected. Although thrombotic phenomena were not searched for or carefully analyzed in the studies during the antepartum period upon which these findings were based, overt thromboembolism was not strikingly impressive. This is not surprising since thromboembolism complicating pregnancy occurs 4–6 times more frequently in the immediate post-partum state than during the gravid state.

2. These facts having been established in pregnancy, comparable studies in subjects receiving Enovid were sought. In a small series of subjects, one laboratory had reported an increase in Factor VIII activity and lesser increase in Factor VII (1) Less impressive changes in other clotting parameters have also been reported (Rapaport) (2) and Hanstell). (3) Eleven women receiving Enovid and eleven healthy women were studied concurrently. Levels of Factor VIII activity, one stage prothrombin times, plasma recalcification times, and platelet numbers were not significantly different in the two groups. (Spittell, Owen, Thompson, and Bowie (Personal communication to the Committee). In order to attempt to determine a possible relationship between elevated levels of Factor VIII and hypercoagulability, experiments were performed by adding semi-purified Factor VII to *in vitro* clotting systems. Significant shortening of plasma partial thromboplastin times below the normal range was not produced when the levels of AFH ranged between 100 and 850 percent of normal. Nei-

* Alexander. B., personal communication with Committee.

ther was there acceleration of prothrombin conversion or of the clotting of whole blood (Penick, for the Committee) (5) (attached appendix Fig. 1–5. The possibility that as yet unknown Factors or interactions may function under such conditions cannot be excluded.

With respect to Enovid, the available data to date do not establish, or exclude, the possibility that the drug produces hypercoagulability as defined by increases in clotting components or acceleration of clotting kinetics. More complete and extensive studies in this area are clearly indicated. Moreover, the question of the relationship between the hypercoagulable state as defined above, to clinical thromboembolic disease is still undetermined.

*Clinical survey*

In order to obtain information regarding the clinical experience of both physicians and clinics using this drug, a survey was undertaken by Dr. Willard Allen. Acting for the Committee he obtained data giving the age distribution of patients receiving Enovid by means of a letter of inquiry sent to representative obstetricians and gynecologists throughout the United States. The data were obtained from 20 private gynecologists and obstetricians, and from six Planned Parenthood clincis. The details of these data will be found in the Appendix. (tables I-V). This study included a total of 5,798 cases. (See table V) This table also gives a percentage distribution. The incidence of reported phlebitis in this total group of cases was 1.55 per thousand. The incidence of pulmonary embolism was 0.34 per thousand (2 cases). There were no deaths in this series of 5,798 cases. This sampling is considered to be representative of the age distribution of patients in the United States who are receiving Enovid, both in private practice and in clinics.

*Review of data on reported deaths*

The Committee reviewed and evaluated the clinical records, the autopsy reported the death certificates and other pertinent material of each patient alleged to have died from thromboembolic disease who had taken or was taking Enovid. From the records a list was developed consisting of those patients who were considered to have died of idiopathic thromboembolism. Excluded from this list therefore were those patients whose deaths were not due to thromboembolic disease and those whose deaths from thromboembolic disease were found to be probably due to recognized causes; such as post-operative state, cancer, including leukemia, pregnancy, extreme obesity (500 lbs. plus), and prolonger dependency edema. One patient was excluded because she had not taken Enovid for 10 months. During the years 1961–1962 there were 14 cases of idiopathic thromboembolic deaths. 13 additional cases were excluded from the series in as much as their deaths were considered not to be idiopathic. There were two cases regarding which the Committee could not agree. Of the 14 idiopathic deaths, 10 occurred during the year 1962, which was then adopted as the year for further analysis because they occurred outside the limits of the continental United States, they were beyond the age limits of the study, or they occurred before 1961. There were 10 cases which were unanimously agreed upon as idiopathic. These cases plus two additional cases about which there was lack of unanimous agreement were accepted for the statistical analysis. In the first of these additional cases, on the basis of the obtainable data the Committee was undecided as to whether the explanation of the entire pathology found within the lung was on the basis of pulmonary infarction due to thromboembolism of an idiopathic nature or whether it was explained by an upper respiratory infection which developed into pneumonia and which in turn was the factor in the development of thromboembolism and infarction in the lungs. In the second case the patient died of the effects of mesenteric venous thrombosis, but the details in the case history were not sufficient to justify a determination as to whether this condition was idiopathic or not.

Once the selection of patients whose deaths could not be explained by some other known etiological factor had been completed, a statistical evaluation became feasible. It is obvious that the ideal study, to measure a given effect as caused by a given agent, takes on the form of an experiment in which two groups are compared which are identical in all respects except for the presence in one of the independent variable (agent) to be evaluated. On extremely rare occasions nature performs this experiment, but by and large such experiments

in nature are not available to us in the precise form presented above. Many variables are uncontrollable and two groups in which contrasting effects are to be noted may indeed not be similar in certain factors which may have bearing on the outcome. Thus, in most situations the pertinent characteristics of the groups must be defined, or adjusted for, in order to permit comparison.

Although a number of undesirable effects have been reported among users of Enovid and these have created suspicion as to their possible relationship to such use, of the most important serious phenomena brought to the attention of the F. D. A. were those of thromoembolism in the form of either thrombophlebitis, and/or pulmonary embolism. The Committee's principal objective therefore was to assess the significance of the association between Enovid use and these latter phenomena.

From to beginning of the Committee's deliberation, it was very apparent that an assessment of the true quantitative values for morbidity from thrombophlebitis would be fraught with great uncertainties. As suggested above such factors as the broad spectrum of the severity of the disease and hence the seeking of medical care for diagnosis with obvious variation in reporting, diagnostic acumen, geographic differences in occurrence, and the number of unhospitalized and medically untreated cases could contribute in a differential way between groups of Enovid users and non-Enovid users and hence create artifactural differences which did not in reality exist.

Mortality data concern themselves with events which have a finality at which point sufficient clinical and laboratory information is frequently available for reasonable diagnosis. Such deaths must be certified and in spite of the lack of precision sometimes noted in death certificates one can assume a higher order of completeness of reporting and of certainty as to diagnosis than may be found in morbidity data dealing with this problem. Thus, the Committee elected to expore available information relative to mortality from thromboembolic phenomena among Enovid users in relation to the occurrence of similar deaths in the general population and to determine whether such an approach might be reliable and provide meaningful information.

METHOD

Inasmuch as Enovid users as a groups were predominently non-pregnant females it was obvious that such a group would have to be compared with the general population of non-pregnant women in the childbearing age groups. This was particularly necessary in view of the fact that pregnancy per se is known to carry with it a risk of thromboembolic phenomena. See Table VII for a graphic comparison of the two numerators and denominators used in estimating the relative risks of using Enovid.

1. *Validity of the numerator counts*

a. *Mortality in Enovid group, first numerator.*—It is felt by members of the Committee that the cases of death for 1962 from thromboembolic phenomena among Enovid users is almost complete, if not entirely so, because the attention of the medical profession and the public had been focused in 1962 by both the Food & Drug Administration and the manufacturer on the need for documenting all events which might conceivably be related to Enovid use.

b. *Mortality in the general population, second numerator.*—Initially, data on thromboembolic mortality in the general population were not available. This was obtained upon request and with the cooperation of the National Vital Statistics Division (NVSD) in the National Center for Health Statistics. The Committee requested a tabulation of all deaths from thromboembolic phenomena (ISC Codes 463, 464, 465 and 466) and the number of deaths from these entities was obtained for the entire United States for 1961. Inasmuch as finalized counts for 1962 were not available from NVSD and since the analysis would be necessity be based on only 1962 data, the Committee attempted to obtain such mortality data from 19 states which had shown a majority of the thromboembolic deaths in 1961 in the United States, and represented a good geographic distribution. Sixteen States provided data in time for the Committee study. These 16 states accounted for at least 60% of the thromboembolic deaths occurring in 1961 and their data for 1962 were utilized in an extrapolation of the expected total number of such deaths in the entire population in 1962. The data provided by the states were actual photocopies of the pertinent

death certificates and included 18 of the deaths of patients known to have taken Enovid. The assumption was then made that the mortality from thromboembolic conditions in the general population for 1962 was at least at the same rate as in 1961.

2. *Characteristics of the numerator counts*

Only deaths occurring among residents of the United States in 1962 were accepted. Furthermore, patients known to be pregnant at the time of their demise and postoperative thromboembolism cases, were excluded by virtue of the fact that the general population numerator would not include these groups in the codings listed above for thromboembolism.

The Enovid numerator had no negro deaths. Inasmuch as it was uncertain whether this lack of deaths among negroes using Enovid, in the data available to us, represented an inadequate population at the risk or not (since total use of the Enovid among negroes was not great and even at "normal" risks of thromboembolic death one would require a very large population at risk to obtain a single death), it was decided to omit negro females from both denominators and the general population numerator.

a. Every death reported in patients exposed to Enovid was again reviewed in detail to determine its suitability for inclusion on the basis of any thromboembolic phenomena irrespective of the underlying cause. These were distributed among the five year age groups into which they fell from 15 to 44 years of age. (For other purposes these were further subdivided into idiopathic and non-idiopathic cases).

b. The general population numerator similarly included all deaths from thromboembolic phenomena exclusive of those occurring among pregnant women or shortly after surgery regardless of other antecedent causes. These deaths were also subdivided into their 5 year age groups from 15 to 44 years of age.

3. *Validity of the denominator counts*

a. Inspection of some available data and the experience of members of the Committee relative to the use of Enovid for conception control indicated that the age distribution of the population of Enovid users would be drastically different from the age distribution of non-pregnant females in the general population. Thus, data were sought from a geographically diversified sampling of Planned Parenthood clinics and private practitioners for a cross-section of the age distribution of Enovid users. There were obtained for both white and negro patients. Although for reasons above noted negro patients were excluded from the final analysis of users, their distribution was not remarkably different from that of the white patients. Further assumptions were herein made: That the sample derived by solicitation was representative of all Enovid users in the United States at least with respect to age; that geographic differences might be accounted for by representation in the sample of data from all parts of the country; and that the blending or private and clinic patients occurred in the same proportion as might exist in the general population. Actually, the age distribution of private patients was not significantly different from that of the clinic patients.

The most unreliable data to be utilized in the calculation of relative risks resided in the denominator for the Enovid user group. The only data available were furnished by the manufacturer on the basis of prescriptions filled and renewed during each of the quarters of the year of 1962. The maximum estimated number of users of Enovid was 1,300,000, but this value contained an unknown proportion of negroes and a lesser but still unknown proportion of duplicate prescriptions. On the basis of the best preliminary estimate the committee could formulate, 300,000 were subtracted, leaving 1,000,000 white users of Enovid. These were then categorized according to the age distribution of the white Enovid user sample. This distribution provided the individual age group denominators which were subsequently used to calculate the thromboembolic mortality rates among such users.

b. The corresponding denominators for the 1962 general population included the distribution of white females for the same individual age groups. NVSD provided these data and also estimates of the age distribution of white nonpregnant women. For each age-interval denominator the estimated number of

pregnant women was subtracted. Thus the individual age-interval denominator continued only white non-pregnant women.

RESULTS

In table VI there is presented a comparison of age-specific mortality rates from the thromboembolic phenomena among white Enovid users and the white non-pregnant United States female population in 1962. The incidence of deaths among all Enovid use was 12.1 per million users. It will be noted that the unadjusted rate for the general population is 7.9 deaths per million. On adjustment of the general population for the age distribution of the Enovid user population this rate becomes 8.4 (table VII). In either case the difference between the Enovid and population rates is not statistically significant (p=.14) utilizing Poisson probability for small expected rates. However, the larger individual age-interval rates among Enovid users in the 35–39 and the 40–44 year age groups are highly significant (P=.001 and P .0001 respectively).

DISCUSSION

Inasmuch as the population number for Enovid users estimated from available data is not an exact figure, but based on drug distribution figures, some attempts were made to determine the effect of a 50% decrease in the estimated population of white users to see what effect this might have on the excessive mortality rates among Enovid users in the older groups. This increase reduced the difference between the 35–39 age groups rates to that of a borderline level of statistical significance (P=.09) whereas the 40–44 year Enovid group rate, although reduced, remained highly significant. A 50% decrease in the estimate of users doubles the Enovid rates and would make them very significantly greater for virtually every age-specific group. These ranges of 50% plus or minus represent extreme possibilities rather than probable range and are highly unlikely. However, an over-all Enovid death rate (all ages) based on a 10% decrease in the estimate of users is very close to statistical significance.

In summary; on the basis of the available data and if the above outlined assumptions are reasonably correct, no significant increase in the risk of thromboembolic death from the use of Enovid in this population group under the age of 35 has been demonstrated. The relative risk, from the available data, of death from thromboembolism does appear to be increased for Enovid users at ages 35 or over. The reasons for this are not clear at this time.

There is a need for comprehensive and critical studies regarding the possible effects of Enovid on the coagulation balance and related production of thromboembolic conditions. Pending the development of such conclusive data and on the basis of present experience this latter relationship should be regarded as neither established nor excluded.

Although a detailed study is not within the scope of this report it is recognized that in judging the over-all risk from and the values of the use of Enovid, data concerning the risks of pregnancy and induced abortion in each age group would be extremely important.

Any firm reliance on the risks as calculated is tempered by the assumptions made. This committee recommends that a carefully planned and controlled prospective study be initiated with the objective of obtaining more conclusive data regarding the incidence of thromboembolism and the death from such conditions in both untreated females and those under treatment of this type among the pertinent age groups.

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C. L. SPURLING, *Baltimore, Md.*

TABLE I.—PLANNED PARENTHOOD CLINICS, WHITE PATIENTS

| | Minneapolis | Baltimore | Pittsburgh | Miami | St. Louis | Indianapolis | Total | Percent of total |
|---|---|---|---|---|---|---|---|---|
| 15 to 19 | 99 | | 6 | 4 | 14 | 88 | 211 | 8.9 |
| 20 to 24 | 460 | 12 | 35 | 11 | 82 | 326 | 926 | 36.8 |
| 25 to 29 | 303 | 14 | 42 | 12 | 108 | 227 | 706 | 28.1 |
| 30 to 34 | 151 | 5 | 21 | 6 | 63 | 139 | 385 | 15.3 |
| 35 to 39 | 90 | 4 | 11 | 3 | 34 | 73 | 215 | 8.5 |
| 40 to 44 | 32 | | | 1 | 8 | 18 | 59 | 2.3 |
| 45 to 49 | 11 | | | | 1 | | 12 | .5 |
| 50+ | | | | | | | | |
| Total | 1,146 | 35 | 115 | 37 | 310 | 871 | 2,514 | 100.4 |
| Phlebitis | | | | | 1 | 2 | 3 | (1) |
| Embolism | | | | | | | | |

[1] Incidence 1.19/1,000.

TABLE II.—PLANNED PARENTHOOD CLINICS, NEGRO PATIENTS

| | Minneapolis | Baltimore | Miami | Miami [1] | Indianapolis | Boston [1] | St. Louis | Total | Percent of Total |
|---|---|---|---|---|---|---|---|---|---|
| 15 to 19 | 11 | 2 | 2 | 2 | 36 | 1 | 7 | 61 | 5.9 |
| 20 to 24 | 20 | 19 | 7 | 19 | 171 | 18 | 45 | 299 | 28.8 |
| 25 to 29 | 25 | 19 | 9 | 27 | 154 | 21 | 52 | 307 | 29.6 |
| 30 to 34 | 11 | 6 | 2 | 23 | 103 | 8 | 35 | 188 | 18.1 |
| 35 to 39 | 5 | 9 | 5 | 25 | 52 | 1 | 18 | 115 | 11.1 |
| 40 to 44 | 2 | 3 | | 30 | 9 | 1 | 2 | 47 | 4.5 |
| 45 to 49 | | | | 18 | 2 | | | 20 | 1.9 |
| 50+ | | | | 1 | | | | 1 | .1 |
| Total | 74 | 58 | 25 | 145 | 527 | 50 | 159 | 1,038 | 100.0 |
| Phlebitis | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | (2) |
| Embolism | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

[1] Not planned parenthood.
[2] Incidence 0.96/1.000.

TABLE III.—WHITE PATIENTS, PRIVATE, ST. LOUIS

| | | | | | Total | Percent of total |
|---|---|---|---|---|---|---|
| 15 to 19 | 19 | 9 | 7 | 4 | 39 | 3.5 |
| 20 to 24 | 83 | 95 | 55 | 59 | 292 | 26.4 |
| 25 to 29 | 69 | 124 | 48 | 25 | 266 | 24.0 |
| 30 to 34 | 54 | 139 | 39 | 27 | 259 | 23.4 |
| 35 to 39 | 34 | 94 | 19 | 11 | 158 | 14.3 |
| 40 to 44 | 26 | 46 | 5 | 6 | 83 | 7.5 |
| 45 to 49 | 2 | 4 | | 1 | 7 | .7 |
| 50 to 55 | 1 | | | | 1 | .1 |
| Total | 288 | 511 | 173 | 133 | 1,105 | 99.9 |
| Phlebitis | 2 | | | | 2=1,81/1,000 incidence. | |
| Embolism | 1 | | | | 1=0.91/1,000 incidence. | |

TABLE IV.—WHITE PATIENTS ELSEWHERE

| | Winston-Salem | Philadelphia | Baltimore | Colorado | Little Rock | Little Rock | Little Rock | Boston | Pittsburgh | Miami | Boston | Total | Percent of total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 15 to 19 | 2 | | | 35 | 5 | 4 | | 2 | 8 | 3 | 11 | 70 | 6.1 |
| 20 to 24 | 14 | 12 | 15 | 88 | 14 | 11 | 25 | 30 | 32 | 14 | 96 | 351 | 30.7 |
| 25 to 29 | 17 | 14 | 14 | 41 | 14 | 6 | 21 | 66 | 25 | 21 | 69 | 308 | 27.0 |
| 30 to 34 | 12 | 4 | 14 | 24 | 7 | | 11 | 63 | 20 | 24 | 20 | 199 | 17.4 |
| 35 to 39 | 6 | 6 | 5 | 11 | 5 | | | 50 | 18 | 24 | 8 | 133 | 11.6 |
| 40 to 44 | 2 | 2 | 1 | 2 | 2 | | | 16 | 8 | 27 | 5 | 65 | 5.7 |
| 45 to 49 | | | | 1 | | | | 1 | | 10 | | 12 | 1.1 |
| 50 to 55 | | | | | | | | | | 3 | | 3 | .3 |
| Total | 53 | 38 | 49 | 202 | 47 | 21 | 57 | 228 | 111 | 126 | 209 | 1,141 | 99.9 |
| Phlebitis | | 1 | | | | | | 1 | | | 1 | 3 | 2.62/1,000 incidence. |
| Embolism | | | | | | | | | | | 1 | 1 | 0.87/1,000 incidence. |

TABLE V.—SUMMARY

| | Table I | Table II | Table III | Table IV | Total | Percent of total |
|---|---|---|---|---|---|---|
| 15 to 19 | 211 | 61 | 39 | 70 | 381 | 6.56 |
| 20 to 24 | 926 | 299 | 292 | 351 | 1,868 | 32.22 |
| 25 to 29 | 706 | 307 | 266 | 308 | 1,587 | 27.36 |
| 30 to 34 | 385 | 188 | 259 | 199 | 1,031 | 17.78 |
| 35 to 39 | 215 | 115 | 158 | 133 | 621 | 10.72 |
| 40 to 44 | 59 | 47 | 83 | 65 | 254 | 4.38 |
| 45 to 49 | 12 | 20 | 7 | 12 | 51 | .88 |
| 50 to 55 | | 1 | 1 | 3 | 5 | .09 |
| Total | 2,514 | 1,038 | 1,105 | 1,141 | 5,798 | 99.99 |
| Phlebitis | 3 | 1 | 2 | 3 | 9 | =1.55/1,000 incidence. |
| Embolism | 0 | 0 | 1 | 1 | 2 | =0.34/1,000 incidence. |

TABLE VI.—COMPARISON OF AGE-SPECIFIC MORTALITY FROM THROMBOEMBOLIC PHENOMENA AMONG WHITE ENOVID USERS AND THE WHITE NONPREGNANT U.S. POPULATION, 1962

| | Enovid users | | | General population | | |
|---|---|---|---|---|---|---|
| Age group | Number of TE deaths | Population,[1] white females | Rate per million | Number of TE deaths | Population, white nonpregnant females | Rate per million |
| 15 to 19 | 0 | 67,200 | 0 | 10 | 5,556,000 | 1.8 |
| 20 to 24 | 4 | 329,600 | 12.1 | 20 | 2,759,000 | 7.3 |
| 25 to 29 | 2 | 268,900 | 7.4 | 30 | 2,861,000 | 10.5 |
| 30 to 34 | 2 | 177,100 | 11.3 | 37 | 4,015,000 | 9.2 |
| 35 to 39 | 2 | 106,300 | 18.8 | 40 | 5,037,000 | 7.9 |
| 40 to 44 | 2 | 43,500 | 46.0 | 66 | 5,374,000 | 12.5 |
| Total | 12 | 992,600 | 12.1 | 203 | 25,602,000 | [2] 7.9 |

[1] Age distribution is based on Dr. Allen's sampling of clinic and private M.D.'s and on an assumed total population of white users of Enovid.

[2] When adjusted for differences in age distribution this rate equals 8.4 deaths per million. The difference between the 12.1 and 8.4 rates is not statistically significant, but the differences between the Enovid users and general population rates for the 35 and over groups are highly significant. The Enovid rate for ages 20–24 is large enough to be of borderline significance (P=.06).

ASSUMPTIONS NECESSARY FOR THESE CALCULATIONS

1. That all users were white.
2. Distribution by age (estimated) is representative for Enovid users.
3. That our 60 percent sample provided a valid estimate of 1962 deaths from TE cases.
4. That all 1962 cases of fatal TE—Pulmonary embolism are known to us.
5. That the proportion of post-operative patients among the Enovid users (in the denominator) is not significantly different from that in the general population denominator.
6. That the proportion of deaths where Enovid was being used for pathologic states (noncontraceptive) is the same as the proportion of Enovid users for such States.

TABLE VII.—THROMBOEMBOLIC DEATHS PER MILLION IN WHITE USERS OF ENOVOID AND IN THE GENERAL POPULATION OF WHITE NONPREGNANT FEMALES

*The two numerators and the two denominators used in obtaining the comparative death rates are shown below:*

*Envoid users:*

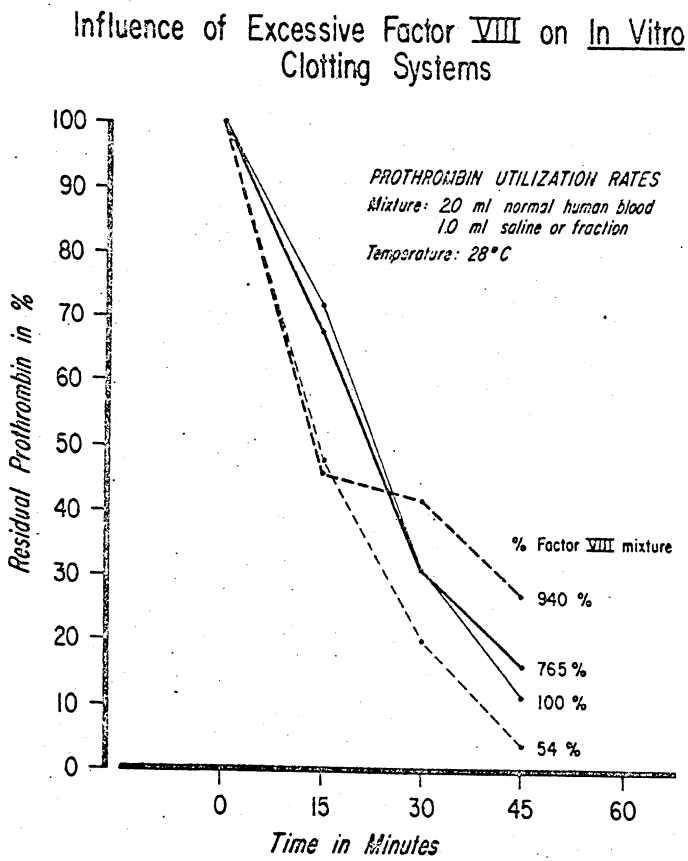
*Deaths (12).*—White nonpregnant females; aged 15 to 44; death associated with PE/TE; excludes post-operative cases. Equals 12.1 deaths per million users.

*Enovid Users (992,000).*—White females; aged 15 to 44.

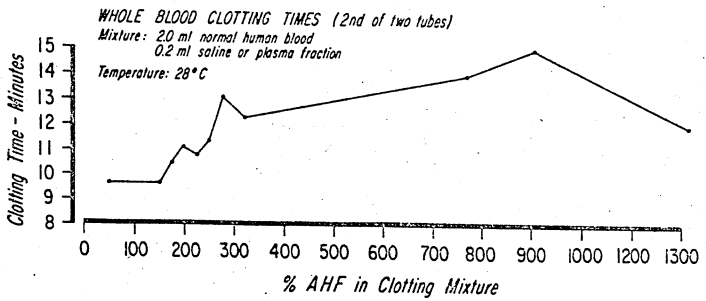
*Nonusers:*

*General population deaths (203).*—White nonpregnant females; aged 15 to 44; deaths classified under ISC codes 463–6; excludes post-operative cases. Equals 8.4 deaths per million users

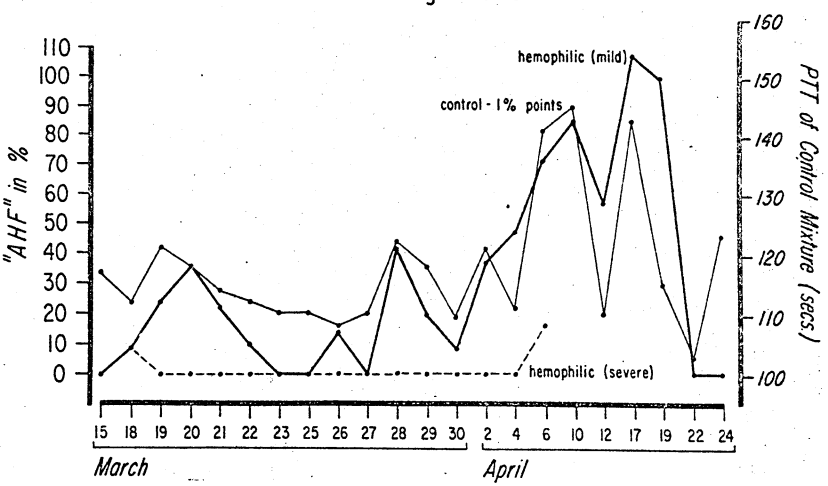
*General population (25,602,000).*—White nonpregnant females; aged 15 to 44.

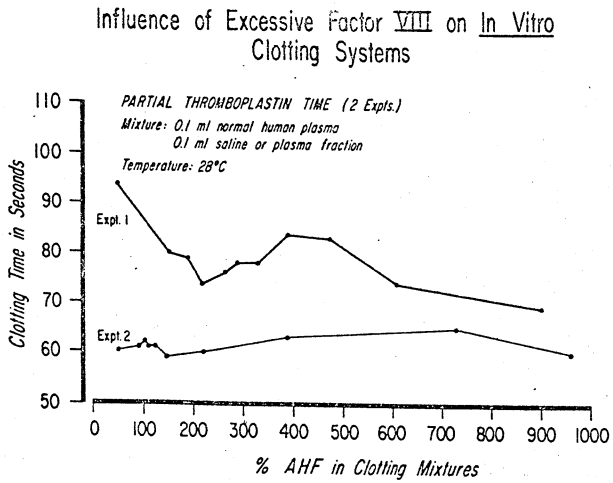

Influence of Excessive Factor VIII on In Vitro Clotting Systems
PROTHROMBIN UTILIZATION RATES
Mixture: 2.0 ml normal human blood
1.0 ml saline or fraction
Temperature: 28°C
Residual Prothrombin in %
100
90
80
70
60
50
40
30
20
10
0
0
15
30
45
60
Time in Minutes
% Factor VIII mixture
940 %
765 %
100 %
54 %

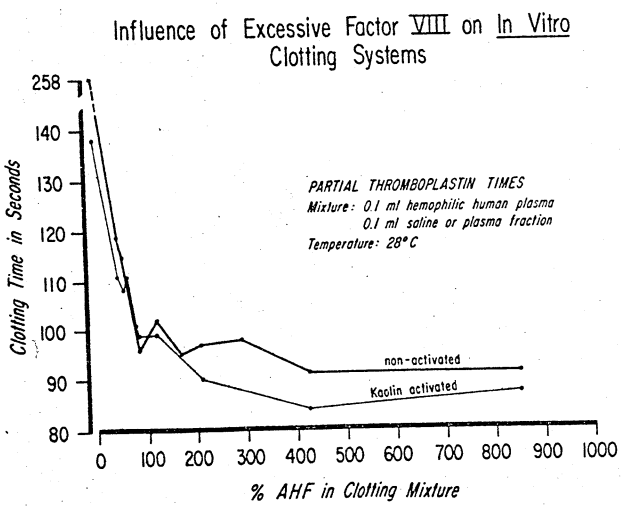
Influence of Excessive Factor VIII on In Vitro Clotting Systems




Factor VIII Activity in Hemophilic Dog on Daily Dose of 5 mg Enovid




Influence of Excessive Factor VIII on In Vitro Clotting Systems
PARTIAL THROMBOPLASTIN TIME (2 Expts.)
Mixture: 0.1 ml normal human plasma
0.1 ml saline or plasma fraction
Temperature: 28°C
Expt. 1
Expt. 2
Clotting Time in Seconds
110
100
90
80
70
60
50
0 100 200 300 400 500 600 700 800 900 1000
% AHF in Clotting Mixtures


Influence of Excessive Factor VIII on In Vitro Clotting Systems
PARTIAL THROMBOPLASTIN TIMES
Mixture: 0.1 ml hemophilic human plasma
0.1 ml saline or plasma fraction
Temperature: 28°C
non-activated
Kaolin activated
Clotting Time in Seconds
258
140
130
120
110
100
90
80
0 100 200 300 400 500 600 700 800 900 1000
% AHF in Clotting Mixture

FINAL REPORT ON ENOVID BY THE AD HOC COMMITTEE FOR THE EVALUATION OF A POSSIBLE ETIOLOGIC RELATION WITH THROMBOEMBOLIC CONDITIONS

SUBMITTED TO THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, SEPTEMBER 12, 1963

* * * * * * *

(Pages 1 through 13 of the Final Report on Enovid were identical to the Report on Enovid and, therefore, have been omitted. The balance of the Final Report on Enovid follows.)

DISCUSSION

Inasmuch as the population number for Enovid users estimated from available data is not an exact figure, but based on drug distribution figures, some attempts were made to determine the effects of a 50% decrease and a 10% decrease in the estimated population of white users to see what effect this might have on the mortality rates among Enovid users and the significance of any difference from those in the general population.

Any increase in this estimate of users would obviously reduce the user death rates and these rates would approach those in the general population. This would be particularly true if we deducted too many as Negro users, a possibility which remains. A 50% decrease in the estimate of users would double the Enovid rates. This would make the overall rate as well as the rates in the 20–24 and 40–44 year age groups very significantly greater. A 50% decrease in the population estimate represents an extreme possibility rather than a probable estimate and is deemed highly unlikely. A 10% decrease in our user-population estimate (which might represent a reasonable error) would, however, *not* yield Enovid-user death rates significantly different from the general population rates (total and individual 5-year age groups) at the level of $P=0.05$.

In summary, on the basis of the available data and if the above outlined assumptions are reasonably correct, no significant increase in the risk of thromboembolic death from the use of Enovid in this population group has been demonstrated.

There is a need for comprehensive and critical studies regarding the possible effects of Enovid on the coagulation balance and related production of thromboembolic conditions. Pending the development of such conclusive data and on the basis of present experience this latter relationship should be regarded as neither established nor excluded.

Although a detailed study is not within the scope of this report it it is recognized that in judging the over-all risk from and the values of the use of Enovid, data concerning the risks of pregnancy and induced abortion in each age group would be extremely important.

Any firm reliance on the risks as calculated is tempered by the assumptions made. This committee recommends that a carefully planned and controlled prospective study be initiated with the objective of obtaining more concusive data regarding the incidence of thromboembolism and death from such conditions in both untreated females and those under treatment of this type among the pertinent age groups.

*References*

1. Egeberg and P. Owen—Oral Contraception and Blood Coagulability-Britain Medical Journal—January 26, 1963
2. Rappaport, S. I.—Coagulation Factor Analysis. Appendix V-Pg. 154-Proc. Conf. Thromboembolic Phenomena in Women-G. D. Searle & Co. 1962
3. Henstell, H. H.—Coagulation Studies in Los Angeles Planned Parenthood Center Patients. Appendix VI pg. 156 ibid.
4. Spittell, J. A., Owen, C. A., Thompson, J. H. and Bowie, W. H. J.—Personal Communication to the Committee-1963
5. Penick, G. D.—For the Committee. 1953

COMMITTEE,

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TABLE I.—PLANNED PARENTHOOD CLINICS—WHITE PATIENTS

| | Minneapolis | Baltimore | Pittsburgh | Miami | St. Louis | Indianapolis | Total | Percent of total |
|---|---|---|---|---|---|---|---|---|
| 15 to 19 | 99 | | 6 | 4 | 14 | 88 | 211 | 8.9 |
| 20 to 24 | 460 | 12 | 35 | 11 | 82 | 326 | 926 | 36.8 |
| 25 to 29 | 303 | 14 | 42 | 12 | 108 | 227 | 706 | 28.1 |
| 30 to 34 | 151 | 5 | 21 | 6 | 63 | 139 | 385 | 15.3 |
| 35 to 39 | 90 | 4 | 11 | 3 | 34 | 73 | 215 | 8.5 |
| 40 to 44 | 32 | | | 1 | 8 | 18 | 59 | 2.3 |
| 45 to 49 | 11 | | | | 1 | | 12 | .5 |
| 50+ | | | | | | | | |
| Total | 1,146 | 35 | 115 | 37 | 310 | 871 | 2,514 | 100.4 |
| Phlebitis | | | | | 1 | 2 | 3 | (1) |
| Embolism | | | | | | | | |

[1] Incidence 1.19/1,000.

TABLE II.—PLANNED PARENTHOOD CLINICS—NEGRO PATIENTS

| | Minneapolis | Baltimore | Miami | Miami [1] | Indianapolis | Boston [1] | St. Louis | Total | Percent of total |
|---|---|---|---|---|---|---|---|---|---|
| 15 to 19 | 11 | 2 | 2 | 2 | 36 | 1 | 7 | 61 | 5.9 |
| 20 to 24 | 20 | 19 | 7 | 19 | 171 | 18 | 45 | 299 | 28.8 |
| 25 to 29 | 25 | 19 | 9 | 27 | 154 | 21 | 52 | 307 | 29.6 |
| 30 to 34 | 11 | 6 | 2 | 23 | 103 | 8 | 35 | 188 | 18.1 |
| 35 to 39 | 5 | 9 | 5 | 25 | 52 | 1 | 18 | 115 | 11.1 |
| 40 to 44 | 2 | 3 | | 30 | 9 | 1 | 2 | 47 | 4.5 |
| 45 to 49 | | | | 18 | 2 | | | 20 | 1.9 |
| 50+ | | | | 1 | | | | 1 | .1 |
| Total | 74 | 58 | 25 | 145 | 527 | 50 | 159 | 1,038 | 100.0 |
| Phlebitis | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | (2) |
| Embolism | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

[1] Not planned parenthood.
[2] Incidence 0.96/1,000.

TABLE III.—WHITE PATIENTS, PRIVATE, ST. LOUIS

| | | | | | Total | Percent of total | |
|---|---|---|---|---|---|---|---|
| 15 to 19 | 19 | 9 | 7 | 4 | 39 | 3.5 | |
| 20 to 24 | 83 | 95 | 55 | 59 | 292 | 26.4 | |
| 25 to 29 | 69 | 124 | 48 | 25 | 266 | 24.0 | |
| 30 to 34 | 54 | 139 | 39 | 27 | 259 | 23.4 | |
| 35 to 39 | 34 | 94 | 19 | 11 | 158 | 14.3 | |
| 40 to 44 | 26 | 46 | 5 | 6 | 83 | 7.5 | |
| 45 to 49 | 2 | 4 | | 1 | 7 | .7 | |
| 50 to 55 | 1 | | | | 1 | .1 | |
| Total | 288 | 511 | 173 | 133 | 1,105 | 99.9 | |
| Phlebitis | 2 | | | | 2 | =1.81/1,000 incidence. | |
| Embolism | 1 | | | | 1 | =0.91/1,000 incidence. | |

TABLE IV.—WHITE PATIENTS ELSEWHERE

| | Winston-Salem | Philadelphia | Baltimore | Colorado | Little Rock | Little Rock | Little Rock | Boston | Pittsburgh | Miami | Boston | Total | Percent of total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 15 to 19 | 2 | | | 35 | 5 | 4 | | 2 | 8 | 3 | 11 | 70 | 6.1 |
| 20 to 24 | 14 | 12 | 15 | 88 | 14 | 11 | 25 | 30 | 32 | 14 | 96 | 351 | 30.7 |
| 25 to 29 | 17 | 14 | 14 | 41 | 14 | 6 | 21 | 66 | 25 | 21 | 69 | 308 | 27.0 |
| 30 to 34 | 12 | 4 | 14 | 24 | 7 | | 11 | 63 | 20 | 24 | 20 | 199 | 17.4 |
| 35 to 39 | 6 | 6 | 5 | 11 | 5 | | | 50 | 18 | 24 | 8 | 133 | 11.6 |
| 40 to 44 | 2 | 2 | 1 | 2 | 2 | | | 16 | 8 | 27 | 5 | 65 | 5.7 |
| 45 to 49 | | | | 1 | | | | 1 | | 10 | | 12 | 1.1 |
| 50 to 55 | | | | | | | | | | 3 | | 3 | .3 |
| Total | 53 | 38 | 49 | 202 | 47 | 21 | 57 | 228 | 111 | 126 | 209 | 1,141 | 99.9 |
| Phlebitis | | 1 | | | | | | 1 | | | 1 | 3 | (1) |
| Embolism | | | | | | | | | | | 1 | 1 | (2) |

[1] Incidence 2.62/1,000.
[2] Incidence .87/1,000.

TABLE V.—SUMMARY

| | Table I | Table II | Table III | Table IV | Total | Percent of total |
|---|---|---|---|---|---|---|
| 15 to 19 | 211 | 61 | 39 | 70 | 381 | 6.56 |
| 20 to 24 | 926 | 299 | 292 | 351 | 1,868 | 32.22 |
| 25 to 29 | 706 | 307 | 266 | 308 | 1,587 | 27.36 |
| 30 to 34 | 385 | 188 | 259 | 199 | 1,031 | 17.78 |
| 35 to 39 | 215 | 115 | 158 | 133 | 621 | 10.72 |
| 40 to 44 | 59 | 47 | 83 | 65 | 254 | 4.38 |
| 45 to 49 | 12 | 20 | 7 | 12 | 51 | .88 |
| 50 to 55 | | 1 | 1 | 3 | 5 | .09 |
| Total | 2,514 | 1,038 | 1,105 | 1,141 | 5,798 | 99.99 |
| Phlebitis | 3 | 1 | 2 | 3 | 9 | (1) |
| Embolism | 0 | 0 | 1 | 1 | 2 | (2) |

[1] Incidence 1.55/1,000.
[2] Incidence 0.34/1,000.

TABLE VI.—COMPARISON OF AGE-SPECIFIC MORTALITY FROM THROMBOEMBOLIC PHENOMENA AMONG WHITE ENOVID USERS AND THE WHITE NONPREGNANT U.S. POPULATION, [1] 1962

| | Enovid users | | | General population | | | |
|---|---|---|---|---|---|---|---|
| Age group | Number of TE deaths | Population [2] white females | Rate per million | Number of TE deaths | Population white nonpregnant females | Rate per million | Probability values [3] |
| 15 to 19 | 0 | 67,200 | 0 | 10 | 5,556,000 | 1.8 | 0.89 |
| 20 to 24 | 4 | 329,600 | 12.1 | 20 | 2,759,000 | 7.3 | 0.22 |
| 25 to 29 | 2 | 268,900 | 7.4 | 30 | 2,861,000 | 10.5 | 0.47 |
| 30 to 34 | 2 | 177,100 | 11.3 | 37 | 4,015,000 | 9.2 | 0.49 |
| 35 to 39 | 2 | 106,300 | 18.8 | 40 | 5,037,000 | 7.9 | 9.21 |
| 40 to 44 | 2 | 43,500 | 46.0 | 66 | 5,374,000 | 12.3 | 0.10 |
| Total | 12 | 992,600 | 12.1 | 203 | 25,602,000 | [1] 7.9 | 0.14 |

[1] When adjusted for differences in age distribution this rate equals 8.4 deaths per million. The difference between the 12.1 and 8.4 rates is not statistically significant (P=0.14), neither are the differences between the rates among the several age groups.
[2] Age distribution is based on Dr. Allen's sampling of clinic and private M.D.'s and on an estimated total population of white users of Enovid.
[3] Probability from poison distribution.

Note—Assumptions necessary for these calculations:
1. That all users are white.
2. Distribution by age (estimated) is representative for Enovid users.
3. That our 60 percent sample provided a valid estimate of 1962 deaths from TE cases.
4. That all 1962 cases of fatal TE—Pulmonary embolism are known to us.
5. That the proportion of post-operative patients among the Enovid users (in the denominator) is not significantly different from that in the general population denominator.
6. That the proportion of deaths where Enovid was being used for pathologic states (noncontraceptive) is the same as the proportion of Enovid users for such States.

TABLE VII.—THROMBOEMBOLIC DEATHS PER MILLION IN WHITE USERS OF ENOVID AND IN THE GENERAL POPULATION OF WHITE NONPREGNANT FEMALES

The two numerators and the two denominators used in obtaining the comparative death rates are shown below:

Enovid users:

*Deaths (12).*—White females; aged 15 to 44; death associated with PE/TE; excludes post-operative cases. Equals 12.1 deaths per million users.

Enovid users (992,000).—White females; aged 15 to 44.

Nonusers:

*General population deaths (203).*—White females; aged 15 to 44; deaths classified under ISC codes 463–6; excludes post-operative cases. Equals 8.4 deaths per million users.

General population (25,602,000).—White females; aged 15 to 44.

Figure I

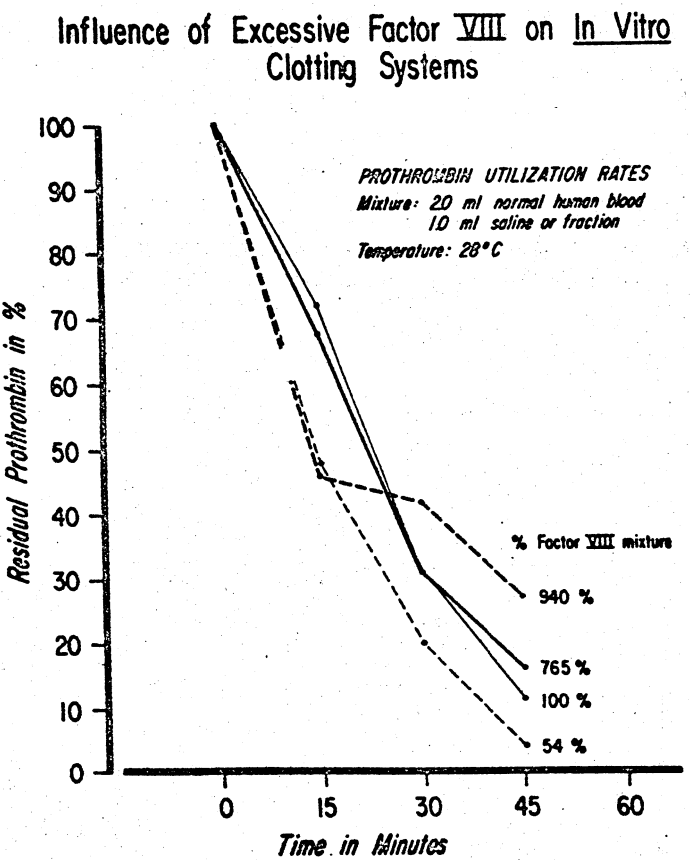

Influence of Excessive Factor VIII on In Vitro Clotting Systems
PROTHROMBIN UTILIZATION RATES
Mixture: 20 ml normal human blood
10 ml saline or fraction
Temperature: 28°C
Residual Prothrombin in %
100
90
80
70
60
50
40
30
20
10
0
% Factor VIII mixture
940 %
765 %
100 %
54 %
0
15
30
45
60
Time in Minutes

Figure II

Influence of Excessive Factor VIII on In Vitro Clotting Systems

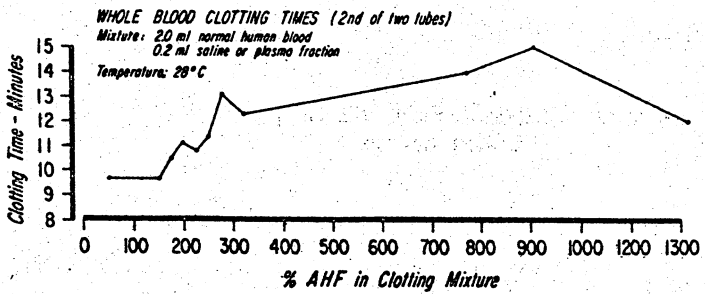



Figure III

Factor VIII Activity in Hemophilic Dog on Daily Dose of 5 mg Enovid

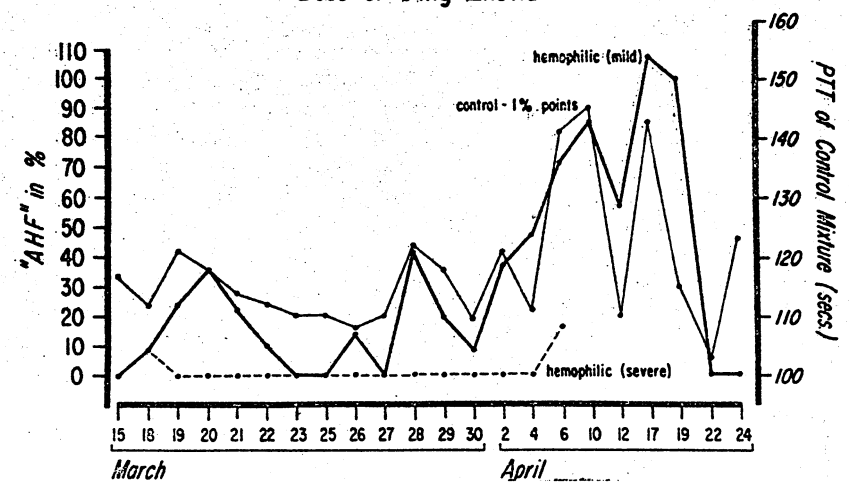


Figure IV

Influence of Excessive Factor VIII on In Vitro Clotting Systems

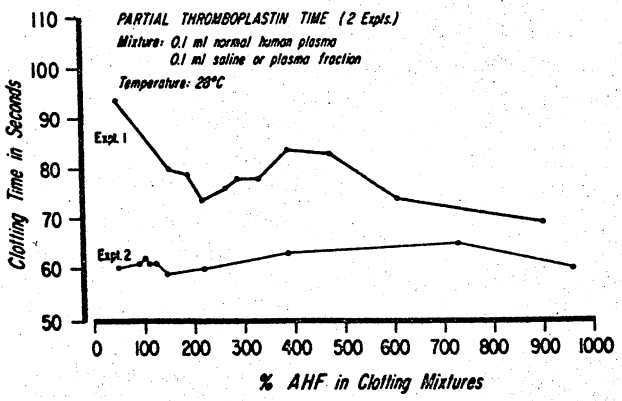
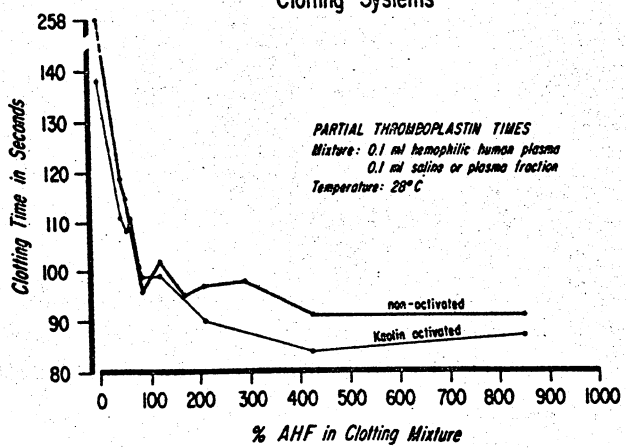



Figure V

Influence of Excessive Factor VIII on In Vitro Clotting Systems



## APPENDIX VI

THE LIBRARY OF CONGRESS,
LEGISLATIVE REFERENCE SERVICE,
*Washington, D.C., February 26, 1970.*

To: Senate Subcommittee on Monopoly, Select Committee on Small Business.
From: Education and Public Welfare Division.
Subject: Study of pharmaceutical advertising and critical reactions regarding oral contraceptives in selected medical journals.

This report is in response to a request from the Chairman of the Subcommittee asking the Legislative Reference Service to undertake an examination of patterns of pharmaceutical advertising appearing in certain medical journals over a three year period. We were asked to determine the quantity and kind of advertising for oral contraceptives and advertising for other pharmaceutical products. In addition, it was requested that we examine any critical reviews, correspondence, editorial comment, etc., which seem to draw to the attention of readers some of the potential or actual adverse effects of oral contraceptive products used by human beings. Due to the limitations of time set by the Committee, we are forwarding here only that portion of the study dealing with oral contraceptive advertising. We will, as soon as possible supply information pertaining to reports of adverse effects of oral contraceptives, such as they appear in the journals surveyed.

1. *The advertising survey design*

At the request of the Subcommittee staff, the Legislative Reference Service undertook a study of pharmaceutical advertising for oral contraceptive products appearing in three medical journals, each of which is published by a different professional association of medical practitioners. Following a conference with the staff, three journals were selected for examination: *The American Journal of Obstetrics and Gynecology*, published by the American Association of Obstetricians and Gynecologists and its affiliated bodies; *GP*, published by the American Academy of General Practice; *Obstetrics and Gynecology*, published by the American College of Obstetricians and Gynecologists.

The survey period covered a span of three years for each publication, from January 1967 through December 1969. Each issue of each magazine was reviewed by the staff. The journals selected were obtained from the collections of the Library of Congress and the National Library of Medicine.

As in the case of other advertising surveys previously submitted to this Committee, the information offered in this report was obtained from a review of the advertising pages in each journal and from a review of the advertising indices which each of the journals publishes in each issue. Where the advertising indices were used, careful examination of the particular index was made to assure that the information contained therein accurately reflected advertising copy appearing in the publication. Where the indices were deemed unreliable, a page-by-page review was made of the issues under study. The criteria employed in tabulating the data contained in this survey have been in line with criteria utilized in previous advertising survey reports to the Committee. Only those advertisments for products which specifically represent a product as designed for contraceptive purposes serve as the basis for the data contained in this report under the classification or oral contraceptive advertising. Combination hormone products, which are often promoted for other therapeutic purposes such as relief of menopausal symptons, amenorrhea, etc., are eliminated from the category of oral contraceptive advertising. Advertising for such products, however, are included in the figures showing total volume of all advertising pages.

The advertising copy published in each of the three journals was studied in detail to obtain the following information: 1) the total volume of advertising in each journal 2) the proportion of advertising copy devoted to oral contra-

ceptives 3) the total number of advertising pages for contraceptive devices other than oral-chemical products. In addition, we were able to compile statistics on the advertising patterns of the leading manufacturers of oral contraceptives, in order to show ratios between advertising for oral contraceptives and advertising for all other products promoted by these manufacturers in each journal. Summary data which appears in the tables at the end of this report were compiled for each journal.

2. *Organization of the report*

The summary and detailed data given in this report are arrayed by the particular journal surveyed and are computed to give total figures for the entire three-year period, rather than a year-by-year breakdown. *GP*, which is published monthly and is the largest of the three publications, in terms of circulation and total volume of advertising, is discussed in Section I of the report. Section II is devoted to the *American Journal of Obstetrics and Gynecology*, which is a semi-monthly specialty journal and ranks second in this survey in terms of advertising volume. *Obstetrics and Gynecology*, a monthly specialty journal, is discussed in Section III.

Each Section in the report begins with summary data covering the entire survey period for each journal studied. The tables also contain a breakdown for each of the seven leading contraceptive manufacturers advertising in the journals. These summaries contain information about the total number of oral contraceptive ads sponsored by each manufacturer and the total number of advertisements for all products sponsored by oral contraceptive manufacturers. For the purposes of this report, we have identified as "leading contraceptive manufacturers" only those manufacturers who advertised frequently in the journals studied. In the tables, the leading manufacturers of oral contraceptives have been organized to show rank order in terms of volume of advertising for oral contraceptive agents.

SECTION I. GP, General Practice.[1] Oral contraceptive advertising represents 3.5 percent of the total advertising copy in "GP" for the period January 1967 through December 1969.

*Volume in pages, Years 1967–69*:

| | |
|---|---|
| Total pages oral contraceptive advertising | 227 |
| Total pages all advertising | 6,536 |
| Total pages advertising for other contraceptive devices | 20 |

[1] Information based on a review of 36 monthly issues.

VOLUME IN ORAL CONTRACEPTIVE ADVERTISING SPONSORED BY LEADING MANUFACTURERS, YEARS 1967–69

| Manufacturers | Total pages oral contraceptive advertising | Total pages firm advertising |
|---|---|---|
| Ortho | 99 | 164 (65) |
| Searle | 58 | 122 (64) |
| Lilly | 27 | 267 (240) |
| Mead-Johnson | 16 | 189 (173) |
| Wyeth | 15 | 193 (178) |
| Syntex | 12 | 12 (0) |
| Parke-Davis | 0 | 200 (200) |
| Total all manufacturers | 227 | 1,147 (920) |

[1] Figures in parentheses indicate total pages of firm advertising minus pages devoted to oral contraceptive ads.

SECTION II.—The American Journal of Obstetrics and Gynecology.[1] Advertising, 1967 through 1969. Oral contraceptive advertising represents 17.5 percent of the total advertising copy in "The American Journal of Obstetrics and Gynecology" for the period January 1967 through December 1969.

*Volume in pages, Years 1967–69:*

| | |
|---|---|
| Total pages oral contraceptive advertising | 1,142 |
| Total pages all advertising | 6,512 |
| Total pages advertising for other contraceptive devices | 102 |

[1] Information based on a review of 72 semimonthly issues.

VOLUME IN ORAL CONTRACEPTIVE ADVERTISING SPONSORED BY LEADING MANUFACTURERS, YEARS 1967–69

| Manufacturers | Total pages oral contraceptive advertising | Total pages firm advertising [1] |
|---|---|---|
| Ortho | 276 | 486 (192) |
| Searle | 224 | 374 (150) |
| Parke-Davis | 168 | 248 (80) |
| Lilly | 165 | 277 (112) |
| Syntex | 165 | 185 (20) |
| Mead-Johnson | 91 | 172 (81) |
| Wyeth | 53 | 131 (78) |
| Total all manufacturers | 1,142 | 1,855 (713) |

[1] Figures in parentheses indicate total pages of firm advertising minus pages devoted to oral contraceptive ads.

SECTION III. Obstetrics and Gynecology.[1] Advertising, 1967 through 1969. Oral contraceptive advertising represents 14.1 percent of the total advertising copy in "Obstetrics and Gynecology" for the period January 1967 through December 1969.

*Volume in pages, Years 1967–69:*

| | |
|---|---|
| Total pages oral contraceptive advertising | 547 |
| Total pages all advertising | 3,914 |
| Total pages advertising for other contraceptive devices | 71 |

[1] Information based on a review of 36 monthly issues.

VOLUME IN ORAL CONTRACEPTIVE ADVERTISING SPONSORED BY LEADING MANUFACTURERS, YEARS 1967–69

| Manufacturers | Total pages oral contraceptive advertising | Total pages firm advertising [1] |
|---|---|---|
| Ortho | 144 | 250 (106) |
| Searle | 94 | 199 (105) |
| Lilly | 81 | 117 (36) |
| Parke-Davis | 75 | 145 (70) |
| Syntex | 70 | 82 (12) |
| Wyeth | 45 | 104 (59) |
| Mead-Johnson | 38 | 102 (64) |
| Total all manufacturers | 547 | 999 (452) |

[1] Figures in parentheses indicate total pages of firm advertising minus pages devoted to oral contraceptive ads.

# APPENDIX VII

THE LIBRARY OF CONGRESS,
LEGISLATIVE REFERENCE SERVICE,
*Washington, D.C., March 4, 1970.*

To: Subcommittee on Monopoly, Select Committee on Small Business.
From: Education and Public Welfare Division.
Subject: Articles discussing side effects of oral contraceptives.

This is in further reply to a previous request from the Staff of the Subcommittee asking the Legislative Reference Service to undertake a study of the patterns of oral contraceptive advertising appearing in selected medical journals and a review of any articles appearing in these journals which seem to draw the attention of the reader to potential or actual side effects of oral contraceptive products used in human beings. We have already forwarded to the Subcommittee the information dealing with oral contraceptive advertising. A description of the number and types of articles discussing the side effects of oral contraceptives is outlined below.

1. *Journal sources and methods used in preparing this review*

As requested by the Subcommittee staff, the medical journals to be examined for this review were the following: *The American Journal of Obstetrics and Gynecology,* published by the American Association of Obstetricians and Gynecologists; *GP,* published by the American Academy of General Practice; and *Obstetrics and Gynecology,* published by the American College of Obstetricians and Gynecologists. The survey period covered a span of three years for each publication, from January 1967 through December 1969.

In order to obtain a complete listing of all articles appearing in these journals dealing with the effects of oral contraceptives, we examined the subject index for each publication which appears at the end of every volume and lists by various subject classifications of every article appearing in each issue, including articles in the form of a research paper, editorial comment, capsule announcement, or correspondence from readers. For the purposes of this review, we have eliminated any articles dealing with oral contraceptives which were limited in discussiion to merely a statistical reporting of the relative success of various contraceptive methods in preventing actual conception. However, if articles falling into the above-mentioned category also made references to actual reported side effects or adverse reactions to the oral-chemical agents, these articles were included in the information presented here. Also excluded from this report were articles which were concerned only with a technical study of the physiological action or oral contraceptives and which did not contain specific reference to potential or actual side effects which might result from the type of physiological action described.

The tables which appear at the end of this report summarize, by journal, the total number of articles discussing potential or actual side effects of oral contraceptives. Also, the data for each journal has been subdivided to show the following:

1. Total number of articles specifically recommending caution in prescribing oral contraceptives for individuals with certain conditions predisposing to adverse side effects.

2. A classification of articles indicating the types of potential or actual side effects under discussion.

We have attached a list of the articles examined in this review arranged alphabetically by title under each journal surveyed. There appears to be a consensus of opinion in the majority of articles surveyed containing recommendations regarding limited prescribing of oral contraceptives for women with certain medical histories that the advantages of the pill outweigh the potential or actual risks in long-term use in human beings. It might also be pointed out

that there was only a very slight increase between 1967 and 1969 in the total number of articles found in these journals discussing the various side effects encountered by users of oral contraceptives. Aside from the articles found in *GP*, which were mainly in the form of letters from physicians or brief reviews of papers appearing in other medical journals, the majority of the articles surveyed were in the form of research papers reporting studies conducted at major hospitals or medical centers.

SECTION I. *The American Journal of Obstetrics and Gynecology*

| | |
|---|---|
| Articles discussing side effects of oral contraceptives, years 1967–69: | |
| Total number articles discussing side effects | 35 |
| Total number articles specifically cautioning against prescription in certain conditions | 9 |
| Breakdown of articles by type of side effect discussed, articles describing: | |
| "Usual" [1] side effects | 7 |
| Effect on vascular system | 9 |
| Effect on metabolic processes | 5 |
| Effect on hepatic system | 1 |
| Effect on reproductive system | 8 |
| All other side effects [2] | 5 |

[1] Refers to broad spectrum of relatively mild complaints, such as nausea, weight gain, breakthrough bleeding, headache, etc., frequently reported by women on oral contraceptive therapy.
[2] Refers to articles discussing all other side effects, including the relationship between oral contraceptive and such things as thyroid function, cancer, intestinal infarction, arthritis, etc.

SECTION II. *GP, General Practice*

| | |
|---|---|
| Articles discussing side effects of oral contraceptives, years 1967–69: | |
| Total number articles discussing side effects | 7 |
| Total number articles specifically cautioning against prescription in certain conditions | 5 |
| Breakdown of articles by type of side effect discussed, articles describing: | |
| "Usual" [1] side effects | 0 |
| Effect on vascular system | 3 |
| Effect on metabolic processes | 1 |
| Effect on hepatic system | 0 |
| Effect on reproductive system | 1 |
| All other side effects [2] | 2 |

[1] Refers to broad spectrum of relatively mild complaints, such as nausea, weight gain, breakthrough bleeding, headache, etc., frequently reported by women on oral contraceptive therapy.
[2] Refers to articles discussing all other side effects, including the relationship between oral contraceptives and such things as thyroid function, intestinal infarction, arthritis, etc.

SECTION III. *Obstetrics and Gynecology*

| | |
|---|---|
| Articles discussing side effects of oral contraceptives, years 1967–69: | |
| Total number articles discussing side effects | 37 |
| Total number articles specifically cautioning against prescription in certain conditions | 13 |
| Breakdown of articles by type of side effect discussed, articles describing: | |
| "Usual" [1] side effects | 9 |
| Effect on vascular system | 2 |
| Effect on Metabolic processes | 7 |
| Effect on hepatic system | 2 |
| Effect on reproductive system | 12 |
| All other side effects [2] | 5 |

[1] Refers to broad spectrum of relatively mild complaints, such as nausea, weight gain, breakthrough bleeding, headache, etc., frequently reported by women on oral contraceptive therapy.
[2] Refers to articles discussing all other side effects, including the relationship between oral contraceptives and such things as thyroid function, cancer, intestinal infarction, arthritis, etc.

ARTICLES DISCUSSING SIDE EFFECTS OF ORAL CONTRACEPTIVES

A. *The American Journal of Obstetrics and Gynecology*

1. "Alkaline Posphatase Activity of Polymorphonuclear Leukocytes in Relation to Oral Contraceptives," Mohamed B. Sammour, FRCSE, and Samir O. Hilal, MRCPE. 103:823–827, March 15, 1969.
2. "Carbonic Anhydrase Concentration in Endometrium After Oral Progestins, Richard A. Nicholls, MD, and John A. Board, MD. 99:829–832, November 15, 1967.
3. "Changes in Blood Coagulation and Fibrinolysis in Women Receiving Oral Contraceptives." Johan Ygge, MD, et al. 104:87–98, May 1, 1969.
4. "Comparative Validity of Oral and Intravenous Glucose Tolerance Tests in Pregnancy; a Study of 144 Patients Tested Both During Pregnancy and in the Nonpregnant State," Fred Benjamin, MD, and Donald J. Casper, MD. 97: 488–492, February 15, 1967.
5. "Control of Postpartum Breast Engorgement with Oral Contraceptives," David E. Booker, MD, and Irwin R. Pahl, MD. 98: 1099–1101, August 15, 1967.
6. "Depression of Physical Activity by Contraceptive Pills," Naomi M. Morris, MD, and J. Richard Udry, Ph.D. 104: 1012–1014, August 1, 1969.
7. "Effect of Estrogen-Progestin Combinations on Clotting Factors," Roger W. Robinson, MD. 99: 163–167, September 15, 1967.
8. "Effect of Mestranol and Chlormadinone Acetate on Urinary Excretion of FSH and LH," Vernon C. Stevens, Ph. D., et al. 102:95–105, September 1, 1968.
9. "Effect of Oral Contraceptives on Glucose Metabolism," Marshall B. Taylor, MD, and Martin B. Kass, MD. 102: 1035–1038, December 1, 1968.
10. "Effect of Prolonged Cyclic Therapy with Estrogen-Progestin Combinations on Thyroid Function," R. Ralph Margulis, MD, and Robert Leach, MD. 99: 263–68, September 15, 1967.
11. "Effects of a Sequential Oral Contraceptive on Endometrial Enzyme and Carbohydrate Histochemistry," Lawrence L. Hester, Jr., MD, et al. 102: 771– 783, November 15, 1968.
12. "Effects of a Sequential Oral Contraceptive on Plasma Insulin and Blood Glucose Levels After Six Months Treatment," William N. Spellacy, MD, K. L. Carlson, BS, and S. L. Schade, RN. 101: 672–676, July 1, 1968.
13. "Factors in Oral Contraception Related Hypertension," Max Rosenberg, MD. 104: 1221–22, August 15, 1969.
14. "High Blood Pressure and Oral Contraceptives; Changes in Plasma Renin and Renin Substrate and in Aldosterone Excretion," Michael A. Newton, MD, et al. 101:1037–45, August 15, 1968.
15. "Incidence of Side Effects with Contraceptive Placebo," Ranon Aznar-Ramos, MD, et al. 105: 1144–1149, December 1, 1969.
16. "The Incidence of Side Effects With Oral or Intrauterine Contraceptives," Joseph W. Goldzieher, MD. 102: 91–94, September 1, 1968.
17. "In Vitro Autoradiographic Study of the Endometrium From Women Treated Wtih Low-Dose Chlormadinone Acetate for Contraception," Hector Marquez-Monter, MD, et al. 102: 896–900, November 15, 1968.
18. "Oral Contraception Started Early in the Puerperium," Richard Frank, MD, William M. Alpern, MD, and Dorothy E. Eshbaugh, MD. 103: 112–120, January 1, 1969.
19. "Oral Contraceptive Medications and Headache," A. W. Diddle, MD. William H. Gardner, MD, and Perry J. Williamson, MD. 105: 507–511, October 15, 1969.
20. "Oral Contraceptives and Carbohydrate Metabolism," C. DiPaola, MD, et al. 101: 206–216, May 15, 1968.
21. "Oral Contraceptives and Elevated Blood Pressure," J. E. A. Tyson, MD. 100: 875–876, March 15, 1968.
22. "Oral Pregestational Agents as a Cause of Candida Vaginitis," Helen Walsh, BS, Richard J. Hildebrandt, MD, and Harry Prystowsky, MD. 101: 991–993, August 1, 1968.
23. "Ovarian Morphology Following Cyclic Norethindrone-Mestranol Therapy," William V. Zussman, MD, Donald A Forbes, MD, and Robert J. Carpenter, MD. 99: 86–89, September 1, 1967.

24. "Patient Acceptance of Oral Contraceptives; 1. The American Indian," Edward E. Wallach, MD, Alan E. Beer, MD, and Celso-Ramon Garcia, MD. 97: 984–991, April 1, 1967.
25. "Patient Acceptance of Oral Contraceptives; 2. The Private Patient," Edward Wallach, MD, Francis M. Watson, Jr., and Celso-Ramon Garcia, MD. 98: 1071–1079, August 15, 1967.
26. "Platelet Adhesiveness and Lipoprotein Lipase Activity in Controls and in Subjects Taking Oral Contraceptives," J. M. Ham, MD, and R. Rose, B. Sc. 105: 628–631, October 15, 1969.
27. "Prolonged Anovulation Subsequent to Oral Progestins, R. Pinkney Rankin, MD. 103: 919–924, April 1, 1969.
28. "Psychiatric Reactions to Oral Contraceptives," Francis J. Kane, MD. 102: 1053–1062, December 1, 1968.
29. "Pulmonary Embolism and Oral Steroidal Contraceptives," Calvin J. Hobel, MD, and Daniel R. Mishell, Jr., MD. 101: 944–996, August 1, 1968.
30. "Relationship Between the Oral Contraceptives and Folic Acid Metabolism," Frederick W. McLean, MD, et al. 104: 745–747, July 1, 1969.
31. "A Review of Carbohydrate Metabolism and the Oral Contraceptives," William N. Spellacy, MD, 104: 448–460, June 1, 1969.
32. "Syndrome of Anovulation Following the Oral Contraceptives," Oscar I. Dodek, Jr., MD, and Herbert L. Kotz, MD. 98: 1065–1070, August 15, 1967.
33. "The Two Hour Sulfobromophthalein Retention Test and the Transaminase Activity During Oral Contraceptive Therapy," Ulf Larsson-Cohn, MD. 98: 188–193, May 15, 1967.
34. "Two Thousand Woman-Years' Experience with a Sequential Contraceptive," Max C. Karrer, MD, and Edward R. Smith, MD. 102: 1029–1034, December 1, 1968.
35. "Zinc and Copper Levels in Pregnant Women and Those Taking Oral Contraceptives," James A. O'Leary, MD, and William N. Spellacy, MD. 103: 131–132, January 1, 1969.

B. *GP, General Practice*

1. "Blood Coagulation and Oral Contraceptives," in Information Please. 39: 135–137, June, 1969.
2. "Intestinal Infarction Associated with Oral Contraceptives," in Tips From Other Journals. 39: 137, April 1969.
3. "Oral Contraceptives and Pulmonary Vascular Disease," in Tips From Other Journals, 38: 157, November, 1968.
4. "Oral Contraceptives in the Puerperium," in Tips From Other Journals. 40: 155, October, 1969.
5. "The Pill and Arthritis," in Medigrams. 40: 139, October, 1969.
6. "The Pill and Folic Acid," in Editorials. 40: 77, July, 1969.
7. "Pulmonary Embolism With Oral Steriodal Contraceptives," in Tips From Other Journals, 39: 121, February, 1969.

C. *Obstetrics and Gynecology*

1. "Achilles Tendon Reflex to Evaluate Thyroid Function During Pregnancy and in Subjects Taking Oral Contraceptives," T. Hilgers, BS, C. Crutchfield, MD, and W. N. Spellacy, MD. 30: 83–88 July, 1967.
2. "Adrenal-Pituitary Responsiveness During Therapy With an Oral Contraceptive," Jorge H. Mestman, MD, Gail V. Anderson, MD, and Don H. Nelson, MD. 31: 378–386, March, 1968.
3. "Amenorrhea Following Oral Contraceptives," David R. Halbert, MD, and C. D. Christian, MD. 34: 161–167, August 1969.
4. "Amenorrhea Subsequent to Treatment With Oral Contraceptives," Robert W. Kistner. 29: 604–605, April 1967.
5. "Anovular Corpus Luteum in a Woman Taking and Oral Contraceptive," Kurt S. Ludwig, MD, and Marshall Horowitz, MD. 33: 696–702, May, 1969.
6. "Biliary Statis After Mestranol-Norethindrone Ingestion; Report of a Case," G. H. Sabel, Lt, MC, USN, and R. F. Kirk, CDR, MC, USN. 31: 375–377, March 1968.
7. "Cholesterol Content of Menstrual Discharge; Influence of Contraceptives," Leon J. DeMerre, Ph.D, Elizabeth B. Gilbreath, BS, and D. Stanley Pattison, MD. 32: 645–648, November, 1968.

8. "Continuous Tablet Therapy for Oral Contraception," Philip J. DiSaia, MD, Clarence D. Davis, MD, and Ben Z. Taber, MD. 31: 119–124, January, 1968.
9. "Contraceptives, GTT, and Insulin Level," William N. Spellacy, MD. 32: 441–442, September, 1968.
10. "Cytolgic Changes Following the Use of Oral Contraceptives," Winifred Liu, MD, et al. 30: 228–232, August 1967.
11. "Effect of an Ovulatory Suppressant on Glucose Tolerance and Insulin Secretion," F. Xavier Pi-Sunyer, MD, and Stuart Oster, MD. 31: 482–484, Arpil, 1968.
12. "Effects of Contraceptive Hormone Preparations on Fine Structure of the Endometrium," Ernst R. Friedrich, MD. 30: 201–219, August, 1967.
13. "Effects of Contraceptives on Glycogen Content of Blood and Menstrual Discharge," Leon J. Demerre, Ph.D, Eizabeth B. Gilbreath, BS, and D. Stanley Pattison, MD. 33: 200–203, February, 1969.
14. "Effects of a Sequential Oral Contraceptive on Endocervical Carbohydrate Histochemistry," William W. Kellett, III, MD, et al. 34: 536–544. October, 1969.
15. "Estrogen-Deprivation Headaches," Eduard Eichner, MD. 32: 294, August, 1968.
16. "Failure of Mestranol to Prepare for the Generalized Schwartzman Reaction," L. L. Phillips, Ph.D, et al in reports of abstracts presented at annual convention of American College of Obstetricians and Gynecologists. 33: 592–593, April, 1969.
17. "Fertility and Contraception After Age 40," Sherwin A. Kaufman, MD. 33: 288–291, February 1969.
18 "Growth Hormone Alterations by a Sequential-Type Oral Contraceptive," W. N. Spellacy, MD, W. C. Buhi, MS, and R. P. Bendel, MD. 33: 506–510, April, 1969.
19. "Hypertriglyceridemia During Treatment With Estrogen and Oral Contraceptives," Herbert Gershberg, MD, Mildred Hulse, MA, and Zenaida Javier, MD. 31: 186–189, February, 1968.
20. "Indocyanine Green Liver Function Studies on Women Taking Progestins," Norman K. Takaki, LCDR, MC, USN, and Carter W. Mathews, LT, MC, USN, 30: 220–227, August, 1967.
21. "Insulin and Glucose Studies After One Year of Treatment With a Sequential-type Oral Contraceptive," William N. Spellacy, MD, William C. Buhi, MS, and Richard P. Bendel, MD. 33: 800–804, June, 1969.
22. "Modified Sequential Oral Contraceptives Employing Mestranol With Chlormadinone," Edward T. Tyler, MD, Eric M. Matsner, MD, and Milton Gotlib, MD. 34: 820–824, December 1969.
23. "Nonpuerperal Galactorrhea and the Contraceptive Pill," Saul W. Rosen, MD. 29: 730–731, May, 1967.
24. "Norgestrel and Ethynyl Estradiol; a New Low-Dosage Oral Agent for Fertility Control," Edris Rice-Wray, MD, Christina Avila, MD, and Juvenal Gutierrez, MD. 31: 368–374, March, 1968.
25. "Norgestrel, a Low Dose, Oral Progestogen for Fertility Control," Maxwell Roland, MD, Max Friedman, MD, and Ralph J. Hessekiel, MD. 31: 637–642, May, 1968.
26. "Ophthalmologic Findings With Oral Contraceptives," Elizabeth B. Connell, MD, and Charles D. Kelman, MD. 31: 456–460, April, 1968.
27. "Oral Contraceptive Medications and Vulvovaginal Candidiasis," A. W. Diddle, MD, et al. 34: 373–377, September, 1969.
28. "Oral Contraceptives During the Immediate Postabortal Period," Jerome W. H. Niswonger, MD, et al. 32: 325–327, September, 1968.
29. "Oral Contraceptives and Intravenous Glucose Tolerance; 1. Data Noted Early in Treatment," Norman Ames Posner, MD, et al. 29: 79–86, January, 1967.
30. "Oral Contraceptives and Intravenous Glucose Tolerance; 2. Long Term Effect," Norman Ames Posner, MD, et al. 29: 87–92, January, 1967.
31. "Oral Contraceptives: Selection of the Proper Pill," Richard P. Dickey, MD. 33: 273–288, February, 1969.
32. "The Oversuppression Syndrome," Benson J. Horowitz, MD, Mark Solomkin, MD, and Stanley W. Edelstein, MD. 31: 387–389, March, 1968.

33. "Plasma Lipids and Lipoprotein Alterations During Oral Contraceptive Administration," Bernard A. Sachs, MD, Lila Wolfman, BA, Norman Herzig, MD. 34: 530–535, October 1969.
34. "Prescribing Contraceptives for Teenagers—a Moral Compromise?" Ronald J. Pion, MD. 30: 752–755, November, 1967.
35. "Reversible 'Cancer' and the Contraceptive Pill," John Graham, MD. Ruth Graham, BS, and Koji Hirabayashi, MD. 31: 190–192, February, 1968.
36. "The Story of Contraceptives," from Editorials. 31: 556–559, April, 1968.
37. "Vaginal Moniliasis in Private Practice," Bernard A. Davis, MD, 34: 40–45, July, 1969.

# APPENDIX VIII

[Planned Parenthood-World Population News Release, June 1965]

## MASS ORAL CONTRACEPTIVE STUDY FINDINGS RELEASED

The findings to-date of a large scale, oral contraceptive research project have been announced by Alan F. Guttmacher, M.D., President, and Gordon W. Perkin, M.D., Associate Medical Director, of Planned Parenthood.

The project, known as the "25 Month Club Study", was initiated in 1962 with the full endorsement of the Federal Food and Drug Administration. This massive clinical research program was established to study, and to follow from then on, women who had by then taken an oral ovulation suppressant (Enovid 5 mg.) for two years continuously.

The examinations and data collection programs were performed by 38 selected Planned Parenthood Centers broadly distributed acorss the United States.

Enrollment for the progam began in mid-1963 and terminated in November, 1964, at which time a total of 11,711 women had received their enrollment examinations (generally in their 25th month of medication—thus the popular pseudonym, "25 Month Club"). Thereafter, all enrollees reported on their physical and mental conditions and were re-examined every six months.

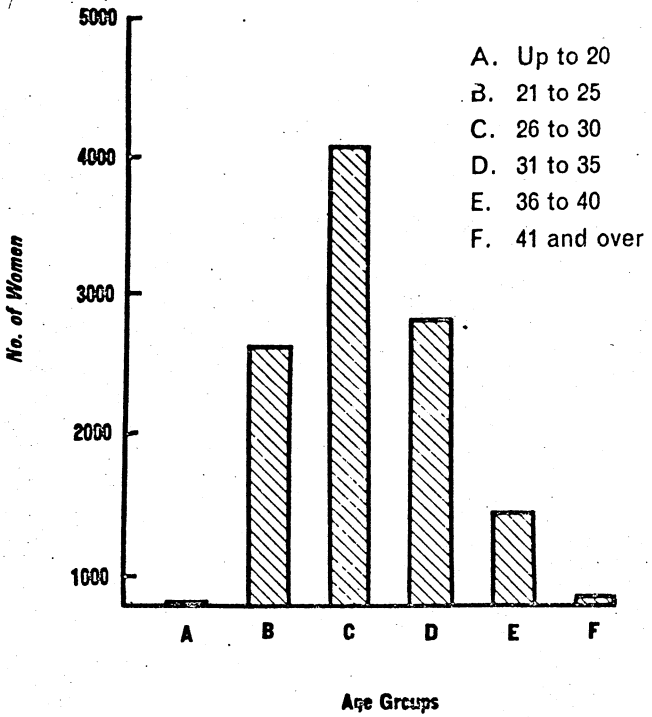
It is important to emphasize, Dr. Guttmacher stated, that the intent of this ongoing study is to follow closely women who remain on oral contraceptive medication for extended periods of time. The data do not generally reflect what is to be expected in women who have used the medication less than two years. The women in this study have presently completed over 29,000 years of experience with the medication.

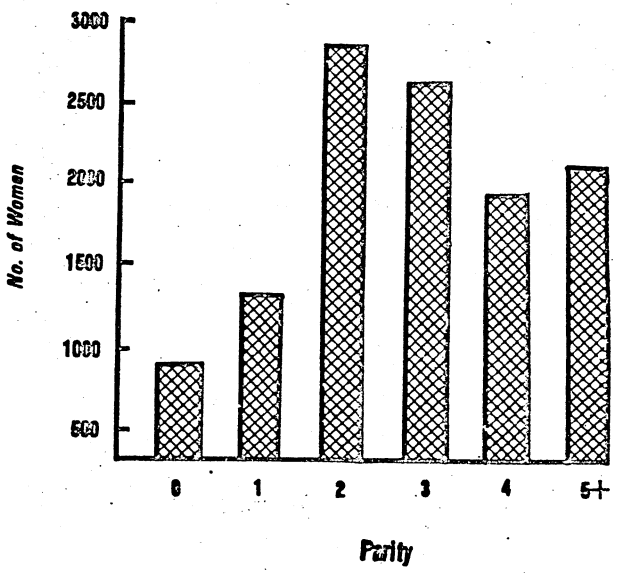
TOTAL USE-EXPERIENCE OF ALL ENROLLEES

| | Total number of women | Total number of months |
|---|---|---|
| Initial enrollment exam (25th month) | 11,711 | 282,553 |
| First revisit (30th month) | [1] 7,355 | 46,159 |
| Second revisit (36th month) | [1] 2,776 | 17,064 |
| Third revisit (42d month) | [1] 617 | 3,712 |
| Total use-experience, in this study, to date (months) | | 349,488 |
| Total in terms of woman-years | | 29,124 |

[1] These are the women who have returned to date, and does not represent dropouts from the study.

(7263)


5000
4000
3000
2000
1000
No. of Women
A. Up to 20
B. 21 to 25
C. 26 to 30
D. 31 to 35
E. 36 to 40
F. 41 and over
A
B
C
D
E
F
Age Groups


3000
2500
2000
1500
1000
500
No. of Women
0
1
2
3
4
5+
Parity

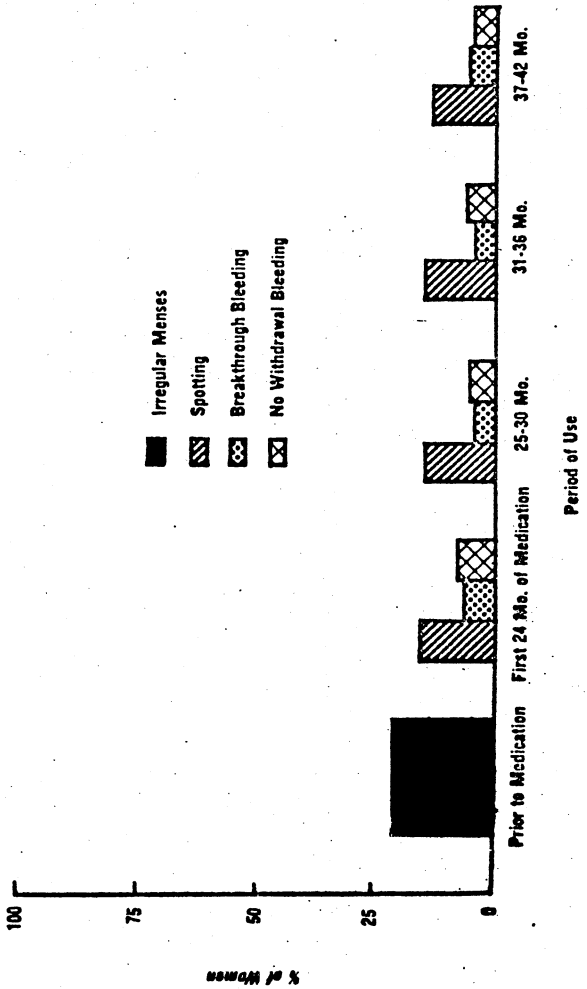
MENSTRUAL HISTORIES

2,652/11, 711 (22.5 percent) reported *irregular* menses prior to taking norethynodrel w/mestranol; none had *similar* irregular menses while on the medication, but:

22.4 percent reported spotting at least once,
6.6 percent reported breakthrough bleeding at least once, and
7.1 percent reported no withdrawal bleeding at least once during the first 2 years of medication.

| | Period of use in percent | | |
|---|---|---|---|
| | 25 to 30 months | 31 to 36 months | 37 to 42 months |
| Spotting | 15.6 | 14.9 | 14.7 |
| Breakthrough bleeding | 4.1 | 4.1 | 4.4 |
| No withdrawal bleeding | 4.9 | 5.1 | 4.4 |

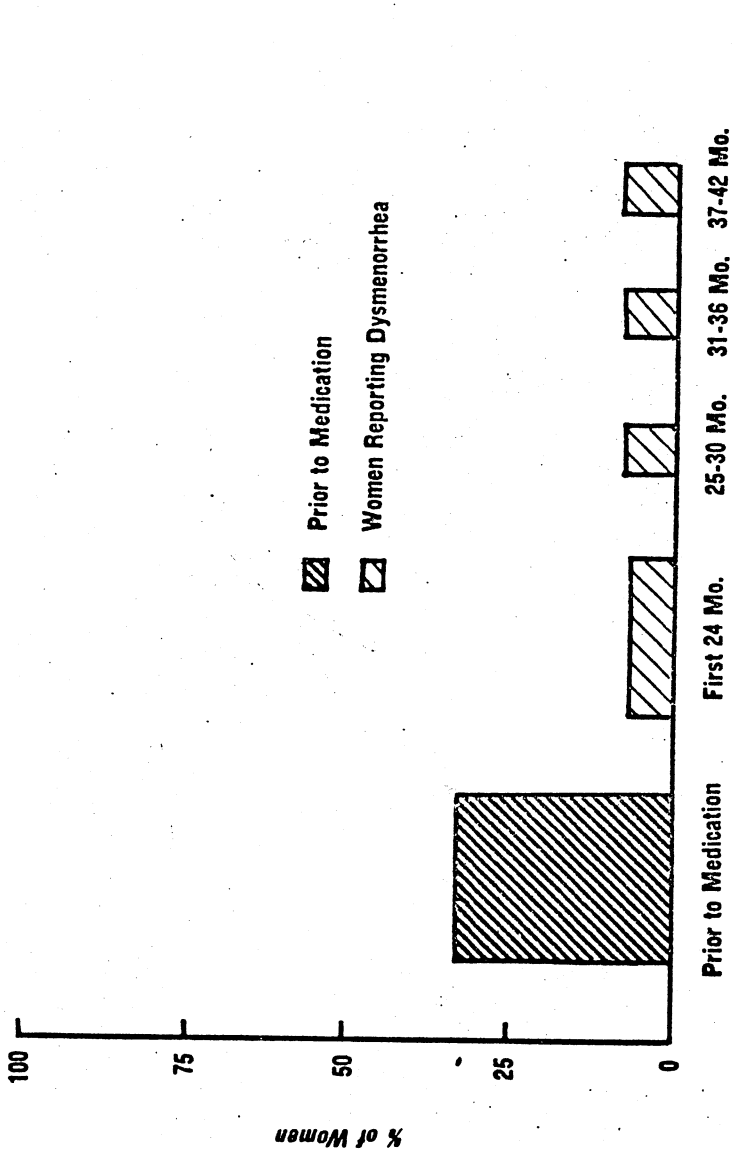
Conclusion: Among women who continue to use this type of oral contraceptive beyond 2 years, approximately 15 percent can expect to have some spotting, about 4 percent some breakthrough bleeding, and about 5 percent some "amenorrheic periods".


Irregular Menses
Spotting
Breakthrough Bleeding
No Withdrawal Bleeding
% of Women
100
75
50
25
0
Prior to Medication
First 24 Mo. of Medication
25-30 Mo.
31-36 Mo.
37-42 Mo.
Period of Use

DYSMENORRHEA

3,577/11,711 (30.2%) women reported having had a history of dysmenorrhea prior to taking norethynodrel w/mestranol; 7.0 percent reported similar dysmenorrhea during the first 2 years of medication.

| Reporting dysmenorrhea: | *Period of use in percent* |
|---|---|
| 25 to 30 months | 8.5 |
| 31 to 36 months | 8.8 |
| 37 to 42 months | 8.9 |

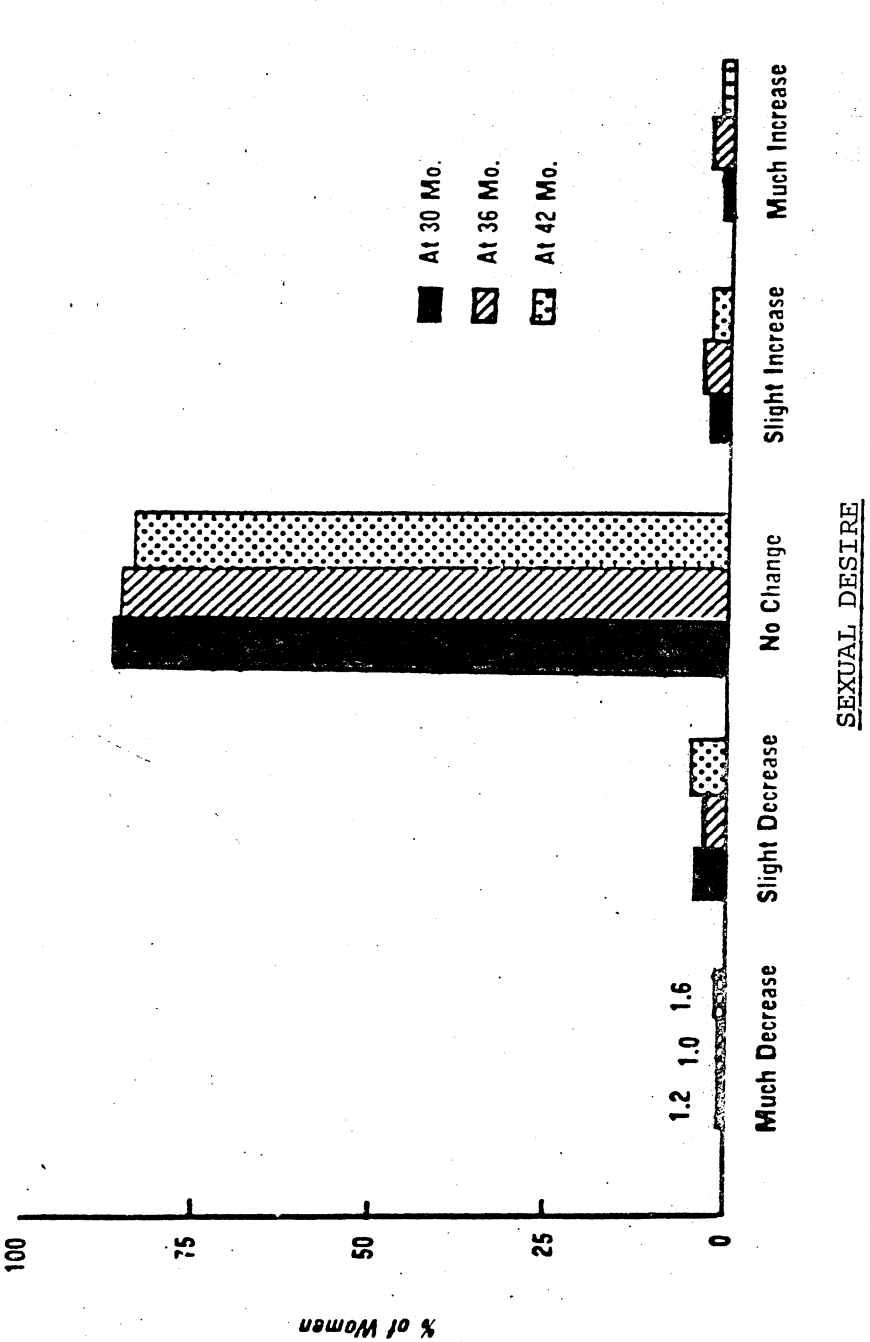

Prior to Medication
Women Reporting Dysmenorrhea
% of Women
100
75
50
25
0
Prior to Medication
First 24 Mo. of Medication
25-30 Mo.
31-36 Mo.
37-42 Mo.
Period of Use

Conclusion: It can be expected from these data that 3 out of 4 women with a history of dysmenorrhea prior to taking the medication will receive persistent relief from dysmenorrhea during the period of medication.

LIBIDO AND GENERAL WELL-BEING

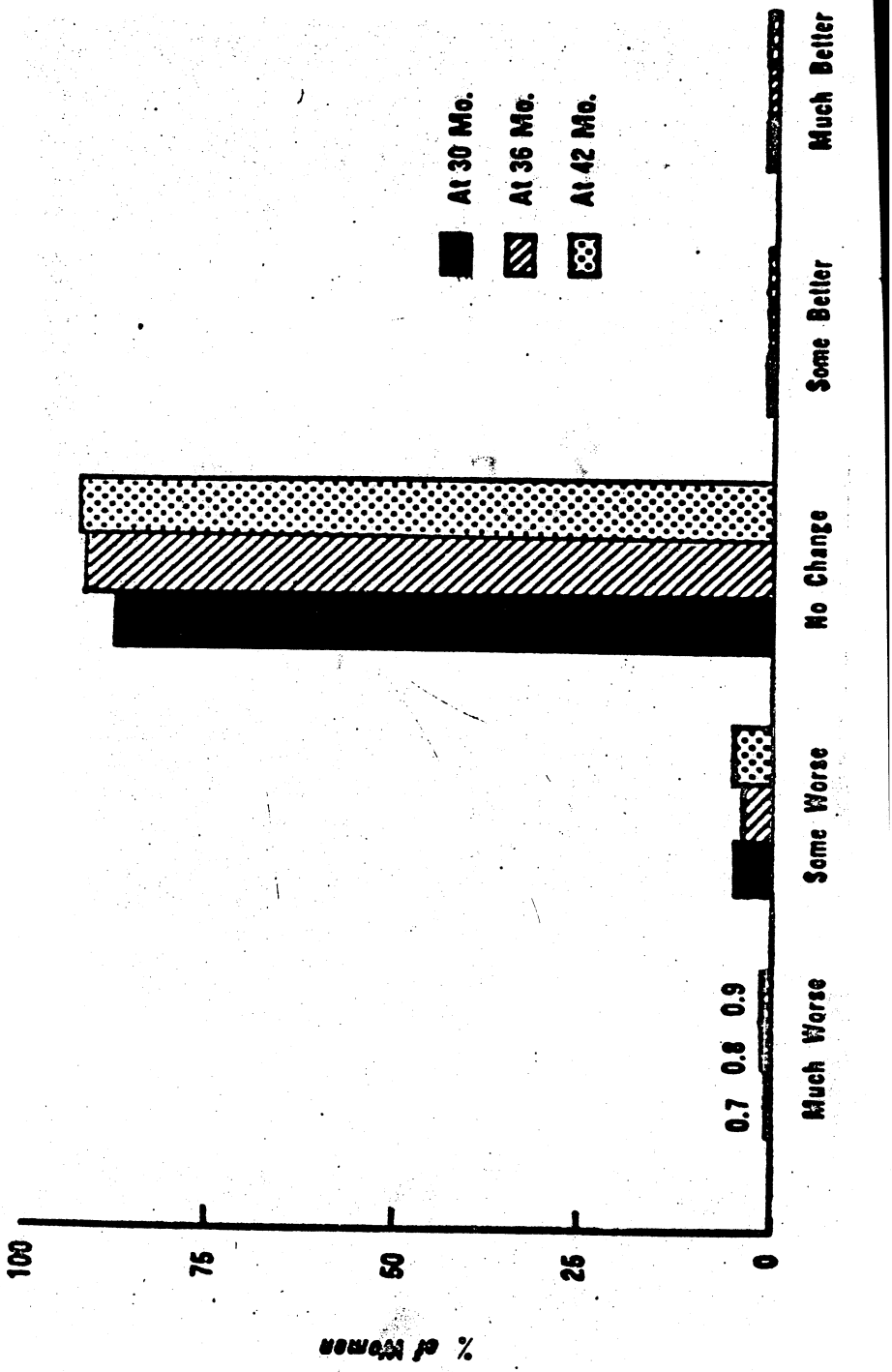
After 2 years of medication, the women were asked, "How is your sexual desire now as compared to before medication?" Over 60 percent reported "no change," 19 percent—"slight increase," 13 percent—"much increase," 6 percent—"slight decrease," and 2 percent—"much decrease."

After each subsequent 6-month period, they were asked, "How is your sexual desire since your last visit?" The responses are shown in the following graph.


100
75
50
25
0
% of Women
At 30 Mo.
At 36 Mo.
At 42 Mo.
1.2 1.0 1.6
Much Decrease
Slight Decrease
No Change
Slight Increase
Much Increase
SEXUAL DESIRE

Similarly, after 2 years of medication, the women were asked, "How are you feeling, in general, now as compared to before medication?" Sixty-seven percent reported "no change," 11 percent—"some better," 17 percent—"much better;" 4 percent—"some worse," and 2 percent—"much worse."

After each subsequent 6-month period, they were asked, "How are you feeling, in general, since your last visit?" The responses are shown in the following graph.


At 30 Mo.
At 36 Mo.
At 42 Mo.
100
75
50
25
0
0.7 0.8 0.9
Much Worse
Some Worse
No Change
Some Better
Much Better

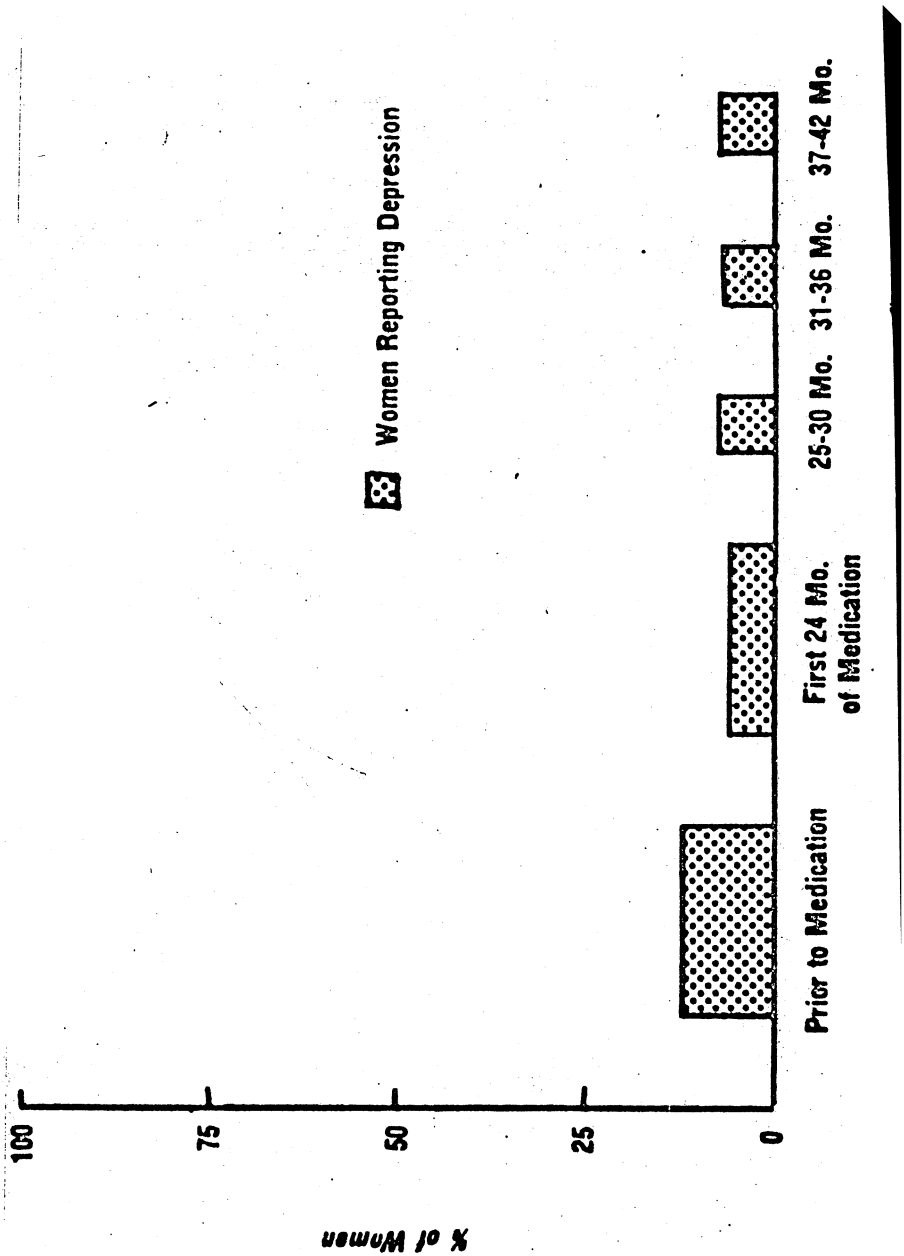
GENERAL WELL-BEING

Conclusion: After 2 years of medication, most women felt no change in their sexual desire or in their general well-being; however, for those who did note a change a greater number persistently said they felt better than worse. Subsequent to the 2-year period, libido and general well-being tend to stabilize.

DEPRESSION

1,268/11,711 (10.8%) women reported depression as a common menstrually-related event in their premedication history; 692/11,711 (5.9 percent) reported similar depression during the first 2 years of medication.

| | *Period of use in percent* |
|---|---|
| Reporting depression: | |
| 25 to 30 months (492/7355) | 6. 7 |
| 31 to 36 months (165/2776) | 5. 9 |
| 37 to 42 months (40/617) | 6. 5 |

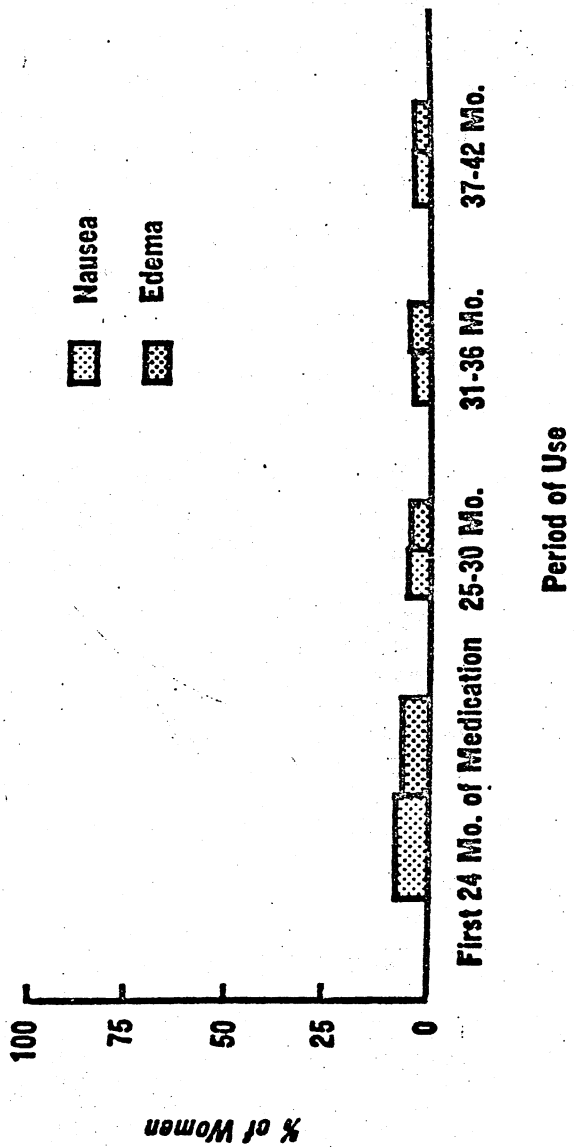

% of Women
100
75
50
25
0
Women Reporting Depression
Prior to Medication
First 24 Mo. of Medication
25-30 Mo.
31-36 Mo.
37-42 Mo.

Conclusion: Menstrually-related depression was reported by 10.8 percent of the study patients prior to medication. The rate decreased to 5.9 percent during the first 2 years and remained at approximately this level from the 25th to the 42d month on medication.

NAUSEA AND EDEMA

The following numbers of women reported these reactions at least once during:

| | Period of use in percent | | | |
|---|---|---|---|---|
| | 24 months | 25 to 30 months | 31 to 36 months | 37 to 42 months |
| Nausea | 7.0 | 5.7 | 4.8 | 4.8 |
| Edema | 6.2 | 4.9 | 5.1 | 4.7 |


Nausea
Edema
100
75
50
25
0
% of Women
First 24 Mo. of Medication
25-30 Mo.
31-36 Mo.
37-42 Mo.
Period of Use

Conclusion: The incidence of nausea and edema occurring in these women during 25th to 42d months of medication is slightly less than that reported by the same group during the first 2 years. After 24 months, the incidence appears to stabilize. No patients in the study group dropped out for these reasons.

[Figures in percent]

| | Class I | Class II | Class III | Classes IV–V |
|---|---|---|---|---|
| At 25 months | 79.1 (5,208/6,583) | 20.4 (1,343/6,583) | 0.4 (26/6,583) | 0.1 (6/6,583) |
| At 30 months | 87.0 (2,090/2,402) | 12.5 (300/2,402) | 0.3 (8/2,402) | 0.2 (4/2,402) |
| At 36 months | 79.9 (1,094/1,369) | 20.1 (275/1,369) | 0 | 0 |
| At 42 months | 88 (88/100) | 12 (12/100) | 0 | 0 |

CERVICAL CYTOLOGY

At the time of enrollment, 6,583/11,711 women had recorded Pap smears.

Conclusion: The incidence of abnormal cytology was low in those women examined, and was not observed to increase with continued use (25–42 months).

THROMBOPHLEBITIS

This study was not designed to provide a comparative incidence of thrombophlebitis. Such an investigation would require more detailed follow-up examinations than were feasible in order to establish (1) a positive diagnosis of the condition, (2) the existence of recognized contributing causes, and (3) whether the patient was hospitalized. Satisfying these criteria is necessary to provide any meaningful comparison with the only reliable base-line incidence data for this disorder which is limited to idiopathic, hospitalized cases.

However, in an effort to provide a rough check on thromboembolic incidence, the women were asked, "Have you had thrombophlebitis?" at the time they were enrolled in the study (25th month of medication), and at each subsequent six-month visit. All those answering "yes" to this question are presently being followed-up to verify the diagnosis and hospitalization. When completed, this data will be analyzed electronically to provide a comparison with the exact population-at-risk at the time of *each* occurrence. The resulting incidence rate will then be released.

Of interest is the fact that 116 of the 11,711 women enrolled reported a prior history of thrombophlebitis; during the first two years of medication 8 reported a recurrence and continued uneventfully on the medication. A total of 58 occurrences (new and recurrent) were reported during the 29,124 woman-years of exposure, resulting in a crude incidence rate of 2 per 1,000 woman-years.

This crude rate based on unverified patient-response will undoubtedly be significantly reduced by verification with each woman's personal physician, and classification as hospitalized and non-hospitalized cases. The crude rate does, however, closely correspond to those comparable estimates of thrombophlebitis rates which include both hospitalized and non-hospitalized cases.*

*Conclusion:* The crude reported incidence of thrombophlebitis in women who have been taking an oral contraceptive (norethynodrel with mestranol) for two years or longer appears to approximate that in the untreated population.

* Health Insurance Plan of New York: 1.97 cases/1,000 enrollees, both sexes, age 15–44 years.
Morbidity Statistics in General Practice (England): 2.4 cases/1,000 non-pregnant women 15–44 years.

PROGRESS REPORT ON "THROMBOPHLEBITIS" CASES

Of the 58 cases of "thrombophlebitis" which were noted in the 22,460 interview and examination reports received to date, careful investigation has revealed that:

Twenty-seven were in error (no diagnosis of thromboplebitis).

Fourteen cases were doubtful (diagnosis of thrombophlebitis could not be confirmed).

Seventeen cases were confirmed as some form of thrombophlebitis.

*Of the 17 with a confirmed episode of thrombophlebitis:*

Nine experienced some possibly precipitating factor such as surgical operation.

Three had some possibly predisposing condition such as obesity.

Five could be termed as idiopathic (at least no other information was available).

Two of the women had had earlier episodes.

There was no pulmonary embolism.

*Subsequent use of enovid:*

Enovid was continued without recurrence in seven women.

Enovid was continued with one recurrence in one woman that cleared while on Enovid.

Enovid was resumed, with recurrence, in one woman.

Enovid was continued, despite chronic "thrombophlebitis" in one woman.

Enovid was stopped in four women.

Enovid was stopped 2–3 months before the episode, in one woman.

Not known whether Enovid was stopped, in two women.

The 17 known cases of thrombophlebitis in the 25-month club study represent an incidence figure of less than 1 per 1,000 and approximates the lowest figure derived to date for a randomly selected population of women of childbearing age.

DROPOUTS

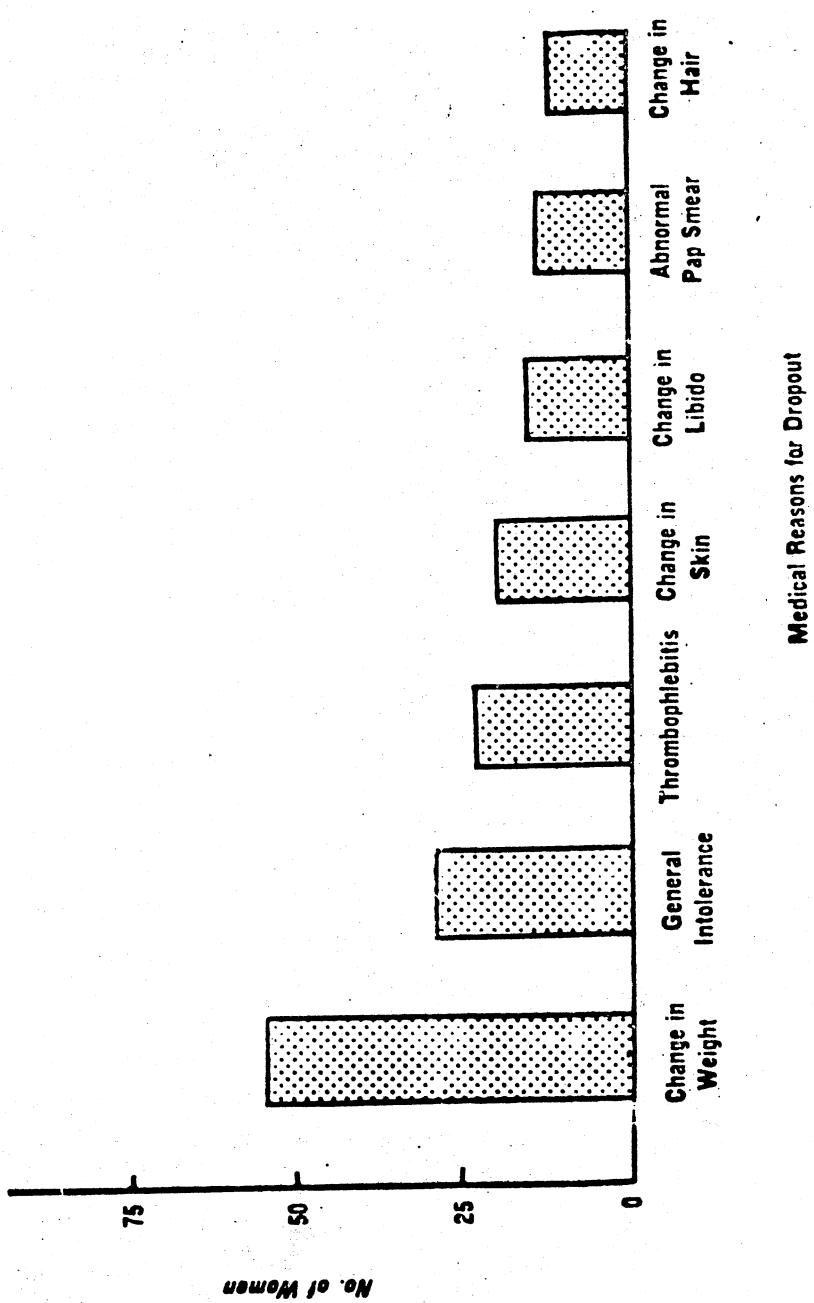
To date, 1,063/11,711 (9.1 percent) have dropped from the study. Of these 892/1,063 (83.9 percent) discontinued for nonmedical reasons. Of these, 135 did so because of the desire to become pregnant; to date, 73/135 (54 percent) are known to have conceived. 170/1,063 (16.1 percent) stopped for medical reasons.

MEDICAL REASONS FOR DROPPING OUT OF STUDY

| Reason: | *Number of women* |
|---|---|
| Change in weight | 59 |
| General intolerance | 30 |
| Thrombophlebitis | 24 |
| Change in skin | 19 |
| Change in libido | 14 |
| Abnormal Pap smear | 13 |
| Change in hair | 11 |

[1] 170/11, 711

[1](1.5 percent) have discontinued for medical reasons, to date. No unplanned pregnancies occurred.


No. of Women
75
50
25
0
Change in Weight
General Intolerance
Thrombophlebitis
Change in Skin
Change in Libido
Abnormal Pap Smear
Change in Hair
Medical Reasons for Dropout

SUMMARY AND CONCLUSIONS

Norethynodrel with mestranol 5 mg. was taken by 11,711 patients in 38 Planned Parenthood centers for a combined use experience of 29,124 years.

All patients had completed two years on the medication prior to enrollment in the study program.

No unplanned pregnancies have occurred.

New side effects have not appeared with extended use up to 42 months.

Pre-existing dysmenorrhea was relieved in three out of four women.

Pre-medication menstrual irregularity occurring in 22% of women was eliminated while on norethynodrel with mestranol; approximately 5% of women experienced some amenorrheic periods, 4% some breakthrough bleeding, and 15% some spotting.

Libido was reported to be unchanged or improved in 94% to 98% of reporting women. Similarly, "well-being" was unchanged or improved in 93% to 95% of women receiving medication.

The incidence of abnormal Pap smears was low in those women examined, and was not observed to increase with continued use of norethynodrel with mestranol.

Menstrually-related depression, reported by 11% of women before medication, was reduced to 6% during the period of the study.

Nausea and edema were reported to have occurred at least once during the study by approximately 5% of the women.

The crude reported incidence of thrombophlebitis appears to approximate that in an untreated population.

* * *

Ovulation suppression by physiological means—the simple act of taking a progestogen-estrogen tablet daily during most of the non-bleeding days of a menstrual cycle—is an epoch-making breakthrough in conception control. This study has re-affirmed that this method is 100% effective and is associated with diminishing side-effects in continued use.

ACKNOWLEDGEMENTS

This collaborative study was made possible through the cooperation and support of G. D. Searle & Co., and the following Planned Parenthood Centers.

| *Planned Parenthood Centers* | *Executive Director* | |
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* Director at time the study was initiated.

| *Planned Parenthood Centers* | *Executive Director* | |
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* Director at time the study was initiated.

There have been many others (nurses, secretaries, social workers, etc. who have worked behind the scenes, but without whose assistance this study would not have been possible).

# APPENDIX IX

[Medical & Pharmaceutical Information Bureau of Science Public Relations, Inc. News Release, February 17, 1966]

ORAL CONTRACEPTIVE NOT CAUSE OF THROMBOEMBOLISMS: DR. GUTTMACHER

New York.—Fears of thromboembolic involvement in women taking oral contraceptives have no basis in proven medical fact, according to Dr. Alan F. Guttmacher, president of Planned Parenthood-World Population.

Writing in *The Physician's Panorama* *, Dr. Guttmacher says that while possible involvement of the orals with embolic phenomena should be kept in mind, medical findings have been negative and he recommends the oral contraceptives as the best method of birth control for the newly married.

Dr. Guttmacher offers this guidance in an article written for the medical magazine which is read widely by general practitioners.

"No one has demonstrated that any of the hematological alterations observed in some women on the orals create hyper-coagulability [excessive clotting] of the blood", Dr. Guttmacher states. "And no one has been able to prove that the use of the orals leads to a greater incidence of thromboembolism."

When possible, Dr. Guttmacher advises his readers to prescribe the oral contraceptives for "two cycles before marriage so that the relatively transient, minor effects will have had time to disappear before the honeymoon. Furthermore, a bride may remain on the pill throughout the honeymoon, taking one pill each day and thus postponing the menses until a more convenient time."

Other counsel Dr. Guttmacher advises physicians to give their patients include:

"Don't be in a hurry to have a baby . . . Be sure first to complete all the education you desire . . . Of course, if you are so fortunately situated that you can afford the luxury of having a baby before completing both educations, that is a different situation. But, even so, don't have a baby immediately. First get better acquainted and adjusted."

Such advice is especially called for in the case of teenage marriages, he emphasizes. Certainly postponement is better for the baby, Dr. Guttmacher adds, because some 40 per cent of youthful marriages end in divorce.

Only when the bride is 25 or past is delay in beginning her family unwise, Dr. Guttmacher writes. "The best ally of pregnancy and birth is youth, and . . . [this makes it] important for doctors to stress this advantage of youth with each couple for whom we prescribe contraception."

Among other contraceptives which Dr. Guttmacher rates as highly effective are the IUCD, or intrauterine device. His article discusses other techniques and devices and evaluates their effectiveness.

*Panorama* is published, primarily for general practitioners, by Sandoz Pharmaceuticals of Hanover, N.J.

* February 1966.

## Appendix X

### Washington Women's Liberation Statement on Birth Control Pills

The furor and confusion about the pill which has erupted during the last 2 months has made one thing very clear. Over the past 10 years women throughout the world have been taking a pill about which they knew little or nothing.

The idea for Women's Hearings on the Pill grew out of Senator Gaylord Nelson's hearings which were supposed to deal with the pill and informed consent, that is, whether or not doctors told women about the possible risks they were taking in choosing the pill as their form of contraception. Weeks before his hearings members of Women's Liberation tried to contact him to talk to him about the organization and content of these hearings. He was at that time, too busy to talk with us, as were his assistants who were doing the administrative and organizational work for the hearings.

During the first round of the Nelson hearings members of Women's Liberation rose up to question the way in which the hearings were being conducted as well as the issues that were being covered. In spite of the fact that it is women who are taking the pill and taking the risks, it was the legislators, the doctors and the drug company's representatives, all men of course, who were testifying and dissecting women as if they were no more important than the laboratory animals they work with every day.

As one of the doctors said: "In an age in which preventive medicine has high priority it is distressing to have women exploited as guinea pigs in order to establish the absolute certitude of the causal relationship of the pill to cancer and other complications. Though it must be admitted that women make superb guinea pigs—they don't cost anything, feed themselves, clean their own cages, pay for their own pills and remunerate the clinical observer."

The pill has been falsely projected as the only effective safe means of birth control and the answer to the control of the population explosion. We think these projections are misleading. The media, the drug industry and the medical profession has advanced the idea that the pill has lead to the sexual liberation of women. But is this really true? Families, they maintain, will be smaller, but the women's place is still in the home. And it is still women who carry the primary burden of contraception and the full responsibility for child rearing.

The pill has not significantly lowered the birth rate and it has not become the panacea for population control. The lowest birth rate in this country occurred in the 1930's, long before the advent of the pill, (implying the importance of social and economic factors). Most proponents of the pill, including the FDA's Advisory Committee, say that the benefits outweigh the risks, but the benefits they are talking about relate to the generalized social philosophy of population control and the risks are taken by us, specific individual women. The only countries that have succeeded in controlling their population growth are Japan and Bulgaria, and this through legalized abortion and not the pill.

If one takes the time to survey the literature in the field, one can see that most of the positive reports on the pill come from drug company sponsored studies, and those adverse reports, which people like Dr. Guttmacher are doing so much to discredit, come from researchers unconnected in any way with the drug companies.

It is not our mission to have all women on the pill discard it and change to another form of contraception. Our mission, if such it can be called, is to rise up, as women, and demand our human rights. We will no longer let doctors treat us as objects to be manipulated at will. Together we will ask for and demand explanations and humane treatment by our doctors and if they are too busy to give this to us we will insist that the medical profession must meet our needs. We will no longer tolerate intimidation by white coated gods, antiseptically directing our lives.

We are trying to offer the facts so that women can exercise a truly free choice and make decisions for themselves. And we are trying to create a forum here for meaningful discussion of these facts.

We are not opposed to oral contraceptives for men or for women. We are opposed to unsafe contraceptives foisted on uninformed women for the profit of the drug and medical industries and for the convenience of men. (Opening statement of Washington Women's Liberation on Saturday, March 7, 1970, at Women's Hearings on the Birth Control Pill.)

EXCERPTS FROM TESTIMONY AT WOMEN'S HEARINGS ON THE PILL, MARCH 7, 1970, WASHINGTON, D.C.

Barbara Seaman, a medical columnist for two women's magazines and author of "The Doctors' Case Against the Pill" said the pill side effects she found most disturbing were personality changes, depression, irritability and fatigue. She said she was alarmed, too, at reports of broken, sore or distended veins and fatal blood clots. This evidence, plus the possibility that the pill leads to cancer and sterility, makes up too strong a case against using oral contraceptives, she siad. Many women said they were confronted with a blank wall when they complained of side effects to their doctors. Most doctors just laughed and prescribed other medications to counteract the side effects.

Mrs. Seaman said when news had got around that she had drafted a book about the suppression of evidence about the pill, the drug industry tried to keep it from being published. Before she had even seen the galleys, she said, five sets had been xeroxed and circulated outside the publishing house. The Searle drug company warned book review editors that they would frighten women if the book was widely reviewed. Investigators quizzed Mrs. Seaman's friends about her private life, and doctors quoted in the book received threatening phone calls; one eventually lost his job.

Mrs. Seaman also said she was annoyed at the way "American men have turned against the condom," which she said has led to a rise in venereal disease.

STUDIES

Elaine Archer, of the New York Women's Health Collective, said that by the end of the third year of the original studies of Enovid, which began in 1957, all 857 women who started with the project had dropped out. The final report covered only 132 women who had taken the pill for one to three years. During that time, five of the women died. No autopsies were performed.

In 1966, Miss Archer said, the FDA Advisory Committee on Obstetrics and Gynecology checked the pill's relation to breast cancer. One case involving a woman taking oral contraceptives had been reported during 1965. Researchers at the National Cancer Institute felt there should have been 1200 cases, but the FDA found only one. Drug companies admitted they had gathered no data on side effects. Several of these companies had been actively discouraging doctors from reporting side effects.

In September, 1968, the American Medical Association Journal reported that there had been no increase in the incidence of blood clots among pill users. This came six months after British studies had pointed to a definite relationship. The author of the AMA article was a man associated with Searle, the company that manufactures Enovid.

The AMA Journal had refused to print another study showing that cancer of the cervix was more prevalent in women who use the pill than in women who depend solely on the diaphragm. The Journal editors had tried to make the authors revise their study. A British medical journal eventually printed it.

DRUG COMPANIES

Miss Archer contended that the pill is the greatest source of increased profits for most drug companies, and has financed four foreign subsidiaries for Searle.

In 1968, more than a fourth of drug company sales were in foreign countries where the Agency for International Development is pushing the use of oral contraceptives.

RESEARCH

Barbara Seaman noted that drug companies spend more on promotion and advertising each year than on research. She said doctors simply are not exposed to adequate information about the pill themselves. Important research by specialists such as neurologists and psychologists rarely reaches many physicians.

A research associate with the Population Council, Sarah Tietze, said that with an estimated 18.5 million women in the world on the pill (8.5 million in the United States), new research is needed on conditions now coming to light. At least two large prospective studies—one in the United States, on 12,000 women, and one in Great Britain, with 40,000 women—are under way.

THE IUD

Further testimony pointed out that with intrauterine devices, used by an estimted 5 to 6 million women, common side effects are bleeding, pain and expulsion. Among the rare complications associated with the IUD are perforation of the uterus and pelvic inflammatory disease (PID). The incidence of perforation, except for the closed, bow type which is no longer used, is about 100 per 100,000 insertions.

ABORTION

In the United States no accurate figures on mortality due to abortion are available. Sarah Tietze believe the estimate of 5000 to 10,000 deaths each year from illegal abortions is unreasonably high. However the number reported for 1966—189 deaths—is certainly too low. More realistic data comes from European and Scandinavian countries. In Czechoslovakia and Hungary, between 1957–67, there were 69 deaths among almost 2.5 million women undergoing legal abortion. This is a rate of 2.8 per 100,000 legal abortions. In Japan the rate was 4.1 per 100,000 based on 278 deaths among 6,860,000 legal abortions for the period 1959–65.

In the Scandinavian countries the death rates were higher—40 per 100,000 legal abortions. This may be because a large number are performed after the third month of gestation, unlike practice in the other countries.

GENOCIDE

Etta Horn, a Washington welfare rights leader, said poor women are being forced by the medical system to seek help from the abortion underground. Officials in the D.C. Department of Public Health are responsible for the death and injury of such women, she charged.

Mrs. Horn said social workers are intimidating women on welfare into using birth control pills. She called it a form of "genocide." These women feel there is no alternative, she said: "You don't want to make anyone mad. You're really on your knees." As a result of this kind of coercion, many women on welfare, who are not in good health to begin with, suffer additionally from side effects of the pill, she contended.

Concern about the "population explosion" has resulted in considerable public discussion of birth control, and increasing pressures on women around the world to use unproven and potentially dangerous oral contraceptives as a means of limiting population growth. These discussions have generally regarded population control as primarily a technical problem—to be solved by more efficient technology, ie, contraceptives. Standing in the way of a technical solution to birth control, are insufficient or suppressed research on other, more desirable methods than the pill, and a lack of safe and inexpensive abortions on demand.

While the development of technically more effective contraceptives is desirable, the questions of population control are primarily socio-political, not technological. The solution to problems of over population and hunger lie not so much in effective technology as in the liberation of women and the redistribution of resources.

The popular media's portrayal of the liberation of women places great importance on her so-called sexual revolution. This "sexual" revolution is presented as a direct result of "improved methods of contraception—notably the

pill. The pill is said to give women the same sexual freedom that men have, as well as the same careers and opportunities.

But this portrayal is very misleading as it does not deal with the total oppression of women and the reasons why women want and have many children.

Alternatives to motherhood do not exist at present. Job situations discriminate against women. Our educational system tracks women into home economics and men into science. Woman's primary role in life is still that of wife and mother. Some are isolated in suburbia, and others are trapped in crowded working class homes. Most live vicariously through their children.

As long as women are defined as bodies to produce children; as long as a woman's goal in life is to "meet a man" and have a child, we are going to have kids—no matter how safe and effective the contraceptive devices. There is no other source of identity given women other than child-rearing and family life.

Judith Blake, chairwoman of the Department of Demography of the University of California at Berkeley, examined the American population policy in Science, May 2, 1969. She questioned those institutional policies which are pronatalist—that is, which encourage reproduction. Thes policies are most obvious in the family, where both male and female sexual roles are standardized in terms of reproductive functions, and in occupational roles which are defined for women in terms of child-bearing, child-raising, and complementary activities.

ON POPULATION CONTROL

She wrote: "The notion that most women will 'see the error of their ways' and decide to have two-child families is naive, since few healthy and energetic women will be so misguided as to deprive themselves of most of the rewards society has to offer them and choose a situation that allows them neither a life's work outside the home nor one within it."

When women are allowed greater diversity and freedom to pursue their own lives, then they will not feel it essential to have many children and a more humane system of population control can develop.

Population control is a socio-political issue involving the redistribution of world resources. The white middle-class male-dominated West has again tended to view population control as providing technical means to control the population growth of others, ie, Third World or Black. A more realistic solution is the redistribution of the 70% of the world's resources now controlled by 7% of the world's population (the U.S.) but this would mean extensive land reform and possible revolutions in nations where land and wealth are owned by only a few or by U.S. corporations.

Such a redistribution of resources would not only help feed overpopulated areas but also create conditions in which people could choose to limit their population growth, if this were seen as advantageous to human interests. In some nations especially socialist ones, human beings are an asset and not a deficit.

There are only two choices. One is to take a technical approach which adopts a solution that must be forced on people regardless of their choices, thereby creating an in-humane though controlled society. The other is to work now to change socio-political conditions—to work toward the liberation of women and the redistribution of world resources.

RESULTS: WOMEN'S LIBERATION SURVEY ON THE ORAL CONTRACEPTIVES

(PRELIMINARY FINDINGS FOR 750 WOMEN IN 35 STATES, 143 U.S. CITIES)

The most obvious impression obtained while tabulating questionnaires was the continuing frustrated search by women for a contraceptive that is both medically safe and 100% effective in preventing pregnancy. Unfortunately, that ideal contraceptive is not available. Those women still on the pill have one thing on their mind—avoiding pregnancy. Some have shut their ears to the dangers all together, others see no other alterntive, since other methods are not as reliable and safe abortion is too expensive and difficult to obtain. Of those women who have gone off the pill, and alarmingly high number, 17%, of literate, financially stable women are using no contraceptive at all or the least effective ones (condoms, withdrawal or rhythm). This seems to indicate that women are generally uninformed about reproductive biology and birth control. (In addition,

8% of women who have gone off the pill are abstaining). The doctors offer little help. Some women don't even see them, they are afraid (he is an authoritarian figure) of him or they are too modest to submit to a pelvic exam or the answer questions about their sex life. Other women go to the other extreme and follow his suggestions without receiving explanations or asking questions. In the area of prescribing oral contraceptives the doctors are especially guilty of 3 things:

1. Not mentioning other means of contraception.
2. Not warning of the side effects caused by the pill and if they do, omitting the serious and often fatal ones.
3. When side effects are reported they are unsympathetic and unresponsive.

In February, 1970, Washington, D.C. Women's Liberation decided to launch a survey to collect information on women and the pill. The response to our questionnaire has been overwhelming and is just one additional proof of how vital this issue is to women. More responses pour into the office everyday but we decided to start the analysis with 750 questionnaires. (We had to do the tabulations manually, as we did not have money to buy computer time). Should we somehow have access to computer time we will go on with a complete analysis of this valuable information.

Our questionnaires were mailed to Women's Liberation groups around the country who were asked to reproduce and distribute them. We now have returns from over 35 states and from women representing all classes and ages. Questionnaires were distributed in shopping centers, high schools, colleges, in government offices, just about everywhere women work and live.

Three quarters of women responding to our survey were between 21 and 30 years old. About ⅓ have family incomes above $10,000. (This compares to 44% of the Gallup sample compiled for *Newsweek*.) 100% of the 750 whose questionnaires we analyzed had had experience with the pill (compared with 25% of Gallup's 895 women).

Over half of these women used the pill as their first form of contraception. For women who did use other means of contraception before starting on the pill ⅓ used condoms and slightly fewer used diaphragms. Foams, jellies and creams, were employed by over 20% of women who used another means of contraception before starting on the pill.

The most often mentioned reason for using the pill—listed by more than half of our respondents was its effectiveness in preventing pregnancy. Women clearly want contraceptive measures which can eliminate all fear of unwanted pregnancy. (Ending in abortions or unplanned for children). Many started on the pill after pregnancies resulting from ineffective methods of contraception (40% of the women asked mentioned the convenience and ease of the pill as a reason for using it. It was aesthetically more pleasing to many. Only 8% of our group started using the pill for medical reasons—usually related to regularizing menstrual cycle.

In spite of this obvious desire for effective contraception, over 40% of the women answering our questionnaire had stopped taking the pill permanently. A shocking 17% who had gone off the pill were using no other means of contraceptive what ever, and another 8% were using abstinence . . . that is, ¼ of the women who had gone off the pill permanently were still looking for another means of birth control. Most often women—about ⅓—who had stopped the pill switched to the diaphragm.

Most of the women in our survey had the pill prescribed by a private gynecologist who did not ask for a medical history, who did give a physical and pelvic exam and who did tell the woman she should return for regular pelvics. *But*, even among this type of group, we find that only one in every four women ever had any other form of contraception described or recommended to her by her doctor before he prescribed the pill. Over 40% of the doctors never mentioned any possible side effects (this compare with 66% in Gallup sample). Of the 55% of women who were warned of side effects, only the most mild ones were normally mentioned . . . nausea and weight gain alone account for half of all side effects warned against by doctors, cancer accounts for only 2% and thromboembolism or infertility are hardly ever mentioned as possible side effects. 75% of the women in our sample experienced some side effects, but only 42% were told by their doctor that they should contact the doctor if they developed side effects.

In conclusion we find that:

(1) Women have not been able to give informed consent to their own use of the pill because they have been grossly ill-informed by their doctors.

(2) Most women are experiencing serious side effects and many are permanently ceasing to use the pill.

(3) However, there is difficulty in finding another means of contraception which will meet the desire for safety, effectiveness and convenience of use.

(4) Although it is not evident in the figures given here we can tell from the letters and personal evaluations of experience with the pill written in answer to question 25 that women acorss the country are facing a dilemma which is causing extreme psychological stress—there is no contraceptive method available which is proven medically safe and effective. Women feel forced into choosing between taking higher risks of becoming pregnant or high risks of developing cancer, diabetes or other serious side effects. Finally women describe how little information support or understanding they receive from their doctors in trying to make these crucial life decisions.

Perhaps the best way to conclude this presentation is with a few representative quotes from our questionnaire:

2–27–70 "I cannot honestly say I have had unpleasant side effects from the pill but I have been to many doctors in the last four years in three cities in which we have lived, concerning headaches, and legaches. Each doctor and planned parenthood center assured me that the pill was not causing or contributing to my difficulties, and so I continued to take the pill. Incidently, no one could give me an answer for the pain.

"The pain lately has been so severe I decided I would go off them just in case they could cause it. Since my doctors have argued for the pill I don't know or feel its my place to judge them, but I do feel every woman deserves to know the truth, and that will only come when we demand further testing in laboratories instead of the current situation which is that the woman is simply their guinea pig."

Mrs. W. Bloomington, Ind.

2–28–70 "I began using the 1mg. pill in June, 1969. Within a few weeks I began experiencing severe breast swelling and tenderness. After seeing my doctor as soon thereafter as an appointment was available (you really could die while you are waiting), I was assured that it was "nothing" and advised to continue on the pill, which I foolishly did for six months. (It's amazing how we believe and trust doctors and assume they know more than we do). During those months I saw him again about the pain and after an examination he concluded that it was due to wearing a bra that was too tight (you see now how buxom I had become). When I protested that I rarely wore a bra, that become the cause somehow. I was beginning to feel very neurotic.

"By the fall, I detected lumps in both breasts, at which point I freaked out and saw a doctor who referred me to a surgeon (more delays). My condition has been diagnosed by him as chronic cystic mastidis, often called "buckshot disease," caused by a hormone imbalance and not unusual in women experiencing menopause. I am 27. The surgeon felt this condition was a direct result of Norlestrin. This is my first month off the pill and there is a noticeable improvement in my condition, although there is no assurance that it will ever disappear entirely."

D. S. Washington, D.C.

2–70 "As indicated in question #21 I had many adverse side effects while taking the pill. The headaches I experience were attributed to "tension" as my male OB put it. Nausea is "normal" and something your system adjusts to with the pill. Weight gain too is just one of those things that go hand and hand with this form of birth control. The irritability and breathing difficulties were supposed to be due to tension and were treated with tranquilizers which only served to make me tired along with being irritable and depressed.

"When I complained of loss of libido, it was suggested that a psychiatrist would be the one to help me. (no doubt a male psychiatrist who supported Freud would have been recommended had I been fool enough to take the advice).

"I finally stopped taking the pill when the chest pains and leg cramps I experienced became excruciating and too frequent to bear. Never once during the 9 months that I was on this medication did the doctor ever suggest that I discontinue the pill or grant the possibility that the symptoms I manifested were pill induced."

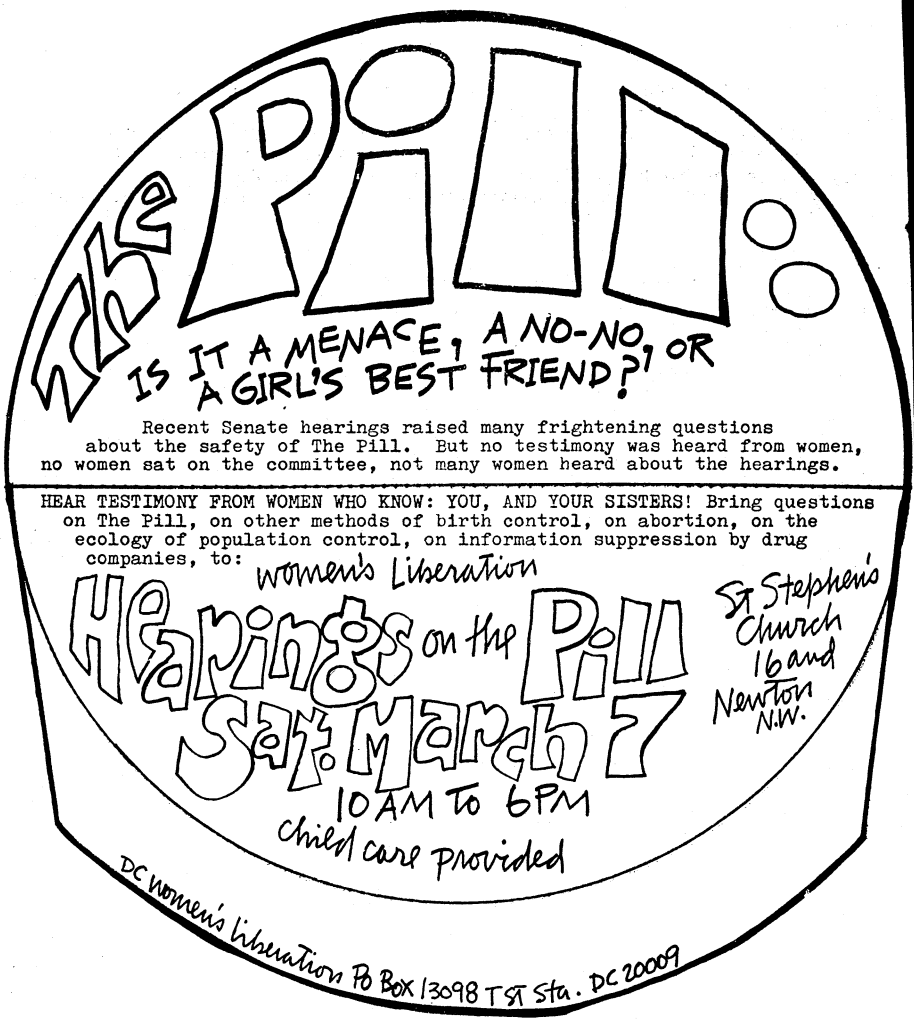
Syracuse, New York

Of 750 women, the following disease conditions were reported in answer to question No. 21 on the questionnaire.

| | |
|---|---|
| Total number | 2070 |
| Response to possibilities listed on questionnaires | 1923 |
| Response to "others" category | 147 |
| Headache | 153 |
| Nausea | 213 |
| Skin blemish | 54 |
| Bleeding gums | 25 |
| Blood clots | 23 |
| Infertility | 22 |
| Stroke | 1 |
| Jaundice | 1 |
| Weight gain | 329 |
| Epilepsy | 1 |
| Swollen breasts | 253 |
| Skin discoloration | 39 |
| Cervicallestions | 14 |
| Cystic ovary | 10 |
| Enlarged uterus | 4 |
| Cancer of cervix | 3 |
| Cervisitis | 16 |
| Cancer of breast | 0 |
| Cancer of uterus | 1 |
| Genetic defects | 1 |
| Breathing difficulty | 29 |
| Hair loss | 35 |
| Depression | 186 |
| Irritability | 171 |
| Changes in metabolism | 46 |
| High blood pressure | 19 |
| Changes in thyroid function | 15 |
| Chemically induced diabetes | 4 |
| Loss of libido | 72 |
| Changes in sensory perception | 26 |
| Other: | |
| Vaginitis | 24 |
| Breakthrough bleeding | 23 |
| Amennorhia or reduced flow | 22 |
| Cyctic mastitis | 11 |
| Impaired circulation | 13 |
| Chest and or leg pains | 10 |
| Hemmorhage | 3 |
| Hirsuiteness (hair gain) | 7 |
| Allergy | 4 |
| Lack of vaginal lubrication | 3 |
| Dizziness | 6 |
| Uterine infection | 3 |
| Shrunken uterus | 1 |
| Anemia | 2 |
| Rheumatoid arthritis | 1 |
| Swollen ovary | 1 |
| Other (indigestion, constipation, etc) | 13 |
| Positive effects reported in answer to question No. 21 (17): | |
| Weight loss | 1 |
| Acne cleared up | 6 |
| Menstrual regularity | 6 |
| Freedom from anxiety | 2 |
| Increased libido | 2 |

| | Number | Percent |
|---|---|---|
| Age distribution: | | |
| Under 20 | 147 | 19 |
| 21 to 30 | 528 | 72 |
| 31 to 40 | 46 | 6 |
| Over 40 | 15 | 2 |
| Income distribution: | | |
| Under $3,000 | 127 | 17 |
| $3,000 to $6,000 | 144 | 19 |
| $6,000 to $10,000 | 178 | 24 |
| Over $10,000 | 264 | 35 |
| Don't know | 37 | 5 |
| Used other form of contraception before pill: | | |
| Yes | 340 | 45 |
| No | 409 | 54 |
| Don't know | 1 | |
| Got pill from: | | |
| Private doctor | 588 | 78 |
| Planned parenthood | 69 | .09 |
| University or student clinic | 35 | .05 |
| Public health | 14 | .02 |
| Private clinic/group health | 8 | .01 |
| Military | 7 | .01 |
| Other | 29 | .04 |
| Doctor was: | | |
| Gynecologist | 478 | 64 |
| General practicioner | 226 | 30 |
| Internist | 23 | 3 |
| Other | 23 | 3 |
| Asked for medical history: | | |
| Yes | 488 | 65 |
| No | 226 | 30 |
| Don't know | 36 | 5 |
| Gave full physical: | | |
| Yes | 468 | 62 |
| No | 272 | 36 |
| Don't know | 10 | 1 |
| Gave pelvic: | | |
| Yes | 595 | 79 |
| No | 121 | 16 |
| Don't know | 34 | 5 |
| Told to return for regular pelvic: | | |
| Yes | 688 | 81 |
| No | 129 | 17 |
| Don't know | 13 | 2 |
| Recommended other form of contraception: | | |
| Yes | 190 | 25 |
| No | 541 | 72 |
| Don't know | 19 | 3 |

| | Number | Percent |
|---|---|---|
| Warned of side effects: | | |
| Yes | 423 | 55 |
| No | 303 | 41 |
| Don't know | 24 | 4 |
| Contact doctor for side effects: | | |
| Yes | 312 | 42 |
| No | 339 | 45 |
| Don't know | 99 | 13 |
| Stopped taking pill permanently: | | |
| Yes | 304 | 41 |
| No | 426 | 57 |
| Don't know | 20 | 2 |
| Now using: | 115 | 31 |
| Diaphragm | 52 | |
| Iud | 46 | |
| Foam, jelly cream | 55 | |
| None | 35 | |
| Condon | 27 | |
| Abstinence | 4 | |
| Withdrawal | 23 | |
| Pregnancy or nursing | 3 | |
| tubal ligation | 1 | |
| hysterectomy | | |
| Other form of contraceptive used before the pill: | | |
| Condon | 133 | 33 |
| Diaphragm | 125 | 31 |
| Foam jelly | 90 | 22 |
| Rhythem | 36 | 8 |
| Withdrawal | 21 | 5 |
| Started or switched to pill: | | |
| Effectiveness | 482 | |
| Convenience | 275 | |
| Medical | 75 | |
| Other | 97 | |
| Side effects mentioned by doctor: | | |
| Nausea | 196 | 26 |
| Weight gain | 192 | 26 |
| Bleeding/spotting | 75 | 10 |
| Swollen breasts | 67 | 9 |
| Headache | 54 | 7 |
| Cancer | 17 | 2 |
| Sterility/infertility | 7 | 1 |
| Will have none | 2 | |
| Other | 130 | 18 |


The Pill
IS IT A MENACE, A NO-NO, OR A GIRL'S BEST FRIEND?
Recent Senate hearings raised many frightening questions about the safety of The Pill. But no testimony was heard from women, no women sat on the committee, not many women heard about the hearings.
HEAR TESTIMONY FROM WOMEN WHO KNOW: YOU, AND YOUR SISTERS! Bring questions on The Pill, on other methods of birth control, on abortion, on the ecology of population control, on information suppression by drug companies, to:
Women's Liberation
Hearings on the Pill
Sat. March 7
10 AM to 6 PM
Child care provided
St Stephen's Church 16 and Newton N.W.
DC Women's Liberation PO Box 13098 T St Sta. DC 20009

18. Before prescribing the pill, did the doctor recommend or describe any other form of contraception to you? Yes ☐ No ☐.

19. Did the doctor warm you of any possible side effects which might result from the pill before he prescribed it for you? Yes ☐. No ☐. If yes, what side effects were mentioned? _____
Did he tell you to contact him if any of these occurred? Yes ☐. No ☐.

20. What kind(s) -- brand name -- of pill have you used? _____

21. Have you had any side effects from the pill? Yes ☐. No ☐. If yes, please check any of the following which you have had:

___ headache
___ nausea
___ skin blemish
___ bleeding gums
___ blood clots
___ infertility
___ stroke
___ jaundice
___ weight gain
___ epilepsy
___ swollen breasts
___ skin discoloration
___ cervicallesions
___ cystic ovary
___ enlarged uterus
___ cancer of cervix
___ cervisitis
___ cancer of breast
___ cancer of uterus
___ genetic defects
___ breathing difficulty
___ hair loss
___ depression
___ irritability
___ changes in metabolism
___ high blood pressure
___ changes in thyroid function
___ chemically induced diabetes
___ loss of libido
___ changes in sensory perception
OTHER_____

22. Have you ever stopped taking the pill for a month or longer and then started taking it again? Yes ☐. No ☐. If yes, why?_____
_____ Did you consult your doctor? Yes ☐ No ☐.

23. Have you now stopped taking the pill permanently? Yes ☐. No ☐. Did you consult your doctor about the decision to go off the pill? Yes ☐. No ☐. If you are NOT now using the pill, what form of contracention, if any, are you using?_____

24. If you have ever gone off the pill, did you notice any body changes? Yes ☐ No ☐. If yes, was it: loss of hair ☐. weight loss ☐. skin problems ☐. disappearance of unpleasant side effects ☐. OTHER_____

25. What is your own personal evaluation of your experience with the pill? Please use another sheet of paper for your reply, if necessary.

Do you have any further comments or suggestions? Do you have any questions you would like to see raised at the Women's pill hearings? Please let us know.

THANK YOU FOR TAKING THE TIME TO HELP US IN THIS SURVEY.

## APPENDIX XI

UNITED STATES SENATE,
*Washington, D.C., March 10, 1970.*

MR. BENJAMIN GORDON,
*Select Committee on Small Business,*
*Senate Office Building, Washington, D.C.*

DEAR Mr. Gordon: Enclosed are several newspaper articles concerning oral contraceptives and the recent hearings of the Monopoly Subcommittee.

I would appreciate them being included in the record of the Subcommittee hearings.

Sincerely yours,

BOB DOLE,
*U.S. Senate.*

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[From The Washington Post, March 5, 1970]

### HEALTH—IUD HAZARDS

(By Morton Mintz)

Sen. Gaylord Nelson's hearings on the Pill, which ended yesterday, have awakened women to known and possible hazards they never heard about from their doctors. Thousands have decided to be fitted with an intrauterine device (IUD).

Some of these women are going to be injured needessly, because certain IUD designs are unduly hazardous, because of improper insertion by doctors and because of inadequate precautions to assure sterile packaging and insertion.

The origin of the problem is that the Food, Drug and Cosmetic Act puts drugs and medical devices in different categories.

Since 1938, when the original law was passed, a manufacturer wishing to market a medicine has carried the burden of truth. That is, it has been up to him to demonstrate to the Food and Drug Administration—before marketing can begin—that the product is safe (and also, since 1961, effective) in the uses for which it is recommended.

But the maker of a medical device has not been required to get premarketing clearance. He is generally free to market what he will.

Once a device is on sale, the FDA, if it sees a need to act, must be prepared to assume the burden of proof; that is, to try to demonstrate in court that a device falls short of the claims of safety and efficacy made for it by the manufacturer.

If the FDA should prevail, it will—probably after lengthy proceedings—get an injunction against further manufacture of the questioned device.

As a practical matter, however, this cumbersome procedure has severely limited the FDA's potential for protecting the public.

In January, 1968, the Advisory Committee on Obstetrics and Gynecology, a consultant group to the FDA, briefly stirred hope for legislative reform.

At that time, when an estimated one million women in the United States, Canada and Puerto Rico had been fitted with IUDs, the committee issued a comprehensive report on the devices.

IUDs come in two basic shapes. By far the more popular is the "open" shape, of which the best known example is the Lippes Loop. The other is the "closed" shape, of which the better known designs are the "bow," the "Incon Ring" and the "Butterfly."

The committee said that in a survey of Fellows of the American College of Obstetricians and Gynecologists 10 deaths were reported among IUD users. A clear cause-effect relation was shown in four of the 10 cases, but not in the others. In addition, the committee estimated that 10 deaths (for a total of 20) had not been reported.

(Even the maximum assumed fatality of 2 per 100,000 was well below the 3 per 100,000 demonstrated for the pill from clotting diseases. The pill also has been shown to cause nonfatal but disabling clotting in some women, psychic depression, skin blotching and hair loss.)

Aside from fatalities, 369 women were reported to have suffered critical inflammatory infections in connection with IUDs.

The committee pointed out that among the fatal and critical IUD cases were an undetermined number of needless victims—women who had been fitted with unsterile or improper devices and insertion techniques.

An additional 177 women were reported to have suffered perforation of the uterus. One fact stood out: A high proportion of the 177 victims had been fitted with one of the "closed" IUD designs.

Even more striking were cases of perforation that were followed by intestinal obstruction. This is a highly dangerous condition which almost always requires surgical removal of the IUD.

Of the 15 such cases reported, 13 had been fitted with a "closed" IUD. In the remaining two cases the design was not ascertained.

In sum, the committee attributed a significant proportion of all deaths and critical illnesses in IUD users to two factors:

First, the use of "closed" designs, and second, the use of nonsterile packaging for most IUDs then being sold, the lack of disposable tools with which physicians insert the devices, and inadequate insertion instructions in the labeling.

The committee warned that "the safety of the material used, the quality control and its manufacture, and the labeling and packaging of intrauterine devices are at present the sole concern of each manufacturer."

Obviously, the problem is even more urgent today. Not only are more women using IUDs, but new designs are being developed including two that unlike early ones can be used in women who have not been pregnant.

Last September Virginia Knauer, the President's consumer affairs adviser, said that defective medical devices were needlessly killing, injuring and exploiting people.

She cited poorly designed artifical kidney machines; "5,000 to 10,000" diathermy machines used to give 20 million heat treatments yearly "that are worthless for any known medical purpose," and 40,000 ineffective emergency respirators.

President Nixon, in his October consumer message to Congress, said "certain minimum standards should be set" for medical devices, with the government being given "additional authority to require pre-marketing clearance in certain cases."

Dr. Theodore Cooper, director of the National Heart and Lung Institute, heads a panel studying legislative reform at Mr. Nixon's request. It is seeking a proposal which will protect the public without denying it the benefits of new technology and is scheduled to report by the end of this month.

Hopeful as this may sound, Presidents Kennedy and Johnson sent six messages to Capitol Hill urging lawmakers to require manufacturers of medical devices to demonstrate before marketing that devices to be implanted in the body are safe, effective and reliable. All were unsuccessful.

Members of Congress have introduced a series of bills aimed at that objective. But all such proposals have had less steam behind them than a $500-million-a-year industry.

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[From The Evening Star, March 8, 1970]

MEDICAL REPORT—'PILL' WARNING TO SET A PRECEDENT

(By Judith Randal, Star Staff Writer)

Within the next two or three weeks a notice will appear in the Federal Register that will set a precedent.

Its publication will serve notice to pharmaceutical manufacturers that the Food and Drug Administration intends to insist that the 8.5 million American women who take "the pill' have access to authoritative information about what the side effects may be.

No longer will it be good enough—as it is for the thousands of other prescription drugs on the market—merely to inform the physician what transient

or lasting harm may befall his patient as a result of the medication. Instead, a leaflet written by the government in clear, simple English will be included in every package of oral contraceptives sold.

The draft text as printed in the Register will spell out the slight added risk of blood clots (pointing out that few are fatal); warn users to see their doctors if they experience such symptoms as sudden headaches, leg or chest pain and counsel that people with breast cancer, serious liver disease or unexplained vaginal bleeding should not take oral contraceptives at all.

The industry will have 30 days to "offer comments." Several months later a final version of the leaflet should begin to become as familiar to women of child-bearing age as "the pill' itself.

A recent Gallup poll reports that two-thirds of the doctors prescribing oral contraceptives make no mention to their patients of its possible side-effects. One possible result of the leaflet, then, will be to protect such doctors against possible malpractice suits.

Nevertheless, its reception by the medical profession is bound to be mixed. Some physicians probably will construe it as "interference in the private practice of medicine" and the drug companies, too, are hardly likely to be pleased.

The way in which the FDA commissioner, Dr. Charles C. Edwards, handled the announcement then must be counted as a master stroke. The last day of the hearings on oral contraceptives conducted by Sen. Gaylord Nelson, D-Wis., as chairman was, of course, a natural forum. But Edwards went beyond merely telling Nelson what in general terms his agency intended to do.

He released the provisional text of the brochure to senators and the press, thus assuring that its contents would become widely known. In this way, it should be more difficult than it otherwise would be for the industry to try to bar the leaflet or to water down the language describing the hazards of contraceptive drugs.

Despite rumblings of dissatisfaction from doctors and industry spokesmen, the FDA's general counsel said he expects no serious opposition and that drug makers will be required to include the leaflets within four months.

The point was often made at the Senate Hearings that nothing was disclosed that was not already available in scientific papers. This is perfectly true. However, what these critics failed to mention was that little of this information had been made known to the public at large.

Will the FDA's consumer leaflet be followed by others for other drugs? Perhaps. Drug side-effects increasingly are the cause of death, disability and illness and both Edwards and his FDA predecessor, Dr. Herbert L. Ley, Jr. are known to favor the principle of "informed consent" and greater consumer education.

In their view, the patient who knows what he may experience from prescription medicine is the one who will call his doctor in time to avoid becoming seriously ill. It would not be surprising, therefore, if the oral contraceptive leaflet were the beginning of a trend.

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[From The Evening Star, March 8, 1970]

## 'PILL' SALES AND STOCKS COOLED BY CONTROVERSY

(By Bailey Morris, Star Staff Writer)

As the controversy over harmful side effects of the pill has heated up, sales of oval contraceptives and stock prices of their manufacturers have cooled off.

Estimates by Wall Street analysts of the number of women who have stopped using the pill since hearings conducted by Sen. Gaylord Nelson, D-Wis., centered national attention on blood clotting and other side effects range as high as 2 million of about 8.5 million users in the United States.

The figures are speculative, but they do give substance to comments from four of the nation's eight largest pill manufacturers that soon after the Senate hearings began, the impact on oral contraceptive sales could be detected.

### BROKERS CONCERNED

This negative effect on an oral contraceptive market estimated at more than $95 million in the U.S. alone has set off a dual alarm in the financial community. It has affected both drug manufacturers worred about public impact in

dollars and cents terms and financial analysts now jittery about recommending pill stocks formerly classified as fast-moving or steady-growth purchases.

"It's too early to assess the full impact, but from reading the polls we know sales are in a slump, and in a couple of months we'll have a clear picture of drugstore prescription sales," says a spokesman for Syntex, a corporation that controls 54 percent of the oral contraceptive market.

"As soon as we find out what's happening, we'll know how to adjust our sales forecasts and promotional efforts," the spokesman said. "Privately, I think sales will slump for a while, then bounce back because too many women have had good results with the pill."

SYNTEX STOCK FALLS

His optimism was not apparent on Wall Street which last week put Syntex on the American Stock Exchange's most active list closing at 35, down 1⅛ on volume of 376,400 shares.

Syntex, the wonder stock of 1963 when its price soared from 20 to almost 100 in a few weeks, is down about 55 percent from its 1969 high.

G. D. Searle and Syntex are the companies most vulnerable to anti-pill feeling because they have the largest percentage of total sales in oral contraceptives, according to a stock broker at Paine, Webber, Jackson & Curtis. "I've seen estimates that if just one-quarter of the women now taking the pill stop, Syntex stock will decrease 30 percent a share and Searle, 15 percent a share," he said.

Another drug company included in the top eight pill producers also admitted a sharp decline in sales, but said it is not too worried.

FIRM IS CONFIDENT

A spokesman at Johnson & Johnson, which through its Ortho Pharmaceuticals Division is the only company making every kind of female contraceptive, said: "We're not just in orals and if we lose a large percentage of pill sales we'll probably pick it up in sales of other devices."

Asked if there has been increased demand for other devices, he said the response from doctors and drug stores has been so large that Ortho salesmen have been devoting most of their time to showing diaphragms and IUD's (intrauterine devices).

Wall Street reaction to the current trial of the pill has been mixed and emotional. "Have you seen any figures on how the average woman is reacting?" asked one broker—and from another: "We have to weigh the benefits-to-risk ratio." Several brokers said they think it possible pill hazard warnings may have the same effect as cigarette warnings and that confirmed users will continue to do so but younger people growing up may shy away from it.

DEMAND CHIEF QUESTION

Six to ten brokers polled said they needed to make a decision on the basic question of whether the American woman will continue to buy the pill despite the fact that the Federal Drug Administration is requiring manufacturers to warn her of excessive bleeding, clotting, arteriosclerosis and other dangers.

The consensus for the long term was that women will still buy the pill because it's cheap, convenient and 100 percent effective and newer and safer products are bound to come.

But their short term outlook is more cautious and ranges from: "We're not recommending any pill stocks," to "we're waiting to see what happens," to "We're recommending a small number of companies who have either a low percentage of oral contraceptive sales or products with low estrogen content." Estrogen is the substance largely responsible for clotting.

## APPENDIX XII

G. D. SEARLE & Co.,
*Chicago, Ill., January 30, 1963.*

AF 13-505.
NDA 10-976 (Enovid).
Enovid medication and increased blood clotting.

On January 25, 1962 an article on Enovid medication and coagulation changes along with Drs. O. Egeberg and P. A. Owren Medical Paper on "Oral Contraception and Blood Coagulability," Brit. Med. Journal, January 26, 1963, page 220 and 221, was addressed to Dr. Frances O. Kelsey by Faye Marley, a Science Service Medical Writer, Washington, D.C.

There are some deficiencies in this Science Service medical writer's summary, that should be corrected before it is released to the press, etc.

First of all—it is not the first time (The report in Brit. Med. Journal—see above) that it has been shown that Enovid medication changes blood coagulation factors towards hypercoagulability. Similar and other changes have been already known to certain investigators and published in the Proceedings of a conference: "Thromboembolic Phenomena in Women," page 154 through 157, copyright 1962, G. D. Searle & Co., Chicago, Illinois. The fact is only that the knowledge of these changes in the coagulation factors has not found its way into the American or World Medical literature nor has the existence of those findings been emphasized in the press releases, therefore they have remained unknown to most of the medical circles and public.

Secondly, in September 1962 nine cases (not six) of deaths were discussed at the meeting in Chicago and the reported number of deaths is now increased over 31, as presented in the letter to physicians by G. D. Searle & Co. of December 26, 1962.

Finally the statement made by Dr. Lee D. VanAntwerp, Searle's Assistant Medical Director is untrue (if only Faye Marley is quoting him correctly) that American scientists have not been able to find a relationship between Enovid medication and changes in the blood coagulation factors. Those changes towards hypercoagulability have been published in the above mentioned proceedings of the conference and should be known to Dr. VanAntwerp.

I recommend that these facts should be made known to the Science Services for appropriate corrections of their review on "Enovid and changes in blood coagulation system."

Further since Dr. Owren is internationally known as an expert on coagulation, I believe he should be invited to serve in our panel, which is going to evaluate the Enovid medication and coagulation changes.

ARTHUR RUSKIN, M.D.,
*Acting Medical Director, IND.*

HAIMO TREES, M.D.,
*Division of New Drugs.*

(7300)

# APPENDIX XIII

STATEMENT OF JOHN R. RAGUE, EXECUTIVE DIRECTOR, ASSOCIATION FOR VOLUNTARY STERILIZATION, INC., 14 WEST 40TH STREET, NEW YORK, N.Y., PREPARED FOR THE MONOPOLY SUBCOMMITTEE, UNITED STATES SENATE COMMITTEE ON SMALL BUSINESS, ON THE SUBJECT OF VOLUNTARY CONTRACEPTIVE STERILIZATION AS A MAJOR METHOD OF BIRTH CONTROL

Senator Nelson, distinguished members of the Committee—Thank you for this opportunity to talk with you today about voluntary sterilization as a modern method of birth control. The organization I represent, the Association for Voluntary Sterilization, Inc., conducts a program of education, research and service on voluntary sterilization as one valuable solution to family and population problems.

In a recent discussion on radio between Dr. R. J. Ederer, a professor of Economics at State University of Buffalo, and H. Curtis Wood, Jr., M.D., Medical Consultant to this Association, Dr. Wood made this statement: "There is an organization known as the Atmospheric Sciences Research Center, which is under federal grant from the National Science Foundation and the National Institutes of Health. Now, this is a fairly respectable organization, and they said—and I'm quoting them—'Ten to fifteen years from now, every man, woman and child in the hemisphere will have to wear breathing helmets to survive outdoors. Streets for the most part will be deserted. Most animals and much plant life will be killed off. In twenty years, if man survives, he will live in domed cities, and will put on semi-space suits and roam around a deserted, dead country.' We ran out of clean air six years ago, the last being in Flagstaff, Arizona. Pollution is increasing far faster than the air can cleanse itself. So this Atmospheric Sciences Research Center is predicting that in maybe ten or fifteen years from now, if a mother wants to put her baby outside in the playpen, she'll have to put a gas mask or helmet on him or something."

A recent national conference sponsored by the Association for Voluntary Sterilization, Inc., in which leaders of several major national conservation organizations participated, had the following theme: "Conservation and Voluntary Sterilization—A New Alliance for Progress". This theme was carefully chosen because we believe that voluntary sterilization could be used by a greatly increased number of Americans in order to stabilize our spiraling population growth and give anti-pollution efforts a chance to succeed.

Dr. Paul R. Ehrlich, outstanding biologist at Stanford University and author of the best-selling book, *The Population Bomb*, stated at that Conference: "The species we are trying to conserve now is *homo sapiens*, and ironically the only hope we have is by reducing the numbers of human beings on the Spaceship Earth. Voluntary sterilization should be promoted all over the world—it is one of the best means of conservation available to us."

We read today of new types of mass transportation in the planning stage, and of architects' visions of new "omni-buildings"—gigantic structures which are practically cities in themselves. All this to *accommodate* and *adjust* to an expected population increase of 100,000,000 Americans within 30 years—a 50% addition to the current population. Even Secretary of Commerce Maurice H. Stans, in a recent lecture, warned us that by the year 2,000, we Americans will be jammed together in an "ant-hill society" due to continuing migration into "megalopolises" already in formation along the east and west coasts. He recommends, among other measures, construction of new cities away from present urban concentrations. Regarding such new cities, he states candidly that to accommodate the 100,000,000 projected population increase within the next 30 years, by this approach alone, would require building a city the size of Tulsa, Oklahoma, every month until the year 2,000.

The tragedy is that nowhere in the thinking of the architects, or in Mr. Stans' attitude, can we discern anything but acceptance of this fantastic population growth. Where is the understanding of the terrible social and economic strains that it will produce in our country? Where is the determination and will not to merely accept it as inevitable but to do something effective to stop it? Where is the national commitment to programs of education, research and service that will enable us to steer clear of the "Ant-hill Society" and head off destruction of what is left of the country we love?

If we can land men on the moon, we can, with an equal commitment, reduce the population explosion in this nation to zero. Zero, in this case, means a great deal. It means the difference between a reasonably good life and a life of impossible overcrowdedness, vanished recreation space, destroyed wildlife, polluted air and water, and an endless floor of cement and asphalt from Boston to San Francisco.

I submit that in both the governmental and private sector, the intellectual and executive leadership of our nation should concentrate *now*—not 10 or 20 years from now—on the immediate necessity for reducing the U.S. population growth rate to zero, and then to implement programs of information, education, service and financial incentives which will make such stabilization possible. There is increasing acceptance among the American people of this idea. A new organization called Zero Population Growth, Inc., started hardly a year ago, has burgeoned at an astounding rate, and now has active and enthusiastic chapters in over 60 localities around the country. College students preparing exhibits and speaking programs for "Environmental Action Day", April 22, are well aware of the importance of zero population growth and its corollary, the two-child family. These students, vitally concerned with the destruction of our environment, understand the basic prerequisite of halting population growth in order to reverse this trend. They have already ordered from this Association thousands of lapel buttons saying *"Stop at Two"*, and more orders are coming in daily.

Nor has the U.S. government entirely ignored this essential point. At a recent Conference on Environment here in Washington, Secretary of Health, Education and Welfare Robert H. Finch bluntly endorsed the idea of the two-child family as a social and family ideal for all Americans. He termed over-population "a paramount concern that must be dealt with if other environmental problems are to be solved." In like vein, President Nixon's chief Science Advisor, Dr. Lee DuBridge, has called the reduction of the earth's population growth rate to zero "the first great challenge of our time." He said: "Do we need more people on the Earth? We all know the answer to that is 'No' . . . Can we reverse the urges of a billion years of evolving life? We can. We know techniques for reducing fertility. We are not fully utilizing them . . . Can we not invent a way to reduce our population growth rate to zero? Every human institution—school, university, church, family, government and international agency such as UNESCO—should set this as its prime task."

Other distinguished men of science and government have also endorsed this concept. Among them is General William H. Draper, Jr., one of the most eminent men in the population field. General Draper recently called for a zero population growth rate for the U.S., "by the end of the present century."

The Committee on Resources and Man, of the National Academy of Sciences, has also gone on record forthrightly declaring the need for zero population growth by the year 2,000.

To these statements, I can only say that the concept is correct, but the time framework is too lenient if we are to save what is left of the quality of life in our country.

To accomplish zero population growth in the U.S., the average number of children per family must be reduced from 2.8, where it is now, to 2.2. This, of course, means that most families must limit children to two.

In September of 1969, the Board of Directors of this Association unanimously passed a Resolution on the Desirability of the Two-Child Family, which states in part: "We have resolved . . . that the medical profession should make voluntary sterilization, for both men and women, more freely available to those who want no more children, regardless of the number of children they already have; and we further resolve that, to prevent over-population, American parents in general, irrespective of race, economic status, educa-

tional background, or age range, should adopt as a social and family ideal the principle of the 2-child family."

Commenting on this, Dr. Paul Ehrlich recently stated: "In view of the seriousness of runaway population growth in the United States and in the world as a whole, no informed or patriotic American couple should have more than two children. I congratulate the AVS on its resolution on the desirability of the two-child family . . ."

Let us understand clearly that overpopulation is not only one of the main roots of poverty, mental illness and crime in the U.S., but it is also the basic root of the environmental pollution that concerns all of us today. Regardless of the most energetic efforts on the part of scientists and technicians to turn back the tide of pollution, their fight will be lost unless effective population control is made a fact in the very near future. Dr. Allan J. Brooke, an ecologist at the University of Minnesota, said in a recent lecture: "If we want to save ourselves, we must stop putting our heads in the sand, and think about sterilization programs and relaxation of abortion laws. We must achieve a change in all our attitudes. We have got to change to the point where we recognize that it is now socially unacceptable for people to have more than two children." Remember, this man is an ecologist—one who understands far better than most of us what the roots of dangerous environmental pollution really are.

Listen to Dr. Wayne H. Davis, who teaches in the School of Biological Sciences at the University of Kentucky. He comments as follows: "I define as most seriously overpopulated that nation whose people by virtue of their numbers and activities are most rapidly decreasing the ability of the land to support human life. With our large population, our affluence and our technological monstrosities, the United States wins first place by a substantial margin. Let us compare the U.S. to India, for example. We have 203 million people, whereas she has 540 million on much less land. But look at the relative impact of people on the land . . . I want to introduce a new term, which I suggest be used in future discussions of human population and ecology. We should speak of our numbers in 'Indian equivalents.' An 'Indian equivalent' I define as the average number of Indian citizens required to have the same detrimental effect on the land's ability to support human life as would the average American. This value is difficult to determine, but let's take an extremely conservative working figure of 25."

Emphasizing that this figure of 25 for an "Indian equivalent" is very conservative, Dr. Davis adds that it has been suggested that a more realistic figure would be 500. He concludes, therefore, that in Indian equivalents, the population of the U.S. is *at least ½ billion*, and the rate of growth is even more alarming. We are growing at 1% a year, a rate which would double our numbers in 70 years. India is growing at 2.5%. Using the "Indian equivalent" of 25, our population growth becomes 10 times as serious as that of India. *One year's* crop of American babies can be expected to use up 25 billion pounds of beef, 200 million pounds of steel, and 9.1 billion gallons of gasoline during their collective lifetime. Even more serious are the demands on water and land for our growing population. We are destroying our land at a rate of over a million acres a year. We now have only 2.6 agriculture acres per person. By 1975, this will be cut to 2.2, the critical point for the maintainance for what we consider a decent diet. By the year 2,000—if we survive that long—the projection would be 1.2 agricultural acres per person, insufficient to feed Americans.

In assessing realistic means of bringing about the acceptance of the two-child family as a social and family ideal in America, we cannot neglect the need for private and governmental education toward a basic change in family attitudes. It has been correctly point out that regardless of available birth control technology, if couples want to have more than two children, they will do so (barring any direct and stringent government action). On the other hand, a broad acceptance of the two-child family ideal among all Americans would still be to little avail unless completely reliable birth control methods, especially sterilization, are readily available to all. As you already know, this is not now the case.

What is less generally known is that sterilization is the most reliable method of birth control known today, and is finding increasing acceptance among millions of American men and women. It is estimated that over 2 mil-

lion living Americans of childbearing age have obtained sterilization, and that each year at least another 100,000 use this method of birth control. (That figure of 100,000, by the way, we consider very conservative; it may be as high as 200,000 per year.) Not only is voluntary sterilization legal in all 50 states, but it is the most appropriate method of birth control for those couples who are sure they want no more children. Properly performed, the operation is virtually 100% reliable, is medically accepted, safe, and has no negative aftereffects, either physical or mental. The sexual harmony of couples is often enhanced as a result of complete freedom from worry about unwanted pregnancies, when the sterilization method is used.

Studies in the U.S. as well as other countries, have repeatedly shown that a significant proportion of couples *do not want any more children.* This is as true of the black community as of the white community. It also includes persons of a much younger age than might be expected. For example, a woman in her twenties who already has two children may have twenty years of fertility stretching ahead of her. She and her husband may both be sure that they want no more children, and may be urgently seeking completely reliable birth control. The AVS receives applications for help from many such women who are dissatisfied with temporary methods of birth control and fearful of some of them. It seems clear that many such women would be better off with a sterilization operation than with any other method. It remains for government and private agencies to make the operation far more readily available than at present. Every hospital, whether tax-supported or not, should have a voluntary sterilization clinic or service for both men and women. The operation should be done at low cost or no cost, both for the obvious benefit of the patient and as a sound national policy. Whatever the government spends on providing sterilizations would be returned twice over through decreased need for basic children's services such as education, avoidance of costly environmental pollution, and lower welfare costs in the Aid to Dependent Children areas. Let me emphasize, however, that we do not suggest sterilization merely as a method for the poor. On the contrary, it should be made freely available to all adult citizens, regardless of income, age, number of children or marital status.

The male operation (vasectomy) has been called by the *Journal of the American Medical Association* "safe, quick, effective and legal." It is more simple than that for the woman, and can be done in less than ½ hour in a doctor's office. Although possibly 100,000 male sterilization operations are done in the U.S. each year, probably 10 times that number would be performed if wide and favorable publicity and government encouragement in the areas of education and direct service were brought into play.

In terms of cost, sterilization for the average person is not expensive compared to other methods of birth control, when one considers the cost of the pill or the condom over a number of years, and when the lower rates of reliability of other methods are brought into the equation. In broad economic terms, there is evidence that vasectomies would cost the government considerably less than some other birth control methods promoted through government programs.

Voluntary sterilization is acceptable to Americans of all religious faiths. The files of AVS show that among people we help to obtain the operation, one or both spouses in a family are Roman Catholic in about 30% of cases. A recent Gallup Poll showed that 64% of the American people approve of voluntary sterilization for socio-economic reasons.

Contrary to common belief, the operation is reversible, in the hands of experienced surgeons, in up to 80% of cases in men and up to 65% of cases in women. Furthermore, the coming use of sperm banks promises a new means of assuring a couple that they can have a child at some future time, even though the man may be sterilized.

In relation to the Pill, and the IUD, it must be acknowledged that sterilization is more reliable than both. Furthermore, it does not interfere with the hormonal system of either the woman or the man, and is a simple operation with a very low degree of medical risk. In a sense, therefore, it can be considered not only more reliable, but less dangerous than some other commonly used methods. You already are well aware of possible dangers of the Pill. You may also know that recent studies reveal the possibility of perforation of the womb, peritonitis, or intestinal obstruction resulting from the use of the

intrauterine device. The overall reliability of the IUD as compared to sterilization is, of course, considerably lower. One estimate, published by *Time-Life Books*, and using recognized medical sources, puts it this way: The number of likely pregnancies among 100 women using sterilization for one year is .003, whereas for the same number of women using the IUD for one year, the figure is 5.

I do not say that sterilization is absolutely safer than either the Pill or the IUD, but it *is* safer in terms of absence of side-effects and avoiding disturbance of the hormonal system. Thus, on all counts of safety, effectiveness, low cost and acceptability, voluntary sterilization scores high.

We are in the last inning of a fight for survival of the human race against environmental pollution. The scientists who know most about this threat are telling us that we have only 30 to 35 more years to go. A root cause of the pollution is too many people. The time for studies, for committees, is over. What is needed now is action—action on a very large social and financial scale. On this point, John D. Rockefeller, III, has declared: "The problems of population are so great, so important, so ramified and often so immediate, that only government, supported and inspired by private initiative, can attack them on the scale required . . . It is for the citizens to convince their political leaders of the need for imaginative and courageous action."

The U.S. government should act *now*, not in 1971 or 1972, but *this year*, to make government-financed birth control services, especially voluntary sterilization, freely available to every adult in the country who wants them. The public acceptance is there; the medical know-how is there; and the need is most certainly there. The intellectual and financial commitment from the government is all that is lacking.

On behalf of the Association for Voluntary Sterilization, Inc., I urge the distinguished members of this Committee to help provide that commitment and those funds before it is too late. Thank you.

# APPENDIX XIV

## EXCERPTS FROM TESTIMONY IN THE CASE OF RAYMOND BLACK VS. G. D. SEARLE & COMPANY

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[NOTE.—This case resulted in a jury verdict for the defense. No appeal was taken.]

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VOL. III—MAY 19, 1969 (PAGES 421 THROUGH 535)

UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF INDIANA, SOUTH BEND, DIVISION

Civil No. 4082

RAYMOND BLACK, AS ADMINISTRATOR OF THE ESTATE OF ELIZABETH BLACK, PLAINTIFF

*v.*

G. D. SEARLE AND COMPANY, DEFENDANT

PROCEEDINGS RESUMED PURSUANT TO ADJOURNMENT

Before the Hon. Robert A. Grant, Judge, and a Jury, Monday, May 19, 1969, at 9:30 o'clock a.m.

Present: Arthur A. May, Esq., Thomas H. Singer, Esq., James H. Pankow, Esq., William Richmond, Esq.

Also present: Mr. Raymond Black and Dr. Victor Drill.

* * * * * * *

Victor A. Drill, M.D., called as a witness on behalf of the Defendant herein, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

By Mr. PANKOW:

Q. Would you state your name, sir?
A. Victor A. Drill.
Q. And in what capacity are you engaged in your work?
A. As a research doctor. I have an M.D. and a Ph. D. Degree.
Q. Dr. Drill, where do you live?
A. 1620 Meadow Lane, Glenview, Illinois.
Q. Where do you work, Dr. Drill?
A. The Laboratories of G. D. Searle and Company in Skokie, Illinois.
Q. And what is your title or your capacity at the G. D. Searle and Company?
A. I am Director of Biological Research for the Laboratories.
Q. How long have you been Director of Biological Research there?
A. Since December of 1953.

* * * * * * *

CROSS EXAMINATION

By Mr. SINGER (continuing):

Q. Your findings for the incidence of thrombophlebitis in users of oral contraceptives, these are the things that you have gotten together yourself from your own work?

A. These are reports, data given to us from clinical studies conducted with our product, Enovid.

We haven't gone out and treated their patients. This is the data that comes back to us.

Q. But you put all these statistics together, have you not?

A. From each of the papers. I took the number of women used in the paper, the number of cycles used, the number of cases of thrombophlebitis, tabulated them for each of the studies in the AMA paper, and arrived at that average.

Q. All right. This is a Searle and Company chart, though? This is your chart?

A. It is my chart.

Q. It is not a Government chart?

A. No, it is not.

* * * * * * *

Q. Right. And you referred, for instance, to the planned parenthood study?

A. Right.

Q. And some twelve to fourteen thousand women participated in that?

A. Yes.

Q. And they belonged to a little group called the "Twenty-five Month Club"?

A. Right.

Q. And are the statistics that you have used in your chart taken from women who belonged to the "Twenty-five Month Club"?

A. Yes.

Q. All right.

A. Part of the statistics and that value came from that.

Q. Well, fourteen—twelve to fourteen thousand people who belong to the "Twenty-five Month Club" are included in your statistics down here of oral contraceptive users?

A. Right.

Q. All right.

In other words, Doctor, that meant that a woman had to stay on the pill for twenty-five months before she would ever be included in your statistics from the planned parenthood study?

A. Right.

Q. All right.

So, then, that if a woman got sick on the way or if she died, she wouldn't be included in this "Twenty-five Month Club," would she?

A. Yes, they would; she would.

Q. Doctor, didn't you tell me that you had to be there twenty-five months before she was included?

A. You said if she died or became sick.

Q. Well, let's take "sick".

A. Yes.

Q. Suppose she got sick and went off the pill and didn't continue for twenty-five months.

A. Yes.

Q. She would not be included in that statistic?

A. That's right, if they dropped out because of nausea, if they dropped out to become pregnant; if they moved out of the neighborhood, they would not be included in the study.

Q. All right.

So, in other words, you took for your study, at least so far as the planned parenthood study was concerned, only those women healthy enough or willing enough to survive for twenty-five months, is that correct?

A. No, I wouldn't put it that way exactly.

Q. Well,—

A. These are women who do give us experience for over two years of use.

Q. Right.

A. They haven't just received the compound for one week; they have had it continuously for two years, and go beyond two years.

Q. All right.

A. So this gives us excellent use experience with a large number of women.

Q. For women who last twenty-five months, correct?

A. For who what?

Q. For women who last on the pill twenty-five months?

A. For women who continue to receive the pill for twenty-five months or longer.

Q. All right. Now, this pill, Doctor, affects some women differently than it affects others?

A. To some degree.
Q. All right.
And some women get nauseated when they start to take this pill?
A. Right.
Q. It is a sign to them that they don't feel good?
A. I would think so.
Q. And some women drop off of the pill at that sign of nausea?
A. Right.
Q. All right.
So the women who either move or want to get pregnant or whose reactions to the pill are such that they don't want to continue with it, are not included in your statistics down here of the oral contraceptive users?
A. They are not in that, but they are included in two other studies that I haven't included.
Q. We are talking about——
A. One study that I have included in there does evaluate the people who dropped out; that's the Frank and Tietze paper. They evaluated—I think they had roughly 11,000 women in the study. I would have to look it up to be sure, but they evaluated—gosh, if I had the paper I could calculate it—a higher percentage of women who dropped out; 50 to 60 per cent, because they wanted to check on the point that you are raising, why do women drop out.
Well, we know some of the reasons; some have nausea; some move; some want to get pregnant, but they canvassed well over a thousand patients in a fairly respectable percentage, 50 to 60 per cent of the drop-out. None of the drop-outs had developed thrombophlebitis, although some of them said they had dropped out because they said they were scared about getting thrombophebitis, but none had the disease.
Q. Doctor, you are talking about 50 to 60 percent of the drop-outs that they interviewed?
A. That's right, of the people that drop out.
They did a check by interviewing 50 to 60 per cent—I say; I'm trying to remember the figure. I can calculate it—just to see if the questions of the type you are raising have any validity, and they did not find any women who had dropped had developed thrombophlebitis.
Q. Now, Doctor, the accuracy of your study done here dealing with the users of oral contraceptives, of course, depends upon the reporting of the incidence of pulmonary embolism?
A. Right.
Q. And if a woman dies of pulmonary embolism and there is no autopsy, you don't know if that is the disease that caused her death?
A. I can't be certain. You go by clinical signs and symptons, obviously.
Q. Yes. But those signs could account for any number of diseases, as heart attack?
It would be symptom of a heart attack that would be almost like pulmonary embolism?
A. I agree; it would be better to have an autopsy to be sure.
Q. So unless you have an autopsy, Doctor, you don't know how many women on oral contraceptives are dying of pulmonary embolism?
You can't tell,can you?
A. Well, first off, you have to have some that are dying, and in the study of Frank and Tietze, again, with 11,000 women, there were no deaths, as I remember it, so I don't * * *.

* * * * * * *

Q. All right.
And you also know that many of the women who buy Enovid for oral contraceptives do not complete their medication?
A. Some don't.
Q. You had studies in the Seattle area where up to 75 per cent of the women went off the pill?
A. There was a certain small study. You must remember, too, that normally some of the studies were done at the ten-milligram dose which did produce more nausea.
With the five-milligram and the two and a half-milligram doses, the incidence of nausea and side effects of that type is very much less.

Q. Well, Doctor, talking about the dose response or whether or not this medication is dose-related, women on even the one-milligram pill are still getting nausea?
A. The nausea is pretty much at the Placebo level * * *.

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Dr. KISTNER.

DIRECT EXAMINATION

Q. In other words, if there is a kinking, if the uterus tips, and in so tipping backwards, the retroversion, it twists (indicating) and kinks the ligament that carries the vein, then there will be obstruction and diminished blood-flow in that vessel.
Now, Doctor, over what period of time have you worked with Enovid?
A. I have worked with Enovid since 1957.
Q. Up to the present time?
A. Up until the present, yes.
Q. And have you received literature from the Searle Company regarding Enovid?
A. Yes; I have.
Q. Insofar as that literature is concerned that you have received from the Searle Company, how does it compare with the knowledge that you have acquired from other sources?
A. Essentially the same.
Q. When you prescribe Enovid, do you have to write a prescription for it?
A. Yes.
Q. For your patients?
A. Yes.
Q. What do you tell them about Enovid when you prescribe it?
A. Well, my routine is—and I hope I may be able to give my routine—
Q. Surely.
A. (Continuing)—is to take a thorough history, to do a complete pelvic examination, a complete physical examination, including a pelvic examination, and then have the patient come back to my office, and if I feel that she should take an oral contraceptive agent, I then describe to her the method of taking the pill, and I also describe to her the most common side effects that she might experience.
In addition to this, I will usually give her one of the prepared booklets that all of the pharmaceutical houses have in order to have her better understand exactly what is going on in the physiology, in her basic physiology.
I like my patients to know what is going on and how the drug that she is taking is effective in preventing pregnancy.
Q. Now then, you are familiar with the package inserts that come with the pill?
A. Yes, I am.
Q. To what extent do you go over the information with your patients?
To what extent do you go over with your patients the information contained in the package insert?
A. I don't relate the package insert to the patient. The package insert is related to me.
Q. Let me ask you this.
When you give Enovid to your patients in the manner which you have prescribed, do you discuss with them the reports that appear in this Searle literature?
Mr. SINGER. Your Honor, I'm going to object unless this question goes to what this doctor told his patients up 'til September 18, 1965.
Mr. PANKOW. That's agreeable with me.
The COURT. I think it should be so limited.
By Mr. PANKOW (continuing):
Q. Doctor, my question is directed only to the period of time of September 18, 1965, and before that time.
A. Yes.
Q. Your routine.
A. Yes.
Q. Did you tell your patients about the reports that appeared in the Searle literature in the package insert regarding the occurrence of thromboembolic phenomena on takers of Enovid?

A. Are you asking me whether I initiated the conversation?
Q. Yes; whether you told your patients about it, yes, as a part of your routine.
A. I told her as a reply or initiation of the discussion?
Q. Well, as an initiation.
A. No, I did not.
Q. How would it come up, if it came up?
A. If the patient asked me that she had read that there were some problems with blood clotting, then I would reply to her question.

* * * * * * *

I have seen no patients who developed thromboembolic disease, including pulmonary embolism, in the over three hundred patients upon whom I have operated who received estrogen-progestin combinations prior to and subsequent to surgery.

Q. Doctor, have—can you compare for us the testing that Enovid received, from your knowledge of it, prior to the time it went on the market as an oral contraceptive?

Can you compare the testing itself with the testing received by other drugs with which you are familiar before they went on the market?

A. In my opinion, I think that the testing that Enovid and all of the other estrogen-progestin combinations received were about as extensive, if not the most extensive, that I have ever considered.

For example, when we were doing clinical investigation with estrogen alone, I would say practically the only studies that we were doing at that particular time were related to the morphology, the changes in tissue, but none of the other multiple facets of body function were studied.

Q. Now then, will you compare for us, from your knowledge, the extent of the testing and clinical study that has been done of Enovid and the other estrogens and progestins?

A. I think I indicated that I think they were, if not the most extensively studied, as extensively studied as any I have known.

Q. My last question went to before they went on the market as oral contraceptives.

A. Yes. I think I should make this clear, that my work in this field, from 1957 and continuing to 1960, was not with the use of these agents, Enovid as an oral contraceptive, but in the disease processes of endometriosis and the regulation of abnormal bleeding, and the change in the lining of the womb which might be precancerous.

My studies were not designated at all—were not designed along the studies as an oral contraceptive would offer.

Q. All right.

Were you aware of such studies going on?

A. Oh, yes.

* * * * * * *

Q. All right.

How many of the people that you see have such a regular cycle that you have described?

A. Not very many, but I am a gynecologist and I see women with menstrual disorders in general.

Q. Okay.

Doctor, as a result of your knowledge and your experience with Enovid, have you an opinion, based upon a reasonable medical certainty, as to whether there exists any causal relationship between the taking of Enovid and the occurrence of thromboembolism or pulmonary embolism?

You may answer that "yes" or "no"; you do or do not have an opinion.

A. At the present time, I do not believe that there is statistical evidence to prove that there is a definite relationship.

Mr. PANKOW. You may cross examine.

* * * * *

CROSS EXAMINATION

Q. Involves some risk.

And the risk being to a healthy female of not using an oral contraceptive, I take it, would be pregnancy?

That would be the only risk, wouldn't it?

A. No.

Q. If she didn't use the oral contraceptive?
A. No. There are other methods of contraceptives.
Q. The other methods of contraceptives such as the diaphragm involve no risk of health to the patient or to the female?
A. Not the way you stated the question. The diaphragm involves a little additional risk. Other methods don't.
Q. Does the diaphragm involve any risk, Doctor, to the female who uses it?
A. No.
Q. No risk to her life?
A. No.

* * * * * * *

Q. What are the other ones in not taking the oral contraceptive?
A. If you just drive down the street, you have an increased risk of losing your life.
If you travel in an airplane, et cetera,—there are risks to everything. The way you are phrasing the question, I can't agree.
Q. That's correct, but driving down the street in an automobile has nothing to do with an oral contraceptive, does it?
A. No, except for the comparison of risk.
Q. And flying in an airplane has nothing to do with whether or not you are taking an oral contraceptive?
It doesn't have a thing to do with it, Doctor?
A. Except for the comparison of risk, which you are comparing.
Q. And when you get in your car, Doctor, you know that there is a risk that you might have an accident?
A. That is correct. That's right.
Q. And when you get into an airplane, as you did to fly out here to South Bend and testify in this case, you knew that there was a risk——
A. (Nodding.)
Q. (Continuing)—in airplane flight?
A. That's correct, yes.
Q. But you never tell your patients that there is a risk to the use of this oral contraceptive pill?
A. No, I do not.
Q. Isn't that correct?
A. That's correct.
Q. All right.
So, while the patient knows about the risk of life, she doesn't know about the risk of this pill, at least from your treatment of your patients, isn't that correct, Doctor?
A. Yes.
Q. All right.
Now, Doctor, you wrote an article recently that was published in the *Woman's Day* magazine?
A. Yes.
Q. And did you see that article before it was published?
A. Yes.

* * * * * * *

Q. We talked about it?
A. Yes.
Q. Did you make this statement in this article: "There is some evidence of increases in both tendencies toward varicose veins and the increase of blood clotting disorders among pill users."
Is this a fair statement of what you said in that article?
A. Yes.
Q. And so, Doctor, you were talking about the risk of a blood clot?
A. I said there was some evidence.
Q. All right.
But when you were talking about the risk, you're talking about the risk that some evidence shows that oral contraceptives are related to blood clots?
A. Yes.
Q. Now, that was one of the facts that you were talking about in this article?
A. Yes.
Q. It wasn't one of the fallacies?
A. No.

Q. Isn't that correct?
A. This is one of the purported facts, yes.
Q. Well, it was one of the facts that you referred to in your article?
A. Yes.
Q. Correct?
A. Yes.
Q. And then, Doctor, you went on to finish that statement by saying:
". . . but the risks for a woman who becomes pregnant are considered greater."
A. Yes.
Q. Is that correct?
A. Right.
Q. So, again, you were balancing the risk of taking this oral contraceptive medication against the risk of pregnancy?
A. That's true.
Q. And there are certain risks to pregnancy, are there not?
A. Yes.
Q. Do you know how many women in this country die in the birth per—
A. Per year?
Q. (Continuing)—per year per million?
A. No, I don't.
Q. Well, there are some risks, though?
A. There are quite a few, yes.
Q. And the risk of blood clots?
A. Yes.
Q. And the risk of death in childbirth?
A. Yes.
Q. Now, Doctor, some of the women who die in childbirth do so because they don't have adequate prenatal care?
A. True.
Q. And adequate postnatal care?
A. True.
Q. And their babies are delivered in facilities that are not adequate?
A. Yes.
Q. And sometimes by doctors who are not well trained?
A. Yes.
Q. Is that correct?
A. Yes, these are all correct.
Q. So to the extent that the human female has good prenatal care, good postnatal care, her babies are delivered in good facilities, she is on a good diet, and she is watched by a good obstetrician, her risk of death lowers in childbirth, isn't that correct?
A. That's true.
Q. And you are aware of the fact, Doctor, that in South Bend, Indiana, we have good medical facilities, is that correct?
A. Yes.
Q. And our gynecologists here are well trained?
A. (Nodding.)
Q. Is that correct?
A. Yes.
Q. And so a woman in South Bend, Indiana, who has good medical attention, and is delivered at one of our local hospitals, is on a good diet, has good prenatal care and good postnatal care, has a much lower incident of death in childbirth than the women who do not, isn't that correct, just from statistics?
A. Yes. I would have to agree.
Q. And that would be true, wouldn't it?
A. Yes.
Q. So to the extent, Doctor, that the risk of death from childbirth goes down, as it is in South Bend, Indiana, where you have good facilities and a good doctor, the risk of a blood clot from an oral contraceptive goes up, as you balance the risks?
A. All right.
Q. Isn't that correct, Doctor?
A. It would have to be, if you diminished the other risks.
Q. All right.
Now, Doctor, I take it as part of your professional attitude toward your

patients, you do not consider it good medical practice to tell a healthy female about the risk of oral contraceptive medication?

A. That is correct.

Q. You don't——

A. Nor do I tell her about the risk of pregnancy when I see a pregnant woman, that she may die of thromboembolic disease.

Q. It doesn't make any difference, then, Doctor; she's already pregnant, isn't that correct?

A. Yes, but she may be considering pregnancy.

* * * * *

Q. All right.

So that the patient wants to become pregnant and she doesn't care what the risks are, isn't that correct?

A. No.

Q. All right.

But the oral contraceptive pill, while it involves some risk of a blood clot, is a risk that you do not discuss with your patients?

A. I do not.

Q. And the medical profession—

A. Beg your pardon. I do not initiate the discussion.

Q. All right.

If she inquires about it, you may tell her about the risk of this oral contraceptive medication?

A. I do if she inquires. I do go into length about this discussion.

Q. And you and the medical profession certainly aren't going to volunteer this information to her, correct?

A. The information has already been volunteered and not only volunteered, but has been made widely available to patients.

Q. Well, this is a prescription drug, Doctor.

Isn't the information that is contained in the package inserts and the doctors' brochures that goes only to the doctor, doesn't it?

A. You asked me if the patients or the public has been informed.

Q. Has the public been informed about the risk of the oral contraceptive medication and its relationship to blood clots?

A. Yes.

Q. Were they informed of that in 1964 and 1965?

A. I think the initial report was in 1962, and subsequent to that time, there was a good deal of publicity.

Q. All right. You are assuming, of course, that everyone has read those articles in the newspaper aren't you, if the patient is to be informed?

A. The information was available.

* * * * * * *

Q. Well, Doctor, haven't you told us that there is some evidence that an oral contraceptive pill is related to blood clots?

A. Yes.

Q. That's number one, isn't that correct?

A. There is some evidence.

Q. All right.

And if we have a woman who has an enlarged uterus that is tipped backward, then there are two more predisposing things to the development of the clot in the right ovarian vein, correct?

A. No. If I may—

Q. No.

A. If I may answer the question?

There's no doubt about the fact that the enlarged, retroverted uterus predisposes to blood clotting, venous statis, because I've seen this.

* * * * * * *

Q. Well, then, you said if your—I'm sorry. I can't remember it; that you might suggest something to them?

A. No. That was in the context with the other questioning about the suggestion of certain symptoms arising as a result of suggestion, but not as a result of surgical procedures.

Q. Oh, I'm sorry.

In other words, when we are talking about medication, if you went through all the side effects or symptoms they might have, they might—those might even be suggested to them in your—

A. This has been well documented.

Q. All right.

Doctor, in all of your experience, have you ever heard of one case where suggestion induced the formation of a blood clot? Have you ever heard of one case?

A. As diagnosed by what method?

Q. Well, Doctor, does suggestion cause blood clotting?

It doesn't, does it, Doctor?

A. Well, it might.

Q. All right.

A. It might. There's a possibility through various adrenal factors and by the excitation of some of the blood clotting mechanisms that it might.

Q. All right.

In other words, you can suggest to somebody if they take this they might get a blood clot and the very suggestion would cause that clot?

A. It very frequently causes the symptoms which are exactly the same as blood clotting, and that's the reason I asked about the method of diagnosis, because if it were not precise, the incidence would be higher.

Q. All right.

Now, Doctor, I'm not talking about symptoms; I'm talking about the existence of a clot.

Can you suggest the formation of a clot and have it occur in a human being?

A. It might be possible to do so, yes.

Q. All right.

A. But very rare.

Q. Very rare?

A. Incidents of fatal blood clots are very rare, anyway.

Q. All right.

Have you ever seen a document case where somebody made a suggestion that, "You are going to get a blood clot," and then it developed?

A. No, I have not.

Q. There's not such a case in all the medical literature, is there?

A. But you asked me if it were possible.

Q. All right.

But there has never been a case like that?

A. I know of no such cases.

* * * * * * *

Q. I'm sure he will.

A. Yes.

Q. You came out here at the request of the G. D. Searle and Company, didn't you?

A. Yes.

Q. They asked you to come and testify?

A. Yes.

Q. And you came here thinking that your testimony would be helpful to them, isn't that correct, Doctor?

A. No, it is not.

Q. All right.

Doctor, do you know Dr. Drill?

A. Yes, I do.

Q. Did you know Dr. Winter?

A. Yes.

Q. And you have worked closely with G. D. Searle and Company over the years?

A. I have worked closely with many companies.

Q. Many drug companies?

A. Many drug companies.

Q. And do these drug companies, Doctor, give you research grants?

A. Yes.

Q. And as a result of the research grants that you get from the drug companies, you write papers?

A. Yes.

Q. All right.
And part of your qualification as an expert witness here today is that you wrote a number of papers?
A. Not necessarily.
Q. Just a minute.
Many of them for drug companies?
A. The qualification is that I have had experience in this field.
Q. All right.
And part of your experience comes in working closely with drug companies, isn't that true, Doctor?
A. No, I disagree.
Q. All right. Doctor, does the Harvard Medical School receive large grants from drug companies to do studies?
A. I don't know.
Q. You don't know?
A. No, I don't.
Q. Well, you receive grants from drug companies to do studies?
A. Yes. The Boston Hospital for Women, yes.
Q. And you are being paid to come out here today and testify?
A. I assume my expenses will be paid, yes.
Mr. SINGER. Thank you very much, Doctor.
The COURT. Now, just a minute. Do you have something by way of redirect?
Mr. PANKOW. Yes.

REDIRECT EXAMINATION

By Mr. PANKOW:
Q. Doctor, will you tell us the type of work you do that you have mentioned in connection with your association with drug companies so far as——
A. Well, the type of work that I do was to obtain the medication that I desired to begin clinical * * *.

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Dr. WINTER.

CROSS EXAMINATION

By Mr. MAY (continuing):
Q. Doctor, you know the difference between a prospective study and a retrospective study, don't you?
A. Yes, sir.
Q. And a retrospective study is where you look back to see what has happened, don't you?
A. That is correct.
Q. In other words, in your studies that were conducted of the pill, you went back and you looked at people who remained on the pill for a certain period of time.
Am I correct in that?
A. I think that is just the other way around; that in our studies which we conducted, we considered them prospective studies. We followed them during the time that they had—they were on the pill from the beginning onward.
Q. Now, you had about a 75 percent dropout, didn't you, on the studies that you conducted of persons that started on the pill?
A. Well, this varied from study to study. I think that's rather high, but eventually, of course, it might reach such a figure.
Q. Pardon?
A. Eventually, if we carried it on long enough, it might reach such a figure, yes.
Q. Well, what would you say would be the dropout rate?
A. Well, as I say, it varied from study to study.
Q. Yes.
Well, I'm asking you, Doctor, if you are familiar with the memorandum that was written to you on April 1st, 1963, which says—which is written by Dr. Chien, Director of Marketing Research for Searle and Company?
A. Yes, sir.
Q. All right.
I will ask you if you do not recall this statement:
"Although we, ourselves, have not made any large-scale study of the dropout rate, a relatively small number of high volume prescription stores were audited by our personnel in order to discover—in order to follow through the refill pattern of Enovid prescriptions. We discovered that as high as 70 to 75 per cent of all patients who take Enovid do not continue its use beyond three months."

That's the initial patient dropout rate for the ten-milligram tablet.

A. Dr. Chien was referring to——

Q. Well, do you recall that statement, Doctor?

A. Yes, sir.

Q. And would this—was this part of your knowledge that you had back there in 1963?

A. Yes, sir.

Q. In any of your studies, did you ever undertake to check on the dropout of the patient, the patients that dropped out?

A. Yes, sir.

Q. What study was that?

A. All of our studies—essentially all of them, at any rate, the ones which we relied on mostly all had what we called dropout forms in which the investigator was to fill out for women who did not continue with the study.

Q. What study was that, Doctor?

A. All of them, as far as I know.

Q. All of them did?

A. I can't answer that exactly.

Q. Would that include Dr. Tyler's study in Los Angeles?

A. I think they had dropout figures, too. I would have to check to be exactly sure.

Q. All right.

A. The dropout forms.

Q. How many of these reports did you follow through on the people that dropped out, off the pill?

A. It was not possible, of course, to follow through into their private life everybody that dropped out of the pill.

What we were more concerned with is why they dropped out.

Q. And do you have any of those statistics?

A. I don't have them with me, no.

Q. You don't have those with you and you don't know how many were made or ever checked on?

A. I would have to look it up, but a large number certainly were.

Q. Yes. Was it the Tyler study?

A. The Tyler study was one.

Q. And they checked on the dropouts?

A. Again, they checked as nearly as was possible to check out why they dropped out.

Again, we didn't follow them on for months or years after they had left the study.

Q. Now, Doctor, isn't it true that the basis of this statistical data which you relied upon which gave you this feeling of security depended upon the reporting of these cases to Searle and Company by the doctors?

A. Yes, sir.

Q. Isn't it also true, Doctor, that there are probably a great many cases where people may die of thromboembolic diseases or pulmonary embolisms that are never reported to Searle and Company by users of the pill?

A. That's possible, but——

Q. All right.

Doctor, when did you first become aware of the death of Elizabeth Black?

A. Well, I can't answer that exactly.

* * * * * * *

Q. Doctor, isn't it true that back in 1963 requests were made to the manufacturers of Enovid, G. D. Searle Drug Company, that they conduct a prospective study on the use of Enovid as an oral contraceptive?

A. I don't remember any formal request of that sort.

Of course, this was one of the possibilities that had been discussed, and the possibility was considered, yes, sir.

Q. Well now, wasn't the suggestion made to them by the Wright Committee?

A. It was suggested that such a study be conducted, yes, sir.

Q. All right.

And wasn't it also suggested in the Chicago meeting of 1962?

A. I'm sorry.

Q. Pardon?

A. I didn't realize you had stopped.

Yes, this was one of the suggestions that came out of that meeting.

Q. All right.

Were you at that meeting in Chicago?

A. Yes, sir.

Q. Doctor, I will ask you, at this meeting, and I'm reading from Defendant's Exhibit Q—this statement was not made by Dr. Mitchell at the meeting:

"Dr. MITCHELL. Could I come back to this?

"As you have referred to anticoagulants, the reason why I am so unhappy about Dr. Tietze's study is that I had the privilege of serving on the Medical Research Council study group on long-term anti-coagulant therapy, and I have seen some of the difficulties that arise. Dr. Tietze makes the point that the answer is wanted two or three months before yesterday. Is it better to get a real answer from a well-planned prospective study taking three years, even though it costs two and a half million dollars, than a rapid answer from not such a well-planned retrospective study, costing much less? Which is going to give the answer?

"Surely it is the right answer we want, not the quickest or the cheapest or the most convenient."

A. I don't remember the exact words, but I'm willing to accept the fact that he did say it just that way.

Q. Well, do you have any question about that statement?

A. No, sir.

Q. I will hand you Defendant's Exhibit Q. Doctor, and ask you if those words do not appear in the first paragraph on page 66?

(Defendant's Exhibit Q handed to witness.)

By the WITNESS:

A. Yes, sir. This is as read.

By Mr. MAY (Continuing):

Q. Did you ever obtain any requests of Dr. Sise or any recommendation from a Dr. Sise about the best way to tell about this thing would be a prospective study?

A. I don't remember exactly that, but I think everyone agrees that this would be the best way to carry out such a study.

Q. All right.

And you never carried on a prospective study, as requested by these gentlemen, did you?

A. No, sir.

Q. I notice in Dr. Mitchell's statements he said the cost would be two million dollars.

Would this be an accurate estimate in your opinion as to the cost of this prospective study?

A. I really have no way of knowing, but I think it would be probably on the meager side.

I think probably it would cost more than that.

Q. Well, at that time, during 1963 and 1962, '64, '65, even, G. D. Searle and Company had money to spend for a prospective study of this type?

A. Yes, sir.

Q. But they never spent it?

A. Not for that reason, though, no, sir.

Q. All right. Okay.

Doctor, are you familiar with the recommendations of the Wright Committee or the Ad Hoc Committee that was formed in 19—rendered in 1963?

A. I read them.

Q. Okay. I will ask you if this was not one of the recommendations:

"Any firm reliance on the risks as calculated is tempered by the assumptions made. This Committee recommends that a carefully planned and controlled prospective study be initiated with the objective of obtaining more conclusive data regarding the incidence of thromboembolism and death from such conditions in both untreated females and those under treatment of this among the pertinent age groups."

Do you recall that?

A. Yes, sir.

Q. Did G. D. Searle Company conduct such a study after this recommendation was made?

A. We discussed it at great length, but no, we did not.

Q. Okay.

In any of your brochures, "Dear Doctor" letters that were sent out, was there any mention made about the request for these prospective studies?

A. Not that I remember.

Q. Was there any mention made about the validity of the statistical studies that you had already communicated or that you had already acquired?

A. Well, I can't remember the exact wording. I don't think that we ever made the statement that these were 100 percent accurate.

Q. Yes. Well, they were far from 100 percent accurate, weren't they?

A. (No audible response.)

Q. They were far from that, weren't they?

A. I don't think we can say that. They were the best we could do.

Q. All right.

Now, you say this, Doctor. Do you recognize this statement?

This was made during the year 1962.

"We have very little data. As I have said, I have thought we might organize the meeting along some lines which may seem a little backward, but I am doing it for a reason; because almost universally when we talk to people about this possibility, the assumption is that young people in their twenties do not have thrombophlebitis and never have pulmonary embolism, and, therefore, Enovid is obviously suspect, if these conditions occur in women who are taking Enovid."

Do you recognize that statement?

A. No.

Q. Doctor, I wonder if I told you that you said that at the Cherry Hills Symposium on April 12, 1962, that that would be correct?

A. I wouldn't be at all surprised. That's exactly the way I felt.

Q. But you didn't have the data. You had very little data?

A. That's correct.

Q. So, in other words, you realized back in 1962 that your data was very little, very incomplete?

A. There was very little known by anyone in the medical profession about this particular condition at that time.

Q. Well, but back in 1962, Doctor, you were getting a tremendous amount of reports of deaths among users of Enovid of thromboembolism, weren't you?

A. Not a tremendous number, no, sir; not considering the number of people who were being——

Q. All right.

Do you remember how many deaths you had prior to 1961 from the users of Enovid before it was being used as an oral contraceptive for treatments of disease?

A. No. No, I surely don't. You are not speaking only of thromboembolism now?

Q. Pardon?

A. You are speaking of all deaths?

No, I have no way of knowing that.

Q. Do you have any recollection or knowledge, Doctor, about the number of reports of clots or deaths that were reported in users of this medication prior to its use for contraception purposes prior to 1965?

A. Yes. I have knowledge, yes. There were none that were reported to us.

Q. There were none?

A. No, sir.

Q. Wasn't there 27 incidents between 1957 and 1961?

A. Of thromboembolism?

Q. Yes.

A. Not to my knowledge.

(Pause in the proceedings.)

By Mr. MAY. (Continuing):

Q. I'm reading, Doctor, from this thick document, Defendant's Exhibit P, and I apologize for having you wait. I guess I didn't do my home work, as far as the pages went, as much as I thought I did.

You are familiar with this exhibit that formed part of your knowledge back in '62?

A. Right.

Q. And under Section 2 you have a summary of cases which were reported up to the date of this document?

A. I don't remember exactly everything that's in every page of that book, but I will accept that, yes.

Q. And I will ask you if a summary of cases reported by date of onset, 1957–1961, was 27?
A. Fatality?
Q. No. I said "cases."
A. You said "fatality."

* * * * * * *

Q. All right.
Now, the study also showed, did it not, that the rate per million of thromboembolic deaths of users of the pill was 12.1, did it not, Doctor?
A. According to their calculations.
Q. All right.
In any of the literature that you sent out following the Wright Committee report, did you include these figures in it?
A. The figures themselves?
Q. Yes.
A. I am not sure.
Q. Can you recall any at this time?
A. I just don't remember. We may have—I'm sure we referred to the Wright Committee, but I don't know whether we included the figures.
Q. All right.
Now Doctor, Searle and Company has what is known as "detail men," do they not?
A. Yes, sir.
Q. And their function is to go around and talk to doctors and discuss the products with the doctors?
A. Right.
Q. And try to familiarize themselves with it and the medical profession?
A. Right.
Q. Following the reports of these deaths from Los Angeles, which is the first ones in 1961, I believe it was, was any instruction given to these detail men?
A. Not as I remember. There was—there were, of course, more conclusions referred at that time.
Our detail men are bound by our official literature, and our official literature didn't call for any such statement.
Q. In other words, the detail men are just supposed to tell the doctors what is in your official literature?
A. Well, what we do in our promotional brochures, that sort of thing, they can elaborate on it, but they are not to—they are not supposed to go outside of what the official literature says, that's correct.

* * * * * * *

Q. Okay.
And you intended that these be given to the patient for their information on the pill?
A. If a doctor so chose, yes.
Q. Do you recall, or did you have any practice with your detail men requesting the doctors to give these booklets to their patients?
A. No. They were not told to do that.
Q. Did you ever know of any instances of them doing that?
A. No, sir.
Q. But this was intended for the information of the patient?
A. That's correct.
Q. And you knew that the patient would rely upon this in the use of the pill, didn't you?
A. These were intended for the doctor to give to the patient and for the doctor and the patient's convenience.
As the doctor gave it to the patient, she would rely upon it in the context with which he gave it to her.
Q. Yes.
And that was true of both of these——
A. Yes, sir.
Q. (Continuing)—pamphlets is it not?
A. Yes, sir.
Q. I think the last one had a calendar in it for the patient to rely upon in keeping her records of the pill?
A. That's right.

Q. So I mean the company knew that when these were given to the patient, the patient would rely upon them in the use of the pill?
A. As far as the booklets went, yes.
Q. Now, there's nothing in these booklets, Doctor, that talked about what to do if they had any chest pains, was there?
A. No, sir.
Q. Or what to do if they suddenly started breaking out in a sweat with chest pain?
A. No.
Q. Or shortness of breath?
A. No.
Q. Or other symptoms that have to do with an embolism, is there?
A. No, sir.
Q. You talk about morning sickness, don't you?
A. Right.
Q. That's not fatal, is it, Doctor, to most people?
A. No.
Q. You talk about weight gain?
A. Yes.
Q. That's not necessarily fatal, is it?
A. Not usually.
Q. I hope not.
You talk about the enlargement of the breasts. Normally, that isn't—in other words, you talk about things that have—can have no real effect upon a person's life?
A. These were the ones that were most commonly observed by patients which gave them the most trouble and which took most of the doctor's time to explain.
Q. Yes.
Well, in this booklet you say some people experience weight gain?
A. That's right.
Q. Right. Some people experience thromboembolisms, too, don't they?
A. We know that that happens, yes.
They experience a lot of other things, too, though.
Q. Doctor, why is it that you didn't put in these booklets the warnings about this potentially deadly thromboembolism?
A. If we put in every possible thing that could happen to a woman, we would have to really give a full course in medicine, and this is almost impossible to do in this short a booklet.
These were designed solely for the convenience of the doctor and the patient. They included the common things that we knew that might occur to a woman who took Enovid, and that this doctor would have to explain.
These were the symptoms which were similar to those which occurred during pregnancy and which we thought a woman would understand, but if we got into things, all sorts of reactions which women have, whether or not they are related to Enovid, this would require volumes, and we despaired of trying to break this down to a point where a lay person could understand.
We felt and still think that this is better done by the physician.
Q. You still think it's better done by the physician?
A. Yes, sir.
Q. Doctor, I will ask you if you are still putting out these information booklets for the patient, aren't you?
A. Yes, sir.
Mr. PANKOW. If it please the Court, I'm going to object.
We didn't go beyond '65 with the doctor. I think——
The COURT. Well, he's answered. I think the answer may stand.
Go ahead.
By Mr. MAY. (Continuing):
Q. Doctor, you still put out these information booklets, don't you, for the information of the patient?
A. Yes, sir, we do.
Q. And in your current literature you are instructing the patient about——
Mr. PANKOW. Wait.
By Mr. MAY (Continuing):
Q. (Continuing)—thromboembolism?
Mr. PANKOW. Wait a minute.
The COURT. Now, just a minute.

This goes to the issue of the duty of the manufacturer as of September, 1965, and the question you posed goes to that point, and that objection is sustained, and the question will not be answered.

(The following is an offer of proof outside the hearing of the Jury:)

Mr. MAY. The plaintiff makes an offer to prove that if the witness was permitted to answer the question, he would answer that in their current booklets they are informing the patients as to the symptons of thromboembolism and pulmonary embolisms and instructing the patients to report to the doctors any swellings or pains in the legs or chest pains and these things that should be reported promptly.

The plaintiff feels that this is a proper question and that that is proper evidence, because the doctor in a prior answer to a prior question said that he still believes that the symptoms—these symptoms should not be given to the patient for their information and still presently is of that belief.

(Whereupon, the following proceedings were had within the presence and hearing of the Jury:)

The COURT. The ruling of the Court stands.

Mr. MAY. This next question, Your Honor, I'm going to ask is going to the question of causation.

The COURT. All right. In that area we are not limited by the September, 1965 date.

* * * * * * *

By Mr. MAY (continuing):

Q. (Continuing)—four hundred-plus incidents of clotting and the users of Enovid, were you?

A. In the sense that we couldn't prove a negative, that is correct.

On the other hand, we could find—well,——

Q. You couldn't find one way or the other, could you?

A. Well, we couldn't find any evidence to indicate that Enovid was the cause, and we were not able to prove a negative. That is correct.

Q. And at that time, as a result of these committees and these experts that you called in, the Wright Committee advised a controlled prospective study, didn't they?

A. Yes, sir.

Q. At this meeting up in Chicago, the experts called for a controlled prospective study to give you more additional information, didn't it?

A. That's right.

Q. The World Health Report called for a controlled prospective study, did it not?

A. Yes, sir.

Q. And Searle and Company never made a controlled prospective study, did they?

A. That's correct.

Q. And this information was never reported to the physicians in the "Dear Doctor" letter, was it?

A. No, sir.

Mr. PANKOW. What information? (Pause in the proceedings.)

Mr. MAY. Mr. Pankow asked what information. I'm speaking about the information that these studies have been requested by these three committees of experts, and that you had never made such a study.

The WITNESS. That's right.

By Mr. MAY (continuing):

Q. That was not reported?

A. That's correct.

* * * * * * *

## APPENDIX XV

U.S. GOVERNMENT MEMORANDUM

MAY 11, 1960.

To: Geo. P. Larrick, Commissioner of Food and Drugs.
From: Bureau of Medicine.
Subject: Enovid Tablets—NDA 10-976.

The New Drug Branch has concluded that the evidence establishes the safety of Enovid Tablets for oral use in conception control and has issued a letter on April 22, 1960, making conditionally effective a supplemental application for this purpose. Because of the considerable general interest and possible objections from some quarters with respect to our action in clearing the drug for such use, we are furnishing the following information concerning the basis for our action.

On the basis of the original data and the presently submitted data G. D. Searle and Company have recommended that Enovid be used for contraceptive purposes at a dose level of one 10-milligram tablet daily starting from day 5 to day 25 of menstrual cycle. Because the studies did not progress beyond 3 years and in view of the lack of longer clinical experience, Enovid is proposed to be limited for use for this purpose to 2 years. This product has always been limited to prescription sale and will continue to be dispensed on prescription.

A supplement for this New Drug Application was conditionally filed on October 29, 1959. This supplement proposed the use of Enovid Tablets for conception control. The original New Drug Application was made conditionally effective May 21, 1957, and fully effective June 10, 1957. Enovid has been on the market since that time. However, it was made effective for its progestational activity and has not been labeled for conception control although we knew at the time of original submission that it does inhibit ovulation. The initially indicated progestational uses of this product were amenorrhea, primary or secondary, Metrorrhagia, menorrhagia, habitual abortion, the inadequate luteal phase as a potential cause of infertility, threatened abortion, idiopathic infertility, endometriosis, premenstrual tension, and dysmenorrhea. Because of the short-term nature of the indications it has not been used for more than 3 or 4 months at a time except in endometriosis in which condition it has been used for periods up to 10 months.

The following studies were conducted in support of this supplemental application proposing the use of Enovid for conception control.

In the initial and subsequent studies it was shown that Enovid does, in fact, prevent ovulation. In April 1956, the first study to investigate the practical usefulness of this agent to control population increases was undertaken. At present, there are 2 studies in Puerto Rico; 1 in Port-Au-Prince, Haiti, and 1 in Rio Piedras section of San Juan, Puerto Rico. The following points were and are being studied:

(1) Inhibition of ovulation over long-term cyclic administration.

On medication 2.7 pregnancies per 100 woman-years occurred. Gregory Pincus, M.D., Shrewsbury, Mass., states that the pregnancies that occurred were due to irregular tablet taking. Edward Tyler, M.D., University of California Medical School, reports 8.6 percent pregnancies (22 pregnancies in 3,082 woman-months), but some of these patients were on other progestational agents such as 17-alpha-acetoxy progesterone and 9-alpha-11-ketoprogesterone. Normally, the pregancy rate in normal woman in the reproductive phase of life under conditions of regular exposure is in the range of 75–85 per 100 women-years. Incidentally, the contraceptive efficacy of other devices under normal conditions of use ranges from 2–10 percent. Therefore, it can be assumed that the product on daily use in efficacious for this indication and if properly used better than the usual mechanical means.

(2) Effect on the menstrual cycle.

When the medication is taken in doses of 10 milligrams from day 5 to 25 as directed, the cycle length is unchanged. A condition known as breakthrough bleeding may occur despite regularity in taking the tablets (6 percent on 10 milligrams of Enovid and 18 percent on 5 milligrams of Enovid daily). Breakthrough bleeding is manifested by the appearance of bleeding sometime in the menstrual cycle other than at the usual menstrual period. The incidence is highest in the first treatment cycle and declines to lower levels by the fifth cycle. After that time, it is a rare occurrence. The amount of bleeding with menses is unchanged although Dr. John Rock of Brookline, Mass., states that after 4 or 5 successive cycles, the duration and amount of flow tends to diminish.

(3) Side effects or reactions.

Side effects such as nausea, dizziness, vomiting, headaches, and gastralgia occur in from 6.3 to 18.3 percent of the subjects in the various series. However, the side effects last only 2 to 3 weeks at the most. There were no apparent changes in weight, well-being, or libido. Any objection by the patient to the side effects, of course, would result in voluntary discontinuances of the use of the product and therefore are of no serious concern.

(4) The effect on fertility when medication stopped.

Altogether in the entire series of clinical cases, 897 women representing 801.6 women-years and 10,427 cycles have been studied. However, only 66 patients have taken Enovid for 24 cycles or more to 38 and an additional 66 women have continued medication for 12 or more cycles to 21. In one of the series in San Juan, Puerto Rico, there were 86 women on Enovid from 1–20 months; 83 percent (54) of those not using other contraceptives became pregnant after a mean exposure time of 6 months after discontinuing use of the drug. Dr. Rock did follicle counts on the ovary to be sure that the potential for production of the egg was left intact on 15 women taking Enovid for 2–20 months and found no change from normal controls.

(5) Possible malignant changes.

Robert Kistner, M.D., Harvard Medical School, administered Enovid to 7 patients; 4 with endometrial hyperplasia, 2 with endometrial carcinoma and one patient with adenocanthoma. Six of these patients were administered daily dosages from 14 to 80 days. The seventh patient with adenocanthoma received 2 other preparations, Delalutin and an estrogen antagonist in addition to Enovid. With one exception, reversal of the malignant endometrial changes occurred and a beginning or fully developed pseudodecidual endometrial response was obtained. The one exception continued to have "carcinoma in situ" remaining. The conclusion here was that "cystic and adenomatous hyperplastic glands may undergo regression and actively growing stroma may be converted into decidus by the action of potent progrestins." However, this in no way implies that this product would be of therapeutic value for malignancy of the female generative tract.

In order to obtain some additional assistance in determining safety for use of this product for this particular indication, conception control, a letter of inquiry was sent to 61 professors and associate professors of obstetrics and gynecology at the medical schools in the United States. We were pleased to receive a 100-percent response. The answers we received were as follows: 14 of the professors felt that they did not have sufficient data to reach a conclusion and said that because of lack of knowledge they did not know whether or not this product should be allowed for this indication; 26 said yes, it should be allowed for contraceptive purposes; 21 of the professors said that even though they could give no specific reason for reaching this conclusion they must say no; however, 2 of the noes were based on religious grounds, and others may have been. Some were based on cost and what was felt to be impracticality so that safety was not a factor.

We asked in our letter of inquiry 7 questions of these professors so that we could determine if there were any side effects or potential dangers of which we were not cognizant. The questions were as follows:

1. Do the side effects such as nausea and break-through bleeding proscribe the use of this product for contraception?
2. Would the fertility of women on this product be effected after the medication is stopped?
3. Is there any concern about the possible carcinogencity after longterm use?
4. Would there be any concern about premature menopause?
5. Would abortion be any higher in these women than usual?

6. Would the offspring of a previously treated mother be affected more than usual? Would congenital abnormalities be greater?

7. Do you feel that Enovid, or Enovid-like product, should be on the market for contraceptive purposes?

Most of the professors who answered no to No. 7 stated that, as far as they could tell, there were no dangerous side effects associated with the use of this product. In view of the data submitted, the brochure which limits the use of this product to 2 years and the majority of favorable answers from the professors, we have concluded the drug is safe and as indicated above have issued a letter making this supplement conditionally effective.

W. H. KESSENICH.

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*ones; business location; and effect on competition;* and (*d*) *Effects on the stability, level, volume or other aspects of employment, wages, costs, sales, prices, or other phases of economic activity.*—As described in the earlier reference "Education and the Atom," the genesis of the atomic energy program stemmed from the academic world. The early history of the atomic energy program describes the impact of institutions such as Columbia University, the University of Chicago, Iowa State University, the University of California and many others in the research and production efforts that led to the first atomic bomb. Ever since, educational institutions have carried a leading role in the total research and development efforts for military and peaceful uses of atomic energy. The present state of development of the atomic energy industry is in no small part due to this research activity and the parallel manpower productivity of the Nation's colleges and universities. The nuclear education and training program of the AEC has significantly contributed to the rapid growth of college and university nuclear education capability.

Due to the complete interrelationship between research and education and training we find it difficult to separate out in a meaningful way the specific contribution of the DNET activity to economic development as requested in your questions. We believe your basic purpose is well served by the following material on "Relationship to Employment," reproduced from "Statement of the USAEC on the Impact on Scientific and Technical Manpower of Federal Research and Development Policies."

(*d*) *Relationship to employment.*—

(*i*) *Direct and secondary impact.*—With the exception of straight employment statistics, * * * we have no quantitative data to describe the impact of our research and development dollars upon a region. We suspect, however, that professional salaries, family housing needs, and localized laboratory procurements are the main instruments through which the sponsored research and development directly affects the nearby community. Considered solely on the basis of dollar flow into a region, we have no evidence which would lead us to believe that this one phase of governmental spending is in any way a unique or more effective mechanism for stimulating local economies than the many others now in being.

There are usually some new small businesses which develop close to our installations and which owe their genesis to the AEC activity. For example, a number of activities have located at Oak Ridge and Albuquerque to take advantage of the nearby technology, people and related sources, or markets. One such firm at Oak Ridge sells science kits, taking advantage not only of proximity to the source of much of the technology but also of the technical information resources at hand. As another case in point, the far-ranging research and development activities of the Los Alamos Scientific Laboratory and the Sandia Corp. have spawned some expansion in Albuquerque of the electronic-support function.

At Hanford (Richland, Wash.), where we are attempting to foster and encourage diversification activities, several of the new contractors who are to operate Government-owned facilities have plans to establish private plants or laboratories in the area. Such new private facilities will not necessarily be related to the AEC-supported work there, but the presence of key management personnel, technical

competence, support facilities, etc., are important factors in deciding to locate such facilities at Hanford. With several successful private facilities in existence, the prospects of others being established would seem to be good.

(*ii*) *Short-term and long-term regional effects.*—Aside from the actual flow of Federal funds to support a given research or development effort, scientific-technological activities have another important influence on the economic well-being of an area and its people. The opportunities and facilities for education at all levels usually are markedly improved. Secondary education systems tend to benefit from the presence of scientific personnel in the community. They often show marked interest in establishing high standards for the school system and at times will participate in the development of curriculums in their field of specialization. If opportunities for higher education do not exist in the community, they are often established. For example, the University of Tennessee and the University of Washington now have extension programs in Oak Ridge and in Richland, Wash., respectively.

Further, the existing institutions of higher education in a region, if they are properly motivated, can benefit considerably by the presence of a sizable Federal research and development installation in the area. Cooperative programs between such institutions and AEC laboratories have already been mentioned.

One has only to look at the many new industrial concerns that have sprung up about the Harvard-MIT and Berkeley-Stanford complexes to see the effects which strong centers of education have on the economics of an area. We can identify several factors which undoubtedly have contributed to this contribution to local economic growth by educational centers. Faculty members have often been instrumental in initiating local commercial ventures which draw heavily on the scientific competence available on the campus. In addition to such personal participation in industrial development, many faculty members also serve as consultants to industry. The availability within the local community of such highly competent technical people contributes to growth of the area. Further, industry can arrange with nearby universities for extension courses and other educational opportunities for their employees. Industrial employers often make participation in such educational activities more attractive to employees by adjusting their work schedules. Such additional education leads to more scientific and technical competence, thereby further strengthening the growth potential of the complex. Thus, the gravitation of Government contracts and other enterprises to those areas which have strong centers of graduate education and research is both evident and logical.

It is also interesting to note that there is usually a rather pronounced effect upon a community's cultural facilities traceable to research and development personnel. For example, the level of interest in and support of local symphonic activity, community drama, and artistic functions in Oak Ridge, is considerably above that of other communities of comparable size.

(*iii*) *Transmission of technology within a region.*—We have very little data about the transmission of specific items of technology to the commercial interests in the same area. Probably the greatest such transmission occurs through the subcontracting process. In the case

**For New York State Industrial Commission**

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d) **Description:**

This was an action brought by the New York State Industrial Commission to deny unemployment benefits to certain individual members of the St. Regis Mohawk Tribe, including the members of the Tribal Council. The Commission denied the benefits because the individuals were receiving per diem payments for services to the Tribe. After an administrative hearing, Mr. Ross issued an order denying repayment of benefits and denying further payments. I appealed the decision on behalf of the Tribal Council to the New York State Court of Appeals, Third Appellate Division, which reversed the Commission's order and reinstated the benefits. The Appellate Court did not accept my basic argument that the State Industrial Commissioner had no jurisdiction over Indian reservations due to their unique federal status and because the Tribal Council members were cloaked with the tribal governmental authority while acting in their official capacity. However, the court decided in favor of the Tribe based on a narrow ground involving the interpretation of the statutory term "employment."

**VIII.**

1. **United States Small Business Administration, Receiver Taroco Capital Corporation, David Ruey-Chyi Chang, et al.**, Civil Action No. 94-863 (U.S. Dist. Ct. for the District of New Jersey)

2. **United States Small Business Administration Southern Orient Capital Corporation**, Civil Action No. H-95-4591 (U.S. Dist. Ct. for the Southern District of Texas, Houston Division)

3. **United States Small Business Administration Japanese American Capital Corporation**, Civil Action No. 95-5007 (U.S. Dist. Ct. for the District of New Jersey)

**BIOGRAPHICAL INFORMATION (PUBLIC)**
**Section I**
**Arthur Joseph Gajarsa**
**Page 29**

a) **Date of Representation:** 1991 to present

b) **Name of Court/Judge:**

U.S. District Court for the Southern District of Texas, Houston Division - Judge Ewing Werlein, Jr.
U.S. District Court District of New Jersey -
Judge John C. Lifland (Taroco)
Judge John W. Bissell (Japanese)

c) **Attorneys:**

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d) **Description:**

In May of 1991, I was retained by the principal shareholders of Taroco Capital Corporation ("TCC"), a small business investment corporation licensed by the Small Business Administration ("SBA") as a minority business enterprise. Although it was headquartered in New Jersey, TCC had been capitalized by the Asian community to finance economic development projects on a national basis for the Asian community. TCC had been placed in liquidation status by the SBA on the basis of certain financial regulatory violations. On February 19, 1991, the United States District Court for the District of New Jersey had granted the SBA's petition to be appointed as the Receiver for TCC.

The regulatory violations which were alleged by the SBA were questions relating to the portfolio investments which had been undertaken by TCC within the Asian community in various parts of the country. For many of these investments, TCC had invested for its own account and had also solicited the participation of several other SBA licensed lenders. When TCC was placed in receivership, it caused the SBA to initiate a review of all the TCC investment portfolios and also those of the participating lenders. Two other participating lenders retained me to represent them in the same proceedings: the Japanese American Capital Corporation ("JACC"), a small business investment corporation located in Jersey City, New Jersey, and the Southern Orient Capital Corporation ("SOCC"), a small business investment corporation located in Houston, Texas. Like TCC, both companies had been transferred to liquidation status by the SBA. The corporations retained me to negotiate with the SBA regarding allegations of regulatory non-compliance.

In February of 1994, the SBA, as receiver for TCC, filed suit against numerous officers and directors who were affiliated with TCC, JACC and SOCC. The lawsuit, filed in the United States District Court for the District of New Jersey, asserted that the defendants had breached their fiduciary duties of loyalty and care to TCC; that they were negligent; and that they had converted assets which rightfully belonged to TCC. We have filed an answer and developed a defense strategy for all of the defendants. To date, we have not been required to proceed to trial because all the parties would like to reach a negotiated settlement of these matters.

On behalf of Taroco Enterprises (a separate company from TCC), SOCC and JACC, I have preliminarily negotiated a global settlement with the SBA that encompasses the lawsuit filed in Federal Court by the SBA as receiver for TCC. A final settlement is pending. The SBA has also filed for the receivership of JACC and SOCC and we are presently negotiating on their behalf to avoid protracted litigation.

**IX.** **United States v. Zaitech Capital Corporation**, (not reported) C.A. 94-2537

a) **Date of Hearing:** July 7, 1995

b) **Name of Court/Judge:**

Federal District Court for the State of New Jersey

Judge Nicholas H. Politan

c) **Attorneys:**

**For Defendant**

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In summary, I believe that federal programs should respond quickly to local initiatives that are fully supported by federally funded programs of technical assistance organized by the states. A single federal official should be authorized to negotiate a comprehensive assistance program with state and local officials immediately upon its presentation. The form of assistance should be extremely flexible to match the unpredictable variety of local situations. The level of federal resources available for state and local use should be set at a level that best approximates the increased costs that would otherwise be passed on to energy consumers if community investments were not made.

Since these recommendations match the provisions of the bill, I heartily support it.

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Senator DOMENICI. I want to thank you, Senator Randolph, for being with us here in New Mexico. I am certain that the good Senator from West Virginia knows about the growth booms and boom-bust problems, but I think we have added a new dimension to it here today.

I think he will understand that there are probably many parts of the United States that are going to have these kinds of problems and, hopefully, we can work together to do what the Federal Government should do perhaps to supplement local government and private sector and State government for providing a decent living environment in these growth areas.

I want to thank you, Mr. Chairman, and I thank the witnesses who have appeared. It has been tremendous for New Mexico and Albuquerque to have you with us.

Senator RANDOLPH. Mr. Cook, how much has your firm expended?

Mr. COOK. $26 million.

Senator RANDOLPH. All private?

Mr. COOK. Stockholder money.

Senator RANDOLPH. Are you discouraged, encouraged, or what?

Mr. COOK. I take the fifth on that, I guess. No; we are not discouraged, yet we are still pushing. We have hopes.

Senator RANDOLPH. I want to underscore what has been indicated here today, but perhaps not stressed enough. New Mexico is first of all our States in uranium production and it exports all of it. You rank fourth in natural gas production and you export 87 percent of it. You rank fifth in the country in oil production and export 80 percent of it. You rank 10th in coal production and export 90 percent of it in the form of coal or coal-generated electricity.

You are a very unusual State.

Senator DOMENICI. Indeed.

Senator RANDOLPH. I doubt if the people of the country generally know the facts that I have just referred to. And this is the place to hold such a hearing as we had today, and I commend you for doing it, and I appreciate what the witnesses have said. Many of them with varying approaches, but all with contributions which will help us when we go back into the Senate itself.

I would like to promise those here today listeners as well as participants that this is in no way just another hearing. This hearing will be the informative base by which we can make this bill a better bill.

I am gratified that I have been permitted to work with you today, Pete. This is entirely worthwhile.

Senator DOMENICI. Thank you very much, Mr. Chairman.

The committee will stand in recess.

[Whereupon, at 1:08 p.m., the subcommittee was recessed to reconvene subject to the call of the Chair.]

MATERIAL SUBMITTED FOR THE RECORD BY MR. WELLS

City of Grants

Building Permit valuation

| | |
|---|---|
| March 1, 1977 to August 1, 1977 | $ 223,294.00 |
| Permits issued in 5 months | 179 |

Water Utility Connections

| | |
|---|---|
| 6 months ending July, 1977 | 114 |

A 10% increase

(Milan Increase 20% Past Fiscal Year)

City of Grants

| General Fund: | FY 72 | FY 77 | % Increase |
|---|---|---|---|
| Total Revenues | 526,000 | 1,433,000 | 272.4 |
| Total Expenditures | 650,000 | 1,660,000 | 255.4 |
| Property Tax | 15,000 | 24,000 | 266.7 |
| Gas Tax | 99,000 | 128,000 | 129.3 |
| Sales Tax | 261,000 | 826,000 | 316.5 |
| Utility: | | | |
| Revenue | 296,000 | 848,000 | 286.5 |
| Water and Sewer Expenditure | 259,000 | 845,000 | 326.3 |

Revenue Sharing - Grants

| | |
|---|---|
| 1973 | 250,782 |
| 1974 | 203,343 |
| 1975 | 204,839 |
| 1976 | 189,796 |
| 1977 | 197,238 |
| July, 1977 | 51,029 |



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Our applications for assistance represent an intensive local effort to timely meet the basic needs of our new residents - both from other New Mexico communities and other states attracted by the employment opportunities created by new National Energy Demands - and of our own basic community.

The principal initial need is obviously housing. Private industry will build the housing and furnish its on-site streets, utilities, at no cost to the City: And they will and are doing this now. A future tax base is thus being created.

This activity then demands its Counterpart: Water: New sources of supply, collection, storage, transmission. (the new areas furnish the distribution and future revenue source). Sewer (collectors furnished by area) interceptors and wastewater treatment plant. Streets: overloaded and hazardous residential streets carrying arterial traffic must be relieved until long-range programs under regular State Highway and Federal Aid Urban Systems can become effective - Possible only after history and statistics can form the bases for financial planning; and, of course, our Today problems have not become history, nor statistically useful, nor will they be in time to be currently valuable.

TO MEET THIS CHALLENGE, many sources have come to our assistance, but most needs are incomplete and must have immediate serious attention without further and unnecessary delay - after all, State and Local laws and the requirements of any one Federal Agency are more than adequate security - competition between them for interpretive and arbitrary acknowledgement defeats the true law as effectively as if direct violations were intentionally committed for personal gain.

WATER . Well, Collector line (well to tank) transmission line (storage to system): project initiated 1975, original HUD project

| | | | | CITY | OTHER |
|---|---|---|---|---|---|
| 1. | WELL | Unable to meet procedural requirements, paid entirely by City W&S Revenue Bond 1976 Fund; (Completed) | | 49,154.66 | |
| 2. | WELL EQUIPMENT: | Unable to obtain assistance in time, 100% City W&S Revenue Bond issue 1976 (Completed) | | 104,130.00 | |
| 3. | COLLECTOR LINE & TRANSMISSION LINE: | | 405,525.23<br>280,000.00 | | |
| | Project Total | | 685,525.23 | | |
| | | | HUD | | 150,000.00 |
| | | | EDA | | 280,000.00 |
| | | | CITY W&S R. 1976 | 78,882.00 | |
| | | | Comm.Assist(State) | | 176,643.23 |

(None of the above is in service until item three is complete)

4. WATER LINE REPLACEMENT

Main line fire and pressure loop and sizing in existing system, inadequate with housing infill older areas. critical and costly, to have been financed with funds now to be used in other high priority and matching projects.

| | | | |
|---|---|---|---|
| | CAC | | 154,589.00 |

5. WATER MASTER PLAN - Critical to proper and efficient use of funding, approved and nearing completion total 50,472.08

| | | |
|---|---|---|
| Four Corners EST | | 37,000.00 |
| CITY EST | 13,000.00 | |
| | $ 244,166.66 | $ 798,232.23 |

| STREET - TRAFFIC SAFETY, minimum immediate: | | City | Other |
|---|---|---|---|
| Nimitz - Elm - Mesa. Due to physical land barriers (lava flow, San Jose - Bluewater creek) only two access streets serve major housing areas - traffic flow and controllability are severely restricted | Project cost $223,000.00 | City: $ 34,358.00<br>NMSHD:<br>CAA: | $ 34,358.00<br>$ 154,284.00 |
| Mesa - Lobo - Roosevelt Intersection<br>Traffic Safety requirement due to major intersection, complicated by El Paso Natural Gas Co. and Gas Co. of New Mexico rights of way, local and state roads, including Nimitz - Mesa. | Project cost $165,000.00 | City $ 30,000.00<br>CAA | $ 135,000.00 |
| Anderman Crossing<br>provide additional access street, although minor, to relieve other two streets | | CAA | $ 66,000.00 |

SEWER: Lobo Canyon - Northeast Interceptor; Santa Fe Sewer Transmission I (Milan); Zuni Canyon Sewer System.

| | | | City | Other |
|---|---|---|---|---|
| 1. | Lobo - Northeast interceptor: Orginally applied for Round I EDA Emergency public works. | | | |
| | Planning target Round II: | EDA | [illegible] | 285,000.00 |
| | Project total $990,160.00 | CITY | 105,160.00 | |
| | Project key to entire NE residential overload and new housing areas. | CAC | | 600,000.00 |
| 2. | Santa Fe Transmission Sewer - Milan approved project. Delayed pending apparent admin. details with Farmers Adm.; and highway permit, the latter near resolution. CAC financing will resolve other. | Four Corners Reg. | | 308,000.00 |
| | | CAC | | 77,000.00 |
| 3. | Zuni Canyon sewer system. - Applied for HUD community Development funding of $250,000.00 maximum. Insufficient points in priority rating. Total project $270,170.00 | | | |
| | Area critical Health, high cost project due to Railroad, US 66, IS-40 and Lava Barriers | CAC | | 270,170.00 |

| | | CITY | OTHER |
|---|---|---|---|
| 4. | Santa Fe Sewer II Interceptor: Intercept transmission line from Milan Sewer System and deliver to treatment plant, also portions of Grants. Anticipated to become critical, but full information must be developed under wastewater PL9500 201 Phase I Master Study Planning Grant, which Grant is delayed at this stage due to questions (in Dallas) of estimated costs and items deemed ineligible but critical to the value of the study. If study could be financed and proceed the interceptor project may well be qualified for Federal and State EIA-EPA aid (87½%); But too late. ( 3 year estimate of priorities and planning minimum)/this project is the least critical for immediate funding and is superceded by all others submitted. | CAC | 582,910.00 |
| 5. | Wastewater requirement - 201 EIA EPA-base for all Aid. Total cost $98,523.00 approved, except for delays. CAC approval would release this project and improve funding assistance from Federal - State on all sewer requirements, now and future | FED<br>STATE<br>CAC | 50,250.00<br>8,375.00<br>39,898.00 |
| | | $ 105,160.00 | $ 2,221,603.00 |

Community Development Committee Project needs July, 1977

## PROJECT NEEDS

| | | |
|---|---|---|
| 1. Road from Lobo Canyon area across from Grants Ridge to 53 North, distance of approximately three (3) miles | HUD | State, Federal, County, Private Industry |
| 2. Ordinance requiring sidewalks and paved parking. | | Property Owners |
| 3. Rehabilitate the old water pump house on San Jose Drive. | HUD | State, Federal - 235,000 |
| 4. 2400 feet 12 inch water line on Santa Fe Avenue. 12" from High to Santa Fe on Nimits; on Santa Fe from Nimitz West Setion line of 32. Will connect with the line coming from Lobo Canyon Road via the section line. | | State, Federal - 30,000 12x2400 3% and 10% engineering |
| 5. Water well and storage tank, NE of Grants. | | 900,000 |
| 6. Water line looping, E. Grants via section line between 20 & 19; 30 & 29; and 31 & 32. | | State, County, Federal - 188,640 +13% |
| 7. Proposed 547 By-Pass. Road following same line as above - connecting Lobo Canyon Road to Santa Fe Avenue, 100 feet right-of-way - four (4) lane. | | Federal, State, County - 3,000,000 + 23% |
| 8. Recreation facility - baseball. | BOR | 1,000,000 |
| 9. Human Resource Center | BOR | lots |
| 10. Paving repairs of existing City streets. | | |
| 11. Street Rehabilitation | | |

GORDON HERKENHOFF & ASSOCIATES, INC.
302 Eighth Street, N.W.
Albuquerque, New Mexico 87102

(505) 247-0295

545-810-77

June 2, 1977

Tony Vasilakis, City Manager
City of Grants
Municipal Building
Grants, New Mexico

RE: SEWAGE FLOW FROM MILAN TO GRANTS TREATMENT PLANT

In accordance with instructions from Mr. Don Des Jardin, and based on the attached memorandum from Mr. Vance Vanderhoof, it appears that the Town of Milan has increased its sewage contribution in the last eight months by about 24.4 percent.

The following is an estimated average flow rate per eight month period from the Town of Milan.

A. For the eight month period from January 1976 through August 1976 the Town of Milan contributed sewage at the rate of 88,612 gpd. This is equivalent to 61.5 gpm of sewage flow to the Grants Sewage Treatment Plant.

B. For the eight month period from September 1976 through April 1977 the Town of Milan contributed sewage at the rate of 110,100 gpd. This is equivalent to 76.5 gpm of sewage flow to the Grants Sewage Treatment Plant. (76.5 - 61.5/61.5) 100 = 24.4 % increase.

Should further information be required, please contact this office.

ROSS E. SCHMIDT
mls
encls.

TABLE 1

TITLE Grants/Milan Population Projections and Allocations

SOURCE: Census, COG Estimates

| ED/Zone | Residential Acres | Population Capacity | Population 1970 | Population 1976 | Population 1980 | Population 1985 | Population 1990 | Population 1995 |
|---|---|---|---|---|---|---|---|---|
| MILAN - | | | | | | | | |
| 27 | 123 | 3,014 | 693 | 1,050 | 1,500 | 1,900 | 2,900 | 2,825 |
| 28 | 99 | 2,426 | 847 | 1,460 | 1,900 | 2,425 | 2,425 | 2,375 |
| 29 | 54 | 1,323 | 645 | 870 | 1,200 | 1,325 | 1,325 | 1,275 |
| G+ | 193 | 4,729 | 50 | 80 | 550 | 1,325 | 2,325 | 2,400 |
| TOTAL MILAN: | 469 | 11,492 | 2,235 | 3,460 | 5,150 | 6,975 | 8,975 | 8,875 |
| GRANTS - | | | | | | | | |
| 21 | 170 | 4,760 | 1,974 | 2,570 | 2,900 | 3,900 | 4,580 | 4,600 |
| 22 | 63 | 1,764 | 1,297 | 1,650 | 1,765 | 1,765 | 1,765 | 1,765 |
| 23 | 118 | 3,304 | 1,228 | 1,570 | 2,000 | 2,500 | 2,750 | 2,650 |
| 24 | 142 | 3,976 | 1,415 | 1,600 | 1,800 | 2,000 | 2,250 | 2,150 |
| 25 | 50 | 1,400 | 1,150 | 1,300 | 1,400 | 1,400 | 1,400 | 1,225 |
| 26 | 333 | 9,324 | 1,704 | 3,000 | 4,240 | 6,740 | 8,900 | 8,950 |
| C+ | -0- | -0- | -0- | -0- | -0- | -0- | -0- | -0- |
| TOTAL GRANTS: | 876 | 24,528 | 8,768 | 11,690 | 14,105 | 18,305 | 21,645 | 21,340 |
| PLANNING AREA - | | | | | | | | |
| A | 57 | 1,496 | 30 | 690 | 800 | 1,000 | 1,100 | 1,000 |
| B | 1,066 | 27,983 | 644 | 920 | 1,600 | 2,800 | 3,000 | 2,880 |
| C | 15 | 394 | - | - | - | 100 | 125 | 100 |
| C' | 20 | 525 | - | - | - | 150 | 200 | 175 |
| D | 683 | 17,929 | 5 | 200 | 500 | 1,700 | 2,500 | 2,350 |
| E | 401 | 10,526 | 10 | 750 | 1,380 | 3,380 | 5,380 | 5,080 |
| E' | 176 | 4,620 | 10 | 20 | 50 | 150 | 175 | 125 |
| F | 56 | 1,470 | - | 260 | 370 | 470 | 500 | 475 |
| F' | 351 | 9,214 | - | 20 | 120 | 220 | 300 | 250 |
| G | 2,520 | 66,150 | 21 | 450 | 550 | 1,100 | 2,500 | 2,300 |
| G' | 262 | 6,878 | 40 | 325 | 425 | 1,000 | 1,500 | 1,400 |
| H | 254 | 6,668 | - | 15 | 50 | 150 | 200 | 150 |
| TOTAL PLANNING AREA | 5,861 | 153,853 | 760 | 3,650 | 5,845 | 12,220 | 17,480 | 16,285 |
| TOTALS: | | | | | | | | |
| MILAN | 469 | 11,492 | 2,235 | 3,460 | 5,150 | 6,975 | 8,975 | 8,875 |
| GRANTS | 876 | 24,528 | 8,768 | 11,690 | 14,105 | 18,305 | 21,645 | 21,340 |
| PLANNING AREA: | 5,861 | 153,853 | 760 | 3,650 | 5,845 | 12,220 | 17,480 | 16,285 |
| GRAND TOTAL: | 7,206 | 189,873 | 11,763 | 18,800 | 25,100 | 37,500 | 48,100 | 46,500 |

TABLE 3
GRANTS/MILAN PLANNING AREA
EMPLOYMENT AND POPULATION PROJECTIONS[1]
1976 - 1995

| | 1970[2] | 1976 | 1980 | 1985 | 1990 | 1995 |
|---|---|---|---|---|---|---|
| TOTAL EMPLOYMENT | 3,800 | 6,675 | 9,450 | 16,175 | 20,800 | 20,450 |
| MINING EMPLOYMENT | 1,921 | 3,300 | 4,875 | 8,425 | 10,700 | 10,100 |
| POPULATION | 11,763 | 18,800 | 25,100 | 37,500 | 48,100 | 46,500 |

1) Population Estimates and Projection Rounded to Nearest 100; Employment Rounded to Nearest 25.

2) Source: 1970 Census, Adjusted

Mining employment by residence for the Grants/Milan area was based upon establishment data for areas within the San Juan Basin (Northwest New Mexico), which in turn was derived from state $U_3O_8$ production and employment forecasts. The allocation ratios were calculated using information from the U.S. Energy Research and Development Administration (ESC), the State Inspector of Mines, and mining companies.

Projected mining employment was combined with forecasts for the relatively small manufacturing sector to yield total basic employment. Nonbasic-to-basic ratios were adjusted over time to reflect the degree of change in basic employment scale of the economy, and other factors.

Total employment was used to calculate the population in each time period, with the population-to-employment (dependency") ratios taken from the U.S. Water Resource Council's OBERS Projections: Regional Activity in the U.S., which includes data on the State of New Mexico. The New Mexico ratios were modified slightly to reflect the varying impacts

# THE GOVERNOR'S ENERGY IMPACT TASK FORCE

A PRELIMINARY REPORT

# MANAGING THE BOOM
# IN
# NORTHWEST NEW MEXICO

PREPARED BY

EITF STAFF

FUNDED BY EDA

UNDER GRANT NO. 08-09-0L784

FEBRUARY, 1977

2. Uranium

a. History

"It is possible that Indians in Northwest New Mexico used uranium minerals as a pigment for hundreds of years. However, the discovery of uranium in New Mexico is credited to a Navajo sheepherder named Paddy Martinez. Martinez was always on the alert for bits of brightly colored or unusual rock, and one day in 1950 he picked up a uranium bearing rock in the vicinity of Haystack Mesa near Grants. When he took the rock to a friend in Grants to determine what the rock was, the ore was discovered to contain uranium. That chance discovery brought Paddy Martinez a lifetime stipend from the Santa Fe Railway, which owned land in the area, and it led to major exploration programs that revealed the most prolific uranium production district in the world.

The first production of uranium was shipped to the Atomic Energy Commission's buying station at Monticello, Utah. Later exploration and development of uranium outcrops brought about the establishment of an AEC buying station and limestone treatment mill built by the Anaconda Company at Bluewater in 1952. In 1951, a major dis-

covery led to the development of the Jackpile Mine, the world's largest open pit uranium mine. In 1955, the discovery of enormous uranium deposits near Ambrosia Lake was made. In the same year, a second mill was completed by Kerr-McGee to process the new ore and a boom was on.

Early production was supported almost entirely by the AEC at the supported prices. Production reached record levels in 1960, but suddenly dropped when the AEC announced a phasing out of its purchases.

Grants/Milan has, since 1950, been influenced by uranium production activities. An analysis of employment by place of residence reveals that in 1970, 49% of the residents of the Grants Census County Division were employed by the mining industry. Wholesale and retail trade contribute the next highest employment, identifying Grants/Milan as a trade center for Western Valencia County and as a service center for Interstate 40 travelers. Community supportive services are the third major employer."

"Total two year expansion = 2345 to 2460 employees

Total five year expansion = 3078 to 3348 employees

*Facility and employees expansion to be operational within two years.

**Facility and employee expansion to be operational within five years.

[1]ERB Questionnaries, 1976

[2]State Planning Office Report, "Grants Mineral Belt", August, 1976

[3]Navajo Nation Report, 1976

EMPLOYED PERSONS 16 YEARS OLD AND OVER - GRANTS CCD*

| Classification by Industry | Percent |
|---|---|
| Agriculture, Forestry and Fisheries | 1 |
| Mining | 49 |
| Construction | 3 |
| Manufacturing | 2 |
| Transportation, Communication, Utilities | 4 |
| Wholesale and Retail Trade | 17 |
| Finance, Insurance, Real Estate | 1 |
| Business and Repair Services | 2 |
| Personal Services | 4 |
| Entertainment, Recreation | 1 |
| Professional and Related Services | 13 |
| Public Administration | 3 |
| TOTAL | 100 |

SOURCE: 1970 Census of Population and Housing
*Census County Division

Grants/Milan

"The occupancy rates in both Grants and Milan are near 100%, with only the most dilapidated homes vacant. The lack of available units and the high construction costs, have contributed to the significant increase in mobile homes in the Grants/Milan area.

The cost of housing construction in the Grants/Milan area generally ranges from $20 - $26 per square foot, which is comparable to prices in Albuquerque. Rental charges may be as high as $250 - $300 per month for either conventional housing or mobile homes. At present, some 100 prefab homes are being constructed in Milan for sale at approximately $25,000 average price. Also at this time, about 80 multi-family units are being built in Grants."

City of Grants

a. "A serious housing shortage in Grants already exists. As a result, mobile homes have become more common place in the community, over 1000 making up 30% of the housing units. Rehabilitating substandard housing is a number one priority (no cost estimate).

b. Construction of rental housing is another priority (no cost estimate)."

C. Sewer, Wastewater Systems, and Storm Drainage

The sewer systems in Northwest New Mexico share many of the characteristics of the water systems in that all communities have serious problems. The majority of these systems are outdated and were constructed for smaller more centralized communities. The rapid increase in population has initially affected the communities by overflow of sewage into the street, substandard cesspool systems and leaking sewage ponds, all of which create serious health hazards.

Wastewater treatment plants in many communities cannot process the volumes of sewage that are presently transmitted through existing lines. Many improvements are needed. One problem is that of lead time planning. These projects need to be started now before the additional impact occurs."

IV. SUMMARY & CONCLUSIONS

"New Mexico is entering into an era of rapid energy resource development. Since the recent energy crisis, our nation's leaders have been debating methods for developing adequate energy supplies. Because of the recent natural gas shortages in the Northeast and Midwest, we can expect some decisions to be made in the very near future as to how Project Independence will be achieved. New Mexico will play a key role in these decisions. With 43% of the nation's uranium production and its large reserves of low sulphur

coal, New Mexico will become one of the nation's largest exporter of energy.

While creating many economic benefits for the citizens of the state, this energy development will also cause some social and economic hardships. The purpose of this report has been to determine what those socio-economic effects will be. In order to do this, the Governor's Energy Impact Task Force has first of all summarized the imminent demands that will be placed on New Mexico's resources, based on the most current available material. From this review, it is estimated that the coal production in the state will increase four-fold by 1985. The uranium ore production will increase narly five-fold by 1985. One coal gasification plant can be expected to be completed and numerous experimental geothermal wells will be tapped.

The next step in the study was to determine what these developments mean in terms of additional jobs being created. The employment icnrease, due to coal and uranium development, will reach 8,500 by 1981 and up to 18,000 by 1985.

Some of these workers will be absorbed from the local labor pool; however, many will come from outside the area, either from other parts of the state, or from out-of-state. After reviewing a multitude of projections based on similar development in other Rocky Mountain States, the staff derived the following ratios to determine how many new people will actually be coming into a coal or uranium development area; every mineral extraction job will create 2.7 jobs in the service sector, 50% of all jobs will be filled by influx, 80% will bring in families with an average of 3.3 household members.

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This means that we can expect a total population influx of 21,000 people into the northwest communities by 1981 or 72,000 people by 1985. This averages out to an annual growth rate for the area of 5%, far above our state average of 1%, and in some areas like West Valencia County, the growth rate may reach as high as 8%.

This rapid influx of people will place serious burdens on local community facilities. A major part of this study was to catalog the existing community infrastructure and determine, first of all, if it is adequately serving the present population and secondly, if it will service the expected population. Without fail, the researchers found a serious shortfall in present services in relation to the demand. Schools are overcrowded, with emergency portable classrooms handling the crunch for this year, but no plans for the future. Law systems are overwhelmed, with a low officer ration yet a high crime rate. Housing is inadequate, with vast capital improvements needed. Sewage systems are substandard or inadequate with a massive need of expansion and rehabilitation. Health and Social Services are swamped, with one of the lowest doctor ratios in the state and yet the highest demand of need.

This shortfall in present services is due to two reasons. First, the area has a high level of need. The communities have already experienced rapid growth impacts in the past and have yet to catch up with the first boom. Secondly, they are mostly rural, isolated, and have inadequate planning or funding resources to cope with the demand. These problems become especially critically when we talk about the future requirements to serve the anticipated population.

The Task Force staff and Council of Governments spent the last six

months researching and evaluating specific project needs that the communities have identified as being necessary to meet the present problem, and to cope with the boom. The capital outlay requirements over the next five years for these projects total 119 million, if we consider just local funding requirements, and up to 242 million, if we consider state and federal highways and education. For example, this figure includes $40 million for water systems, $40 million for streets and roads, $27 million for sewer, and $8 million for social services. However, money is not the only solution.

PROJECTED FACILITY REQUIREMENTS: for the region from the various planning bodies in Northwest New Mexico.
These figures are approx. and only include projections for the next 2-5 years.

($1000's)

| | MCK. COUNTY | SAN JUAN COUNTY | W. VALENCIA | SANDOVAL COUNTY | NW QUADRANT |
|---|---|---|---|---|---|
| WATER..... | 4185 | 18072 | 7653 | 405 | 30315 |
| SEWAGE, WATERWASTE, & STORM DRAINAGE.. | 2570 | 5141 | 7138 | 8224 | 23073 |
| SOLID WASTE..... | 300 | 250 | | 75 | 625 |
| HEALTH & SOCIAL SERVICES..... | 1215 | 5650 | | | 6865 |
| TRANSPORTATION (Local)..... | 22350 | 4269 | 4050 | 981 | 31650 |
| FIRE PROTECTION... | 710 | 550 | 92 | 50 | 1402 |
| PUBLIC SAFETY..... | 720 | 5000 | | | 11720 |
| RECREATION..... | 2230 | 4509 | 844 | 263 | 7846 |
| OTHER (MUNICIPAL BUILD.).. | | 4841 | 333 | 425 | 5599 |
| SUBTOTAL..... | | | | | 119095 |
| U. S. HI-WAYS & ST. HI-WAYS..... | | | | | 85160* |
| EDUCATION..... | | | | | 40000** |

| | | | | |
|---|---|---|---|---|
| TOTALS..... | 40280 | 48282 | 20110 | 10423 |
| | | | GRAND TOTALS | 244,255 |

* State Highway Department (I-40 Costs not Included)

** DFA Public School Finance

In order to avoid the building of sporadic mobile home units, concerted local and regional planning must be done. Planning capabilities of the Northwest area need to be augmented to perform this job. Additional technical assistance and cooperation of state and federal planning authorities is also needed to cope with zoning problems, land use, title clearance, and financing problems. Possible incentives that should be investigated and utilized are subsidized construction funds, increased federal funding, tax credits, low interest loans, and rent subsidies.

Planning is also needed in the area of health and medical programs. Shortages should be addressed by new and innovative programs. Environmental health problems need more attention. The areas should receive greater priority in the competition for federal and state funds.

Emergency funds should continue to be allocated from the state to impacted areas, but more long term solutions need to be explored. School finance formulas should be altered to accommodate the sudden influx of students so as not to penalize individual districts that become overwhelmed. Skill training programs should be set up for local residents in order to gain the skills the expanding industry needs. Higher education and adult night classes need to be expanded.

Since there is a long lead time needed for construction of sewer, water, and other utilities, forecasting capabilities in boomtown communities need improvement, in order to project with some accuracy the timetable for initial construction. Public and private utilities should be encouraged and required to develop implementation schedules, which make these utilities available in an orderly manner.

Adequate fire and law protection services should be available to the communities and surrounding areas. This will require state and county support. The definition of functions should be made to clearly establish jurisdictional responsibility between city, county, state and tribal officials.

In boomtown conditions, social service agencies will experience dramatic increases in caseload, especially in child abuse and drug abuse. Increases in mental health counseling, public assistance and crisis intervention should be planned for immediately.

Environmental concerns are also present in the northwest communities. Local and state agencies should focus their attention and increase their capacities to monitor the potential environmental impacts of developments.

Finally, local government financing capabilities need to be increased to cope with boomtown problems. One of the major conclusions of this report is that the cities and counties cannot pay for the construction of the needed facilities out of their own revenues. The increase in property tax does not come until the boom is on its way. There is a lag of up to five years between the time the people come needing facilities and the time that tax revenues are flowing into the communities to pay for these services. Even if the cities were allowed to raise their mill levies and general obligation bond limits beyond the constitutional limit, their financial ability to pay back the debts would be seriously constrained by this lag time and boomtown phenomena."

# THE GRANTS URANIUM BELT

A REPORT TO THE
STATE PLANNING OFFICER

NEW MEXICO STATE PLANNING OFFICE
DIVISION OF NATURAL RESOURCES

CAPITAL OUTLAY FOR URANIUM BELT BY 1985

| Service | Low Estimate | High Estimate |
|---|---|---|
| Water | $ 4,893,184 | $14,118,976 |
| Sewer | 4,160,816 | 12,005,774 |
| Solid Waste | 80,480 | 232,220 |
| Fire | 708,224 | 2,043,536 |
| Library | 370,208 | 1,068,212 |
| Recreation | 1,046,240 | 3,018,860 |
| Health[1] | 434,592 | 1,253,988 |
| Police | 482,880 | 1,393,320 |
| Streets and Roads | 5,875,040 | 16,952,060 |
| Local Government | 345,064 | 995,546 |
| Schools | 6,438,400 | 18,577,600 |
| TOTAL | $24,836,128 | $71,663,092 |

GRANTS/MILAN CAPITAL OUTLAY-TWO YEAR POPULATION GROWTH

| Service | Low Estimate | High Estimate |
|---|---|---|
| Water | $1,055,488 | $2,709,856 |
| Sewer | 897,512 | 2,304,269 |
| Solid Waste | 17,360 | 44,570 |
| Fire | 152,768 | 392,216 |
| Library | 79,856 | 205,022 |
| Recreation | 225,680 | 579,410 |
| Police | 104,160 | 267,420 |
| Local Streets (@ $265/Capita) | 460,040 | 1,181,105 |
| Local Government | 74,648 | 191,651 |
| TOTAL | $3,067,512 | $7,875,519 |

GRANTS/MILAN CAPITAL OUTLAY-FIVE YEAR POPULATION GROWTH

| Service | Low Estimate | High Estimate |
|---|---|---|
| Water | $1,632,480 | $ 4,190,336 |
| Sewer | 1,388,145 | 3,563,164 |
| Solid Waste | 26,850 | 68,920 |
| Fire | 235,290 | 605,496 |
| Library | 123,510 | 317,032 |
| Recreation | 349,050 | 895,960 |
| Police | 161,100 | 413,520 |
| Local Streets (@ $265/Capita) | 711,525 | 1,826,380 |
| Local Government | 115,455 | 296,356 |
| TOTAL | $4,744,395 | $12,178,164 |

CAPITAL OUTLAY FOR GRANTS/MILAN BY 1985

| Service | Low Estimate | High Estimate |
|---|---|---|
| Water | $2,740,256 | $ 7,906,432 |
| Sewer | 2,330,119 | 6,723,068 |
| Solid Waste | 45,070 | 130,040 |
| Fire | 396,616 | 1,144,352 |
| Library | 207,322 | 598,134 |
| Recreation | 585,910 | 1,690,520 |
| Police | 270,420 | 780,240 |
| Local Streets (@ $265/Capita) | 1,194,355 | 3,446,060 |
| Local Government | 193,801 | 559,172 |
| TOTAL | $7,963,869 | $22,978,068 |

From the above figures, capital outlay in the Uranium Belt varies from a low estimate of $9,568,886 in two years to a high of $71,663,092 in 1985. Capital outlay for Grants and Milan ranges from $3,067,512 in two years to $22,978,068 by 1985. This is based on a required capital outlay of $3,086 per capita in the Uranium Belt and $1,767 per capita in Grants and Milan.

Present operating expenses in Grants and Milan are $150 and $153 per capita per year. This is compared to an average of $221 per capita per year for communities in the Four Corners Region.[2] With more growth and new sources of revenue, the operating costs for Grants and Milan could be expected to approach the regional average.

The later chapter on revenues will discuss the ability or inability of local governments to meet the costs of the growth generated by the uranium industry.

Thus, the local funds that might be available would be about $280,000 in general obligation bonds for Grants, $65,000 in general obligation bonds for Milan, and $500,000 in revenue bonds for Grants. (Done) Any further revenue bond capacity would require study by a bond consultant. General obligation bonding capacity also should

increase with growth.

Grants/Milan could raise about $845,000 through bonds if the existing citizens are willing to pay higher taxes. This compared to the estimated capital outlay required in two years indicates a defecit of $2,222,512 - $7,030,519. If we assume the communities to be competitive for state and federal water, sewer, and recreation grants, capital outlay could be further reduced to $746,605 - $3,319650.[3] Other federal grant money might be available from the Economic Development Administration, Farmers Home Administration or the Four Corners Regional Commission. In any case, it appears unlikely that Grants/Milan will be able to entirely support the uranium impact either by bonding or by competition for grant funds. This leaves the state as the next potential source of funding available to the communities through taxation of the uranium industry.

These rates are about 15 mills over the state average (about 42.2 from 1970-1975) and about six mills over the median rate paid in Grants and Milan over the past six years.[2] It would probably take some salesmanship to carry a general obligation bond issue in Grants and Milan. The following consideration might help sell the bond issue to the voters: 1) the prospect of using increased revenues do not increase proportionally from the growth instead of property taxes to meet some of the obligation; 2) about half of the present obligation is expiring in 1978 and almost all of it will be paid off in 1980; 3) as growth brings in more property owners and higher valuation, tax rates would diminish or else bonds would be paid off more rapidly.

According to Grants Mayor E. M. Well, Grants has a $500,000 water and sewer revenue bonding capacity as estimated in the fall of 1975. Issued $500,000 Jr. lien to Farmers Home Administration, 1976.

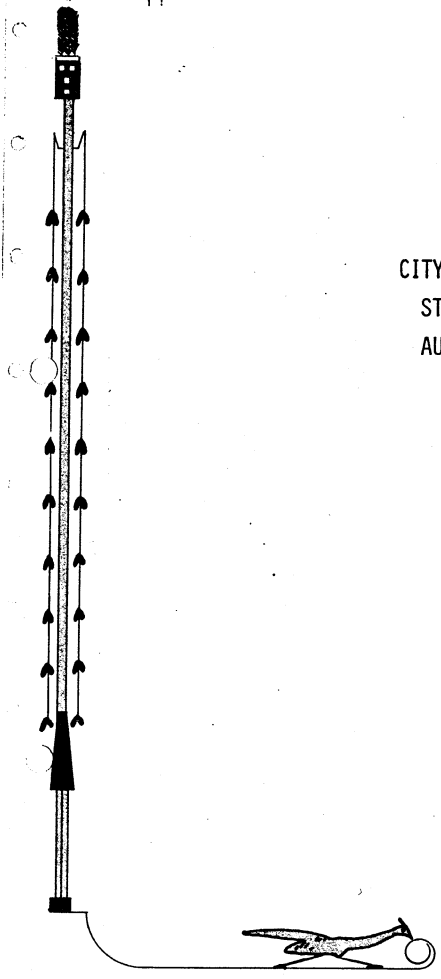
Although it would seem reasonable to assume that present and future residents of Grants/Milan could pay for the operation and maintenance of expanded public facilities, once they are built, there are several problems that go beyond the ability of local communities to deal with them:

1. In order for growth to occur in such a way as not to cause a deterioration of quality of life for existing residents to impose unnecessary hardship on newcomers, housing and necessary public facilities should be available as new people arrive. A local community cannot come up with large capital outlays before its taxing capacity has been expanded by new people and new building.
2. The large equipment and improvement investments and the production of the uranium companies are located outside Grants/Milan and not available to these communities as a source of revenue. Though it would seem reasonable that impact costs that are a result of uranium activity should be borne by that industry and not by the existing residents of Grants/Milan, the industry is beyond the authority of the communities to tax that activity.
3. Communities dependent on mineral development are traditionally faced with boom and bust situations. Grants grew from 2,250 people in 1950 to 10,274 people in 1960 and then went down to 8,768 by 1970. Present national energy policy seems to call for a large dependence on nuclear power, but environmental concern could change this drastically. If the nuclear industry does develop as the Energy Research and Development Administration predicts, it is likely that the uranium in the Grants Belt will be exhausted by the year 2000. State action could help to mitigate the effects upon Grants/Milan of extreme fluctuations in uranium development.

MATERIAL SUBMITTED FOR THE RECORD BY MR. WEBB

UTAH COLO.
ARIZ. N.M.

CITY OF FARMINGTON, NEW MEXICO



# CITY OF FARMINGTON
## STATUS REPORT
## AUGUST 25, 1977

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PREPARED BY:
The City of Farmington
PLANNING DEPARTMENT

Farmington, New Mexico

## INTRODUCTION

Since the early 1970's the northwest part of New Mexico has been identified to receive anticipated major energy resource development impacts. The City of Farmington is the major trade and financial center of this area. The City is currently suffering from its inability to adequately meet the needs generated by these on-going developments. This report briefy documents the City's dilemma and immediate need for assistance.

Enclosed is a summary of the City's needs and resources. The document identifies the location of the City of Farmington, present and anticipated economic developments, constraints, projected municipal needs for the short run and long run periods. Also included is a summary of projects that the City must undertake in order to cope with the present population and anticipated growth.

A brief synopsis of the City's bond issues and resources is reviewed. Also enclosed is the status of the City's present attempts to acquire State and Federal funds.

CITY OF FARMINGTON

I. City of Farmington

The City of Farmington is situated in the northwest portion of the State of New Mexico. The City is the center of population of San Juan County. The municipality is located in the northcentral part of the county, at the junctions of U. S. Highways 550 and 64. In addition to these major highways, New Mexico 371 extends south from Farmington and presently links the City with the Navajo Irrigation Project. This highway will also serve as the major route between the City and the proposed gasification projects.

Table No. 1 summarizes population forecasts which were included in the City's Water Master Plan of 1974. The high projection of 35,790 for 1977 approximates the current population estimate. This represents an increase of better than 60 percent over the 1970 population of 21,979.

Graph No. 1 depicts population projections for both Farmington and San Juan County, to the year 1985.

II. Economic Development

San Juan County is endowed with an abundance of natural resources which are, at present, in the early stages of economic development, and ultimately will result in a rapid growth of jobs and population. The evidence points out that the projected population growth will be a long-lasting versus a temporary surge.

The economy of San Juan County is well diversified and depends mainly on trade, government construction, oil and gas production, electric power generation and agriculture.

TABLE 1
SUMMARY OF FARMINGTON POPULATION FORECASTS

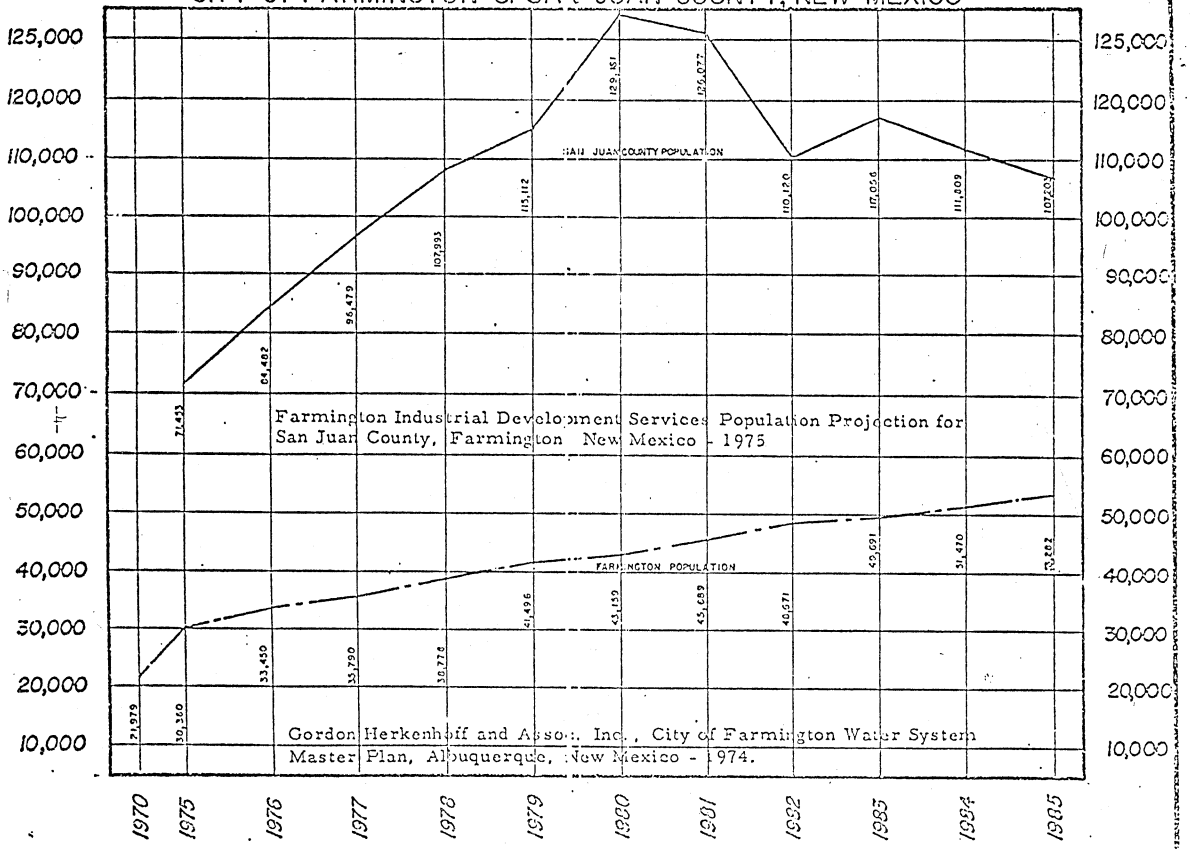
| Year | Basic Forecast (Low) | Effects of Coal Gasification Plants: With New Town | Effects of Coal Gasification Plants: Without New Town | Total Potential Population (Medium) | Total Potential Population (High) |
|---|---|---|---|---|---|
| 1973 | 26,000 | | | 26,000 | 26,000 |
| 1974 | 27,340 | | | 27,340 | 27,340 |
| 1975 | 28,680 | 1,680 | 1,680 | 30,360 | 30,360 |
| 1976 | 29,720 | 3,730 | 3,730 | 33,450 | 33,450 |
| 1977 | 30,760 | 4,759 | 5,030 | 35,519 | 35,790 |
| 1978 | 31,800 | 6,104 | 6,978 | 37,904 | 38,778 |
| 1979 | 32,840 | 7,328 | 8,656 | 40,168 | 41,496 |
| 1980 | 33,880 | 7,167 | 9,279 | 41,047 | 43,159 |
| 1981 | 34,557 | 8,106 | 11,132 | 42,663 | 45,689 |
| 1982 | 35,249 | 9,918 | 13,422 | 45,167 | 48,671 |
| 1983 | 35,953 | 9,804 | 14,016 | 45,757 | 49,696 |
| 1984 | 36,672 | 9,677 | 14,798 | 46,349 | 51,470 |
| 1985 | 37,403 | 10,042 | 15,879 | 47,445 | 53,282 |
| 1986 | 38,152 | 10,409 | 16,606 | 48,561 | 54,758 |
| 1987 | 38,914 | 9,528 | 16,548 | 48,442 | 55,462 |
| 1988 | 39,694 | 9,132 | 16,522 | 48,826 | 56,216 |
| 1989 | 40,487 | 8,913 | 16,628 | 49,400 | 57,115 |
| 1990 | 41,296 | 8,717 | 16,615 | 50,013 | 57,911 |
| 1991 | 42,123 | 8,493 | 16,543 | 50,616 | 58,666 |
| 1992 | 42,967 | 8,235 | 16,406 | 51,202 | 59,373 |
| 1993 | 43,827 | 8,235 | 16,406 | 52,062 | 60,233 |

Gordon Herkenhoff and Associates, Inc., City of Farmington Water System Master Plan - 1974

Albuquerque, New Mexico - January, 1974

GRAPH NO. 1.

# POPULATION PROJECTIONS
FOR
## CITY of FARMINGTON & SAN JUAN COUNTY, NEW MEXICO



The tremendous growth is expected during the next five (5) years due to the new economic developments proposed as follows:

1. Development of the $ 300 million Navajo Indian Irrigation Project funded by Congress and administrated by the Navajo Tribe and the BLM.
2. Current and projected expansion of Four Corners and San Juan Generating Stations.
3. New drilling and exploration for oil and natural gas.
4. Construction of two (2) coal gasification plants.
5. Uranium exploration by Exxon in the Navajo Indian Reservation.
6. Public Service Company of New Mexico, generating station ($ 2.5 billion).

The growth history of an area can be illustrated with the aid of building permit information. Table No. 2 and Graph No. 2 depict the valuation of both residential and non-residential permits issued in the city of Farmington since 1970.

TABLE NO. 2
CITY OF FARMINGTON
VALUATION OF BUILDING PERMITS ISSUED
1970 - 1977 (July)

| YEAR | RESIDENTIAL | NON-RESIDENTIAL |
|---|---|---|
| 1970 | $ 1,253,070. | $ 916,100. |
| 1971 | 1,081,929. | 697,530. |
| 1972 | 3,738,624. | 1,760,335. |
| 1973 | 3,564,845. | 4,333,230. |
| 1974 | 3,785,328. | 3,483,273. |
| 1975 | 7,250,626. | 5,544,984. |
| 1976 | 7,187,096. | 8,987,228. |
| 1977(Jan. - July) | 8,577,892. | 6,447,966. |



95-826 O - 77 - 33

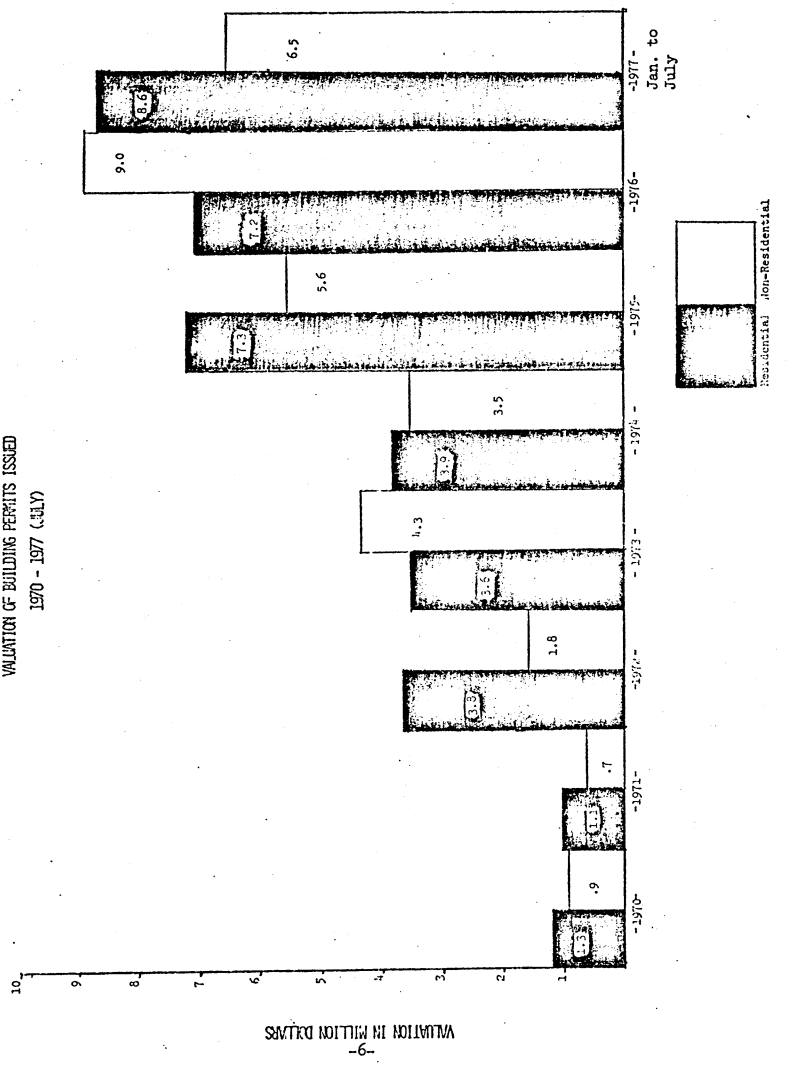

GRAPH No. 2
CITY OF FARMINGTON
VALUATION OF BUILDING PERMITS ISSUED
1970 - 1977 (JULY)
VALUATION IN MILLION DOLLARS
10
9
8
7
6
5
4
3
2
1
-1970-
-1971-
-1972-
-1973-
-1974-
-1975-
-1976-
-1977-
Jan. to July
.35
.9
1.1
.7
3.8
1.8
4.3
3.5
1.9
5.6
7.3
7.2
9.0
8.6
6.5
Residential
Non-Residential

Table 3 reflects the growth which the county is likely to experience through 1985. While these increases have not been allocated to specific portions of the County, Farmington is certain to be impacted by this growth.

TABLE NO. 3
SAN JUAN COUNTY
Assessed Valuation

Actual

| | | |
|---|---|---|
| 1970 | $ 172,752,321 | |
| 1971 | 181,802,966 | |
| 1972 | 238,687,092 | |
| 1973 | 270,714,577 | |
| 1974 | 320,437,169 | |
| 1975 | 396,057,270 | |
| 1976 | 396,057,270 | |
| 1977 | 453,348,953 | est. |

Projection

| | |
|---|---|
| 1978 | $ 470,000,000 |
| 1979 | 490,000,000 |
| 1980 | 510,000,000 |
| 1981 | 530,000,000 |
| 1982 | 550,000,000 |
| 1983 | 560,000,000 |
| 1984 | 570,000,000 |
| 1985 | 575,000,000 |

SOURCE: Quinn & Company, Albuquerque, New Mexico, August, 1977.

III. Constraints

A. One of several constraints is the land ownership pattern of the County, which is outlined as 59% Indian (Navajo Reservation), 29.2% Federal (BLM), 5.3% State (New Mexico), 0.2% Inland Water, and 5.4% private land. The County is composed of approximately 5,516 square miles.

* B. The "people" impact on the San Juan Area is resulting, and will continue to result, in an accelerated demand for services. These services are costly and long-range ones that must be provided primarily by local governments, school districts, health and social service agencies and other special districts. The burden facing these agencies is awesome indeed, even with federal funding assistance and virtually insurmountable without it.

C. The City of Farmington is utilizing the property tax for capital improvements through the use of general obligation bond issues. In a period of "boom" or high growth, property values skyrocket, increasing the tax base. This may appear then to be a self-supporting situation, however, this is not the case. This is because there is at least a year's lag time in the property tax system and a limitation of bonding capacity. By the time the "boom" is underway, the inflation in local construction costs and land prices tends to offset the increase in property tax values and hold down local financing capability even more. It is difficult to get the old property taxpayers to assume a new bond obligation for the benefit of a wave of newcomers and builders from the outside. Most of the energy related industry will be developed outside of the City of Farmington and this tax base will not contribute to meeting the needs of Farmington.

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* Source: Southwest Federal Regional Council Meeting at Farmington, N. M., October 16th and 17th, 1974 (prepared by the San Juan Council of Governments).

IV. Current and Projected City Budgets

The City of Farmington is forecasted to increase annual municipal budget expenditures from $ 27.6 million in FY 1978 to $ 34.2 million in FY 1979, an increase of 45%. Also, assuming that the City increases from 35,790 (1977 population) to 54,758 population by 1986, the City is anticipated to invest an estimated $ 77.9 million for capital improvements during this time period. Operation and maintenance costs will increase to $ 32.0 million annually by the year 1986.

The budgets for FY's 1976 - 1978 are shown on Table No. 4. Table No. 5 and Graph No. 3 depict the projected capital improvement and maintenance cost for FY's 1979 - 1986. The formula used to arrive at these costs is given on both the table and the graph.

TABLE NO. 4

CITY OF FARMINGTON
FY 78 BUDGET RECAP

| | FY 76 BUDGET | FY 77 BUDGET | FY 78 BUDGET |
|---|---|---|---|
| General Fund | $ 4,318,517. | $ 5,461,764. | $ 6,290,600. |
| Recreation Fund | 60,000. | 60,000. | 70,000. |
| Sanitation Fune | 410,000. | 533,603. | 512,758. |
| Airport Fund | 559,949. | 116,999. | 120,814 |
| Golf Fund | 38,488. | 41,428. | -0- |
| Fire Fund | 39,000. | 85,000. | 28,000. |
| Lodgers Tax Fund | 24,000. | 25,000. | 25,000. |
| Revenue Sharing Fund | 322,085. | 307,290. | 270,000. |
| Utility Operating Fund | 6,494,351. | 8,993,275. | 11,802,353. |
| G. O. Interest Fund | 59,248. | 49,255. | 41,325. |
| G. O. Principal Fund | 205,000. | 130,000. | 130,000. |
| Total Budgeted Funds | $12,530,638. | $15,803,614. | $19,291,220. |
| City Share - Construction | | | $ 320,154. |
| City Share - Utility Construction | | | 3,958,712. |
| Sub Total - City Share Construction | | | $ 4,278,866. |
| State and Federal Contribution for Construction | | | $ 4,016,671. |
| Grand Total FY 78 | | | $27,586,757. |

TABLE NO. 5

PROJECTED CITY OF FARMINGTON
BUDGETS - FISCAL YEAR 1978-1986

| YEARS | 1) POPULATION PROJECTIONS | POPULATION INCREASE | FISCAL BUDGET YEAR | 2) CAPITAL IMPROVEMENT COSTS IN MILLIONS | 3) MAINTENANCE COSTS IN MILLIONS |
|---|---|---|---|---|---|
| 1977 | 35,790 | | | | |
| 1978 | 38,778 | 2988 | 1978 | $ 12.0 *($14.0) | $ 21.5 *($13.6) |
| 1979 | 41,496 | 2718 | 1979 | 10.9 | 23.3 |
| 1980 | 43,159 | 1663 | 1980 | 6.7 | 24.9 |
| 1981 | 45,689 | 2530 | 1981 | 10.1 | 25.9 |
| 1982 | 48,671 | 2982 | 1982 | 11.9 | 27.4 |
| 1983 | 49,691 | 1020 | 1983 | 4.0 | 29.2 |
| 1984 | 51,490 | 1799 | 1984 | 7.2 | 29.8 |
| 1985 | 53,282 | 1792 | 1985 | 7.2 | 30.9 |
| 1986 | 54,758 | 1476 | 1986 | 5.9 | 32,0 |
| | | | TOTAL: | $ 75.9 | $ 244.9 |

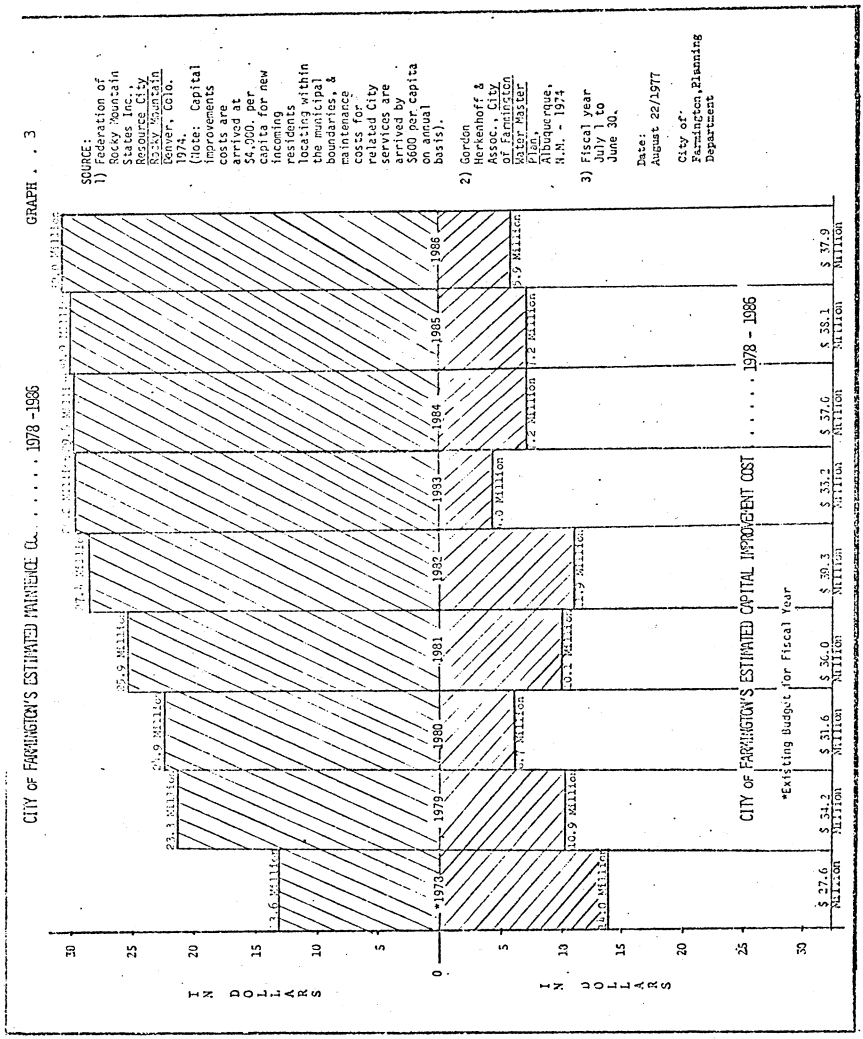
* Actual 1978 Budget for the City of Farmington.

1) Population Projections by Gordon Herkenhoff & Associates, City of Farmington Water Master Plan, High Projections, Albuquerque, New Mexico, 1974.

2) & 3) Federation of Rocky Mountain States, Inc., Resource City Rocky Mountain Denver, Colorado, 1974. (Note: Capital Improvements cost arrived at $ 4,000.00 per capita for new incoming residents locating within the municipal boundaries and maintenance costs for related City services are arrived by $ 600.00 per capita on annual basis.)

Date: August 22, 1977

City of Farmington
Planning Department


CITY OF FARMINGTON'S ESTIMATED MAINTENANCE CO. . . . . 1978 -1986
GRAPH . 3
IN DOLLARS
SOURCE:
1) Federation of Rocky Mountain States Inc., Resource City Today Rocky Mountain Denver, Colo. 1974. (Note: Capital improvements costs are arrived at $4,000 per capita for new incoming residents locating within the municipal boundaries, & maintenance cass for related City services are arrived by $600 per capita on annual basis).
2) Gordon Herkenhoff & Assoc., City of Farmington Water Master Plan, Albuquerque, N.M. - 1974
3) Fiscal year July 1 to June 30.
Date: August 22/1977
City of: Farmington,Planning Department
CITY OF FARMINGTON'S ESTIMATED CAPITAL IMPROVEMENT COST . . . . . 1978 - 1986
*Existing Budget for Fiscal Year
1978 $ 27.6 Million
1979 $ 34.2 Million
1980 $ 31.6 Million
1981 $ 36.0 Million
1982 $ 30.3 Million
1983 $ 33.2 Million
1984 $ 37.6 Million
1985 $ 38.1 Million
1986 $ 37.9 Million

V. Bonding Capacity

A. General Obligation Bonds:

According to New Mexico law, a community can issue General Obligation Bonds to a maximum of 4% of the City's assessed evaluation excluding water and sewer improvements. At present, the City of Farmington has a maximum of $ 2,204,000 General Obligation Bonds excluding water and sewer. Therefore, the remaining amount that the City can issue under the General Obligation Bond category is $ 1,394,000 excluding water and sewer.

B. Revenue Bonds:

The City has Revenue Bond Issues which are characterized by Utility Bonds and Sales Tax Bonds. Utility Revenue Bonds are emplcyed for electric, water and sewer programs. Sales Tax Revenue Bonds are for public building and parking lots. Currently, the City of Farmington has $ 22,625,000 in Utility Revenue Bonds and $ 3,936,000 in Sales Tax Revenue Bonds outstanding or authorized to be sold. The total Revenue Bond Issues outstanding and authorized for sale is $ 26,561,000.

VI. Capital Improvement Program - 1977-1981

At present, the City has over twenty major projects in the areas of water, sewer, fire, etc., which must be undertaken as soon as possible to bring the City in line with the present population. (Refer to population projections, Table No. 1). These projects are estimated at nearly $ 43 million. The time frame in which these projects should be undertaken is 5 years, to begin in 1977 and be completed by 1981.

The following is a summary by major categories:

| Area of Capital Improvements Needs | 1977-78 | 1978-81 |
|---|---|---|
| Parks and Recreation | $ 826,300. | $ 381,000. |
| Electric Utility | 1,650,000. | 4,750,000. |
| Public Works: | | |
| A. Water | 3,212,888. | 7,980,400. |
| B. Sewer | 1,971,759. | 6,273,200. |
| C. Streets | 1,645,600. | 2,740,556. |
| D. Drainage and Storm Sewer | 100,000. | 3,000,000. |
| E. Municipal Operations Center | 125,000. | 4,000,000. |
| F. Municipal Airport | 200,000. | 400,000. |
| Fire Department | 1,001,200. | 1,019,044. |
| Criminal Justice (Police Dept.) | 883,832. | 884,880. |
| Civic Center | 11,800. | 141,840. |
| Total | $ 11,633,379. | $ 31,570,920. |
| GRAND TOTAL | $ 43,204,299.00 | |

SUMMARY OF APPLICATIONS

SUBMITTED TO VARIOUS AGENCIES

As of August 25, 1977, the City is awaiting the out-come of a number of grant applications. The total value of these projects to be funded by these grants is $ 12,184,466.00 of which $ 2,132,404.00 are local funds.

If the projects are approved, the remaining non-local share will come from the following:

| | |
|---|---|
| ECONOMIC DEVELOPMENT ADMINISTRATION | $ 6,700,573.00 |
| COMMUNITY ASSISTANCE COUNCIL | 2,089,600.00 |
| BUREAU OF OUTDOOR RECREATION | 50,000.00 |
| SAN JUAN COLLEGE | 25,000.00 |
| FOUR CORNERS REGIONAL COMMISSION | 86,889.00 |
| ENVIRONMENTAL IMPROVEMENT AGENCY | 100,000.00 |
| TOTAL NON-LOCAL SHARE | $ 9,052,062.00 |

STATUS REPORT

City of Farmington's Applications submitted to various state and federal agencies.

| | APPLICATION | MATCH | TOTAL | STATUS |
|---|---|---|---|---|
| 1. | Project<br><br>City of Farmington Water Line Replacement and Extension (12 inch line replacement along N. M. Highway 64.) | United States Economic Development Administration<br>75%<br>$337,500.00<br><br>City of Farmington<br>25%<br>$112,500.00 | $450,000.00 | Submitted 2/2/76 |
| 2. | Project<br><br>Installation of Water Lines | U. S. EDA<br>60%<br>$508,073.00<br><br>City of Farmington<br>28%<br>$238,716.00<br><br>Environmental Improvement Agency<br>12%<br>*$100,000.00 | $846,789.00 | March, 1976 |

Grantor

U. S. Dept. of Commerce
ECONOMIC DEVELOPMENT
ADMINISTRATION;
ENVIRONMENTAL IMPROVEMENT AGENCY

* These funds allocated to the City through the Water Supply Construction Act, August 6, 1976.

| | APPLICATION | MATCH | TOTAL | STATUS |
|---|---|---|---|---|
| 3. | Project | | | |
| | Improve the City of Farmington Raw Water Supply | EDA 75% $4,500,000.00 | | |
| | | City of Farmington 25% $1,500,000.00 | $6,000,000.00 | August 11, 1976 |
| | Grantor | | | |
| | U. S. Dept. of Commerce ECONOMIC DEVELOPMENT ADMINISTRATION | | | |
| 4. | Project | | | |
| | a. Street Construction - construction of Thirtieth Street between Butler Avenue and Sullivan Avenue, and the construction of Sullivan Avenue between Twentieth and Thirtieth. | EDA 100% $676,500.00 | $676,500.00 | Submitted 7/11/77 |
| | b. Elementary School Parks - entails improvements to recreation areas within four elementary schools; Animas, Country Club, McKinley, and McCormick. All schools are within the Farmington Municipal School District #5. | EDA 100% $200,000.00 | $200,000.00 | Submitted 7/11/77 |
| | c. Senior Citizen Center Addition - the addition will be linked to the existing facility by an enclosed walk-way. The new facility will have an enlarged game room, a large kitchen with stoves, refrigeration serving area and storage space. | EDA 100% $150,000.00 | $150,000.00 | Submitted 7/11/77 |
| | d. Phase III North Interceptor - the proposed sewer improvements project consists of 6,500 L. F. of VDP sewer line ranging in size from 8 to 15 inches. | EDA 100% $328,500.00 | $328,500.00 | Submitted 7/11/77 |
| | Grantor | | | |
| | ECONOMIC DEVELOPMENT ADMINISTRATION | Total Projects: | $ 1,355,000.00 | |

| APPLICATION | MATCH | TOTAL | STATUS |
|---|---|---|---|
| 5. Project | | | |
| a. Treatment plant expansion, additional storage tank, and inter-system transmission lines. | Community Assistance Council 63% $1,366,785.00 | | |
| | City of Farmington 37% $802,715.00 | $2,169,500.00 | Submitted 7/15/77 |
| b. Replacement of structures in Farmer's Ditch. Add earthen dikes to increase capacity of Lake Farmington. Install pump station at Lake Farmington. | Community Assistance Council 63% $ 722,815.00 | | |
| | City of Farmington 37% $ 424,510.00 | $1,147,325.00 | Submitted 7/15/77 |
| Grantor | | | |
| Community Assistance Council - Energy Impacted Monies STATE OF NEW MEXICO | Total Projects: $ 3,316.825.00 | | |
| 6. Project | | | |
| Recreational Facilities located at the San Juan College New Mexico State University, San Juan Branch and the City of Farmington | San Juan College 25% $ 25,000.00 | | |
| | City of Farmington 25% $ 25,000.00 | | |
| | Bureau of Outdoor Recreation 50% $ 50,000.00 | $100,000.00 | August 1976 |
| Grantor | | | |
| New Mexico State Planning Office - Bureau of Outdoor Recreation | | | |

| | APPLICATION | MATCH | TOTAL | STATUS |
|---|---|---|---|---|
| 7. | Project<br><br>City of Farmington - Drainage Master Plan | City of Farmington 25% $ 28,963.00<br><br>Four Corners Regional Commission 75% $ 86,889.00 | $115,852.00 | Submitted May, 1977 |
| | Grantor<br><br>Four Corners Regional Commission | (The Planning Department anticipates little or no possibility of funding this project through the Four Corners Regional Commission.) | | |
| 8. | Project<br><br>Surplus and Excess property. | | | On-going project. |
| | Grantor<br><br>The State of New Mexico and Four Corners Regional Commission. | | | |

MATERIAL SUBMITTED FOR THE RECORD BY STATE SENATOR JOSEPH GANT

The city of Carlsbad has experienced a rapid growth in population over the past 3 years as a direct result of energy related activities in the area. The activities include development of oil and gas, the planning of the atomic waste isolation pilot research project, the establishment of anhydrous ammonia plants which use natural gas as feedstock, and increased mining of potash.

The Carlsbad area is of major importance to every section of our Nation because of several pertinent facts.

1. The energy crisis requires that every effort be made to develop new oil and gas sources. The Carlsbad area has led the permian basin month after month in oil and gas drilling activities (exhibit 1) as documented in the weekly rig report published on a weekly basis by the petroleum information corporation, Midland, Tex. These activities need to continue and Carlsbad must keep abreast of the increased population and need for services caused by these operations moving into the area.

2. The potash mines and anhydrous ammonial plants in the area (exhibits 3 and 4) provide fertilizer throughout our Nation and the free world.

The production of these two of the three major elements essential to grow our food and fiber crops are direct factors in our domestic and foreign trade. Any Carlsbad area deficiencies that would cause difficulty in maintaining these industries and encouraging their continued growth would be of great detrimental affect to our Nation.

3. Of equal or greater importance to the above is the waste isolation pilot plant project that is now progressing rapidly in the Carlsbad area. Without a proper, safe and efficient method of storing nuclear waste, our Nation cannot make the strides necessary in solving our energy crises. The people of the Carlsbad area are working with ERDA and Sandia laboratory to assist the orderly progress being made. The impact upon the Carlsbad area as this project materializes (exhibit 2) will be tremendous as detailed in the Larry Adcock and Associates report on the socioeconomic impact analysis of the proposed waste isolation pilot plant.

Exhibit 1

DRESSER INDUSTRIES DRESSER

OILFIELD PRODUCTS GROUP DRESSER INDUSTRIES INC. 3229 ANDREWS HIGHWAY ODESSA TEXAS 79762 915/333-3111

MONDAY, JULY 25, 1977

PETROLEUM INFORMATION CORP.
Anderson Oil Report
P. O. Box 1842
Midland, TX 79702

WEEKLY RIG REPORT BY
SECURITY ROCK BIT - WEST TEXAS DIVISION

| OPERATOR | LOCATION | CONTRACTOR | APPROX DEPTH | PROP DEPTH |
|---|---|---|---|---|
| | ANDREWS COUNTY | | | |
| Exxon | 835 Fullerton Clfk Unit | Rod-Ric #3 | 4695 | 7300 |
| Exxon | 1172 Means San Andres Unit | Tom Brown #18 | Spud | 4700 |
| | BORDEN COUNTY | | | |
| Monsanto | 1 Good | Wes-Tex #11 | 9400 | 9800 |
| Texaco | 3442 Jo Mill Unit | D-B #8 | 7000 | 7500 |
| | COCHRAN COUNTY | | | |
| Coline | 189 West Levelland Unit | Sitton #1 | 4800 | 4950 |
| Coline | 190 West Levelland Unit | Sitton #1 | 4200 | 5000 |
| Dyco | 20 Masten "4" | Verna #9 | TD | TD |
| Union Calif. | 2 Masten "B" | KKA #8 | TD | 4925 |
| Union Calif. | 5 Masten "J" | Rial #8 | 3300 | 4700 |
| | COKE COUNTY | | | |
| R. L. Burns | 1 Ellwood "20" | Fortune #1 | 6980 | 7000 |
| Kendrick & Mulligan | 1 Hendry | Texland #3 | 6000 | 6900 |
| | CRANE COUNTY | | | |
| Atlantic | C-5 Block 31 | Johnn #8 | 8140 | 9100 |
| Atlantic | K-6 Block 31 | Johnn #8 | 4250 | 10,500 |
| Getty | 3711 North McElroy | T. H. Blue #1 | 1750 | 3450 |
| Gulf | 16 M | GEM #2 | 4320 | 10,500 |
| Gulf | 284 McElroy | Tom Brown #2 | 1426 | 3200 |
| Sabine | 2 Glenn | Capitan #1 | 2150 | 7400 |
| | CROCKETT COUNTY | | | |
| Amarex | 1-A Baggett "8" | Wes-Tex #9 | 4150 | 10,700 |
| Anderson | 3-4 J. S. Pierce | Wes-Tex #10 | 4975 | 6450 |
| Anderson | 14 Millspaul "2-A" | Wes-Tex #15 | 2140 | 5600 |
| Delta | 1 Joe Couch "A" | Delta #2 | 9870 | 12,500 |
| Delta | 3 Delta | Delta #2 | 2931 | 10,500 |
| Delta | 2 Friend | Delta #60 | 1145 | 9000 |
| Gulf | 10 Henderson | Tom Brown #5 | TD | 6750 |
| Gulf | 1 Hoover | Tom Brown #6 | Fshg | |
| H&D Well | 7 Shannon | H&D | Completing | |
| H&W | 4 University "9" | John Wilson #1 | 600 | 2400 |

CROCKETT COUNTY (Cont'd)

| | | | | |
|---|---|---|---|---|
| n J. Harrison | 1 Jack Wilkins | Tucker #6 | TD | 8400 |
| dian Wells | Montgomery | Wes Tex #7 | 3981 | 7000 |
| dian Wells | 2 Montgomery "10" | Tucker #1 | 6200 | 7000 |
| dian Wells | 3 Montgomery "10" | Tucker #1 | 2190 | 7000 |
| dian Wells | Montgomery | Tucker #5 | 5050 | 7000 |
| thane Gas | 2 Baggett "C" | Wes-Tex #6 | 3110 | 5200 |
| oltz, Wagner & Brown | 1-8 Hoover | Wes-Tex #2 | 6510 | 10,000 |
| Cleo Thompson | 2 Bailey "B" | Wes-Tex #9 | 3000 | 9000 |
| xoma | 1 Hudspeth | Wes-Tex #16 | 900 | 5200 |

CULBERSON COUNTY

| | | | | |
|---|---|---|---|---|
| erican Quasar | 1 Meeker Unit | Sharp #15 | "TIGHT" | 15,650 |
| lantic | 1 Delaware Basin | Coffland #32 | 7600 | 17,200 |

DAWSON COUNTY

| | | | | |
|---|---|---|---|---|
| ntex O&G | 1 Alta Byrd | MGF #1 | 8260 | 12,000 |
| F | 1 Webb Estate | MGF #1 | Spud | 9600 |

DICKENS COUNTY

| | | | | |
|---|---|---|---|---|
| hland | 1 Pike Dobbins | D P #6 | 7000 | 7550 |

ECTOR COUNTY

| | | | | |
|---|---|---|---|---|
| merada | 12 Carlinville Nat'l Bank | Cactus #32 | 10,600 | 11,000 |
| noco | 138 E. F. Cowden | Johnn #10 | 6800 | 9500 |
| lantic | 76 J. L. Johnson | Cactus #58 | 3300 | 4300 |
| lantic | 97 North Foster | Cactus #58 | 2200 | 4400 |
| noco | 106 Gist | R. H. Smith #51 | 4190 | 4400 |
| illips | 4 Cowden | Paul's #4 | 2800 | 4500 |
| un | 716 Foster-Johnson | Hillin #6 | "TIGHT" | 4400 |
| xaco | 14-12 West Jordan Unit | Norwood #1 | 3720 | 3750 |
| xaco | 15-12 West Jordan Unit | Hillin #8 | "TIGHT" | 3400 |

GAINES COUNTY

| | | | | |
|---|---|---|---|---|
| merada | 2309 Seminole Sadr Ut. | Cactus #59 | 3457 | 5400 |
| merada | 2312 Seminole Sadr Ut. | Cactus #59 | 5181 | 5400 |
| merada | 2709 Seminole Sadr Ut. | Cactus #63 | 4915 | 5400 |
| merada | 2710 Seminole Sadr Ut. | Cactus #63 | 2354 | 5400 |
| ities Service | 1 Peters "A" | Big West #11 | 10,190 | 12,000 |
| xxon | 8002 Robertson Clfk Ut. | Sod-Ric #7 | 6800 | 7200 |
| ytech | 1 Sherman | Byrd #2 | 4999 | 5600 |
| obil | 11 Tom May | Hillin #3 | "TIGHT" | 5600 |
| obil | 4 Braddock | Norton #4 | 5115 | 5600 |
| obil | 1 H&J "B" | Norton #4 | 5480 | 5400 |
| hell | 23 Stark | Sod-Ric #2 | 4649 | 4850 |
| exaco | 90 Wharton | Cactus #65 | 4306 | 4820 |
| exaco | 93 A. B. Wharton | Cactus #54 | TD 4840 | |

GARZA COUNTY

| | | | | |
|---|---|---|---|---|
| General Crude | 1 Spinning "18" | CCO #3 | 8301 | 8500 |
| Maguire | 1 Slaughter Lott "18" | CCO #5 | 5200 | 8500 |
| Sun | 9 Swenson "B" | CCO #4 | 7300 | 8500 |
| M. R. Young | 1 Spinning | McCutchen #4 | 7500 | 8300 |

GLASSCOCK COUNTY

| | | | | |
|---|---|---|---|---|
| Estoril | 1 G. W. Curry | Gene Sledge #1 | 3435 | 9700 |
| Newbourne Oil | 2 Riley | Tri-Service #4 | 2835 | 8100 |
| Tamarack | 2 August | Tom Brown #3 | 6386 | 8000 |

HALE COUNTY

| | | | | |
|---|---|---|---|---|
| Amoco | 356 Anton-Irish Clfk Ut. | Chico #1 | 3200 | 5600 |
| Amoco | 365 Anton-Irish Clfk Ut. | Norton #2 | 2000 | 5600 |
| Amoco | 374 Anton-Irish Clfk Ut. | Cactus #54 | 5600 | 6300 |
| Amoco | 375 Anton-Irish Clfk Ut. | Chico #2 | 5200 | 6300 |
| Inexco | 1 Carson | Ard #4 | TD | 10,70 |

HOCKLEY COUNTY

| | | | | |
|---|---|---|---|---|
| Amoco | 322 Central Mallet Lt. | Sitton #2 | TD | |
| Amoco | 1 Post Montgomery "B" | Verna #8 | TD | 4900 |
| Gulf | 28 M. G. Gordon | Cactus #8 | TD | 8200 |
| Lovelady | 1 WLB | Robinson Bros. #3 | TD | 10,20 |
| Joe Melton | 3 Wrenchey | Cherokee #1 | 3500 | 4800 |
| Sun | 5 Roberts-Cobb "A" | Verna #4 | 3100 | 5050 |
| Texas Pacific | 206 Central Levelland | Sitton #4 | 3100 | 5000 |
| Union Calif. | 2 Ellwood Est. "E" | Norton #3 | TD | 5700 |
| Wheeler Properties | 109 A. A. Slaughter "66" | Verna #3 | 4900 | 6060 |

HOWARD COUNTY

| | | | | |
|---|---|---|---|---|
| Amoco | 3 Iben "A" | Robinson Drlg. #3 | 6800 | 8750 |
| Atlantic | 1 Dodge Est. | Riley #1 | 1000 | 2900 |
| D. L. Dorland | Edwards | Fiscus #1 | 1000 | 2450 |
| Enserch | 2 S. E. Luther "C" | Robinson Drlg. #2 | 3000 | 10,000 |
| Phillips | 6 Bellnolia | Riley #2 | 1000 | 2900 |
| Kendrick-Mulligan | 24 Chalk | Texland #6 | 100 | 3250 |
| Resources Investment | 2 Flanagan | West-Tex #1 | 8400 | 9600 |
| Samedan | Chalk | Fiscus #3 | 1000 | 3250 |

IRION COUNTY

| | | | | |
|---|---|---|---|---|
| John L. Cox | 1 Miss Ela "K" | TWA #12 | "TIGHT" | 8100 |
| Dunigan | 1 Field "1129" | Serendipity #2 | 4075 | 6800 |
| Fortune | 7 Murphy | Fortune #3 | 2891 | 8000 |
| Kerr-McGee | 1 Scott "14" | Robinson #5 | 7986 | 8100 |

LAMB COUNTY (Cont'd)

| | | | | |
|---|---|---|---|---|
| Amoco | 390 Anton-Irish Clfk Ut. | Chico #3 | 5600 | 6300 |
| Fred Olsen | 1 V. C. Hart | CCO #6 | TD | 7000 |

LOVING COUNTY

| | | | | |
|---|---|---|---|---|
| Exxon | 2 Linebery | Thompson #5 | 5050 | 20,5( |
| Hunt Oil | 1 Harrison "10" | Parker #86 | 19,505' | 22,5( |

LUBBOCK COUNTY

| | | | | |
|---|---|---|---|---|
| Kewanee | 1004 Harrison | Norton #1 | 4900 | 4900 |

LYNN COUNTY

| | | | | |
|---|---|---|---|---|
| Kewanee | 908 North Welch Ut. | Norton #1 | 4900 | 4900 |

MARTIN COUNTY

| | | | | |
|---|---|---|---|---|
| Hytech | 2 Mabee | Tri-Service #3 | 2412 | 10,50 |

MENARD COUNTY

| | | | | |
|---|---|---|---|---|
| Anadarko | 1 Sorrells | FSW #5 | 4516 | 4600 |

MIDLAND COUNTY

| | | | | |
|---|---|---|---|---|
| J. L. Cox | 1 Braun | FWA #3 | "TIGHT" | 9500 |
| MWJ | 1 Fasken "13-A" | FWA #2 | "TIGHT" | |
| Mobil | 3 C. B. Haley "A" | Brahaney #1 | 11,760' | 12,20( |

MITCHELL COUNTY

| | | | | |
|---|---|---|---|---|
| CAG | 1 Coleman "A" | Fiscus #2 | 1815 | 1900 |
| Mallard | 1 Ellwood Est. "6" | CCO #1 | 6700 | 7100 |
| Sun | 18 McCabe "B" | Wes-Tex #12 | 5300 | 6450 |
| Sun | 19 McCabe "B" | Wes-Tex #12 | 3100 | 6500 |
| Sun | 6 Stubblefield | Wes-Tex #14 | 4000 | 6450 |
| TIPCO | 7 Parks | CCO #2 | 5960 | 6500 |

PECOS COUNTY

| | | | | |
|---|---|---|---|---|
| Amarillo | 1 Dixel Gas | Sharp #55 | 18,800 | 23,000 |
| American Quasar | 1 Elsinore "65" | Warton #3 | 14,000 | 16,000 |
| BTA | 1 Riggs | Loffland #324 | TD | 23,000 |
| Exxon | 1 Marjorie Crawford | Thompson #8 | 6900 | 23,500 |
| Exxon | 14 John May | Sharp #32 | 11,000 | 12,000 |
| Getty | 1 Montgomery "38" | Sharp #38 | 4750 | 12,000 |
| Getty | 2 Mendel "26" | Noble N-87 | 5200 | 12,400 |
| Ge-ty | 4 Mendel Est. "36" | Sharp #36 | Fshg | 12,000 |
| Gfrd, Mtchl, Wsnbkr | 1 Raymal-Eagle | Parker #6[illegible] | 14,000 | 22,700 |
| Gulf | 1 Emma Lou | Sharp #57 | Whipstocking | 25,500 |
| Hilliard | 1 Grant-State | Norwood #3 | 5300 | 5700 |
| Hillin | 4 Moore-Gilmore | Hillin #2 | "TIGHT" | 9700 |
| Lovelady | 2 Chalkley | V-B #1 | 1400 | 4750 |

PECOS COUNTY (Cont'd)

| | | | | |
|---|---|---|---|---|
| Mid-American | 4 Shelby | Ard #1 | 11,629 | 11,500 |
| Monsanto | 6 Bernice | [illegible] #25 | 8900 | 10,800 |
| Monsanto | 5 Bernice "D" | [illegible] #4 | 6600 | 10,800 |
| Monsanto | 1 Bunger | Parker #89 | 14,109 | 18,000 |
| Northern Natural | 1 Hershenson | Thompson #12 | 15,150 | 16,500 |
| Phillips | Mitchell | Sharp #14 | 9450 | 12,000 |
| Texas Pacific | 11 Folk | Parker #16 | 1000 | 14,000 |

REAGAN COUNTY

| | | | | |
|---|---|---|---|---|
| Bill Beach | 1 Freeze | TWA #14 | "TIGHT" | |
| W. W. Buchanan | 3 Rocker B "H" | Lee Brown #1 | 2501 | 7225 |
| W. W. Buchanan | 6 Rocker B "M" | Lee Brown #1 | 6331 | 7400 |
| W. W. Buchanan | 4 Rocker B "O" | Lee Brown #14 | 5950 | 7500 |
| Cities Service | 1 University "BC" | Carter #15 | 9915 | 9950 |
| Gulf | 2 Nachlinger | Holmes #5 | 8340 | 8340 |
| Saxon | 2 Weatherby "H" | TWA #1 | "TIGHT" | 7700 |
| Tamarack | 3 Gladys Clark "A" | Lee Brown #4 | 6240 | 7850 |
| Jay & Mills | 1 University "11" | Clark #1 | 1020 | 3300 |
| J. L. Cox | 1 Neal | TWA #20 | "TIGHT" | |

REAVES COUNTY

| | | | | |
|---|---|---|---|---|
| ATAPCO | 1 Adams Est. | Terry #43 | 9600 | 22,500 |
| Adobe | 1 Graham State | Chapman #1 | TD | 13,900 |
| American Quasar | 1 Worsham "16" | Carter #21 | 16,724 | 17,000 |
| ATA | 2 7607 Orla | Brown #28 | 10,150 | 16,000 |
| Chevron | 3 TXL "17-39" | Orahoney #7 | 9950 | 14,500 |
| Cyco | 1 Caldwell State | Terry #48 | 8700 | 11,200 |
| Inserch | 1 Amarillo | Terry #1 | 3180 | 3300 |
| Inserch | 2 Amarillo | Terry #3 | 3200 | 3400 |
| Exxon | 1 McIntire | TXL #76 | 4018 | 11,000 |
| Gulf | 7 S. F. Ligon | Ligon #55 | 6988 | 17,600 |
| MG | 1 McFarland "28" | Parker #38 | 10,453 | 18,500 |
| MG | 1 Sabine State | Parker #85 | 12,800 | 19,500 |
| Hunt | New Location | Parker #66 | 4105 | 18,000 |
| Northern Natural | 1 TXL "19" | Thompson #9 | 18,798 | 19,000 |
| Texaco | 1 Reeves "AB" Fee | Reeves #12 | 3100 | 18,000 |
| Texaco | 1 Reeves "BD" Fee | Reeves #4 | TD | 3400 |
| Texaco | 9 Reeves "J" Fee | Thompson #13 | TD | 18,000 |

SCHLEICHER COUNTY

| | | | | |
|---|---|---|---|---|
| Gulf | 1 State "FF" | [illegible] | 7915 | 8500 |
| Meyer & Assoc. | 1 White | [illegible] | 3110 | 5600 |
| J. I. O'Neil | 1 Barrow "A" | [illegible] | 5480 | 6850 |
| Tucker | 1 Womack | [illegible] | 300 | 5800 |
| Edgco | 1 Parker Foods | Lee Brown #15 | TD | 7800 |

STERLING COUNTY

| | | | | |
|---|---|---|---|---|
| Dorchester | 1 Foster-Price "7" | D-B #7 | Stuck 7622 | 8400 |
| Stoltz, Wagner & Brown | 8 Hildebrand "18" | Wes-Tex #3 | 5303 | 8200 |
| Texaco | 4 Sterling "H" Fee | Capitan #6 | 5400 | 8100 |
| Texaco | 3 Sterling "I" Fee | Capitan #3 | 8100 | 8100 |

SUTTON COUNTY

| | | | | |
|---|---|---|---|---|
| Atlantic | 1 Cauthorn "15" | Fortune #2 | 9500 | 9550 |
| HNG | 2 Kirby "183" | Tom Brown #13 | 6150 | 7050 |
| HNG | 1 Shannon "52" | Tom Brown #13 | 3870 | 7000 |
| HNG | 2 Brown "78" | Tom Brown #11 | 4985 | 5300 |
| Lively | 1 Aldwell "17" | Tom Brown #12 | 7100 | 9400 |
| Way & Mills | 4 Hicks | Sioux #5 | 1073 | 3750 |
| Wewoka | 9 Whitehead | Delta #61 | Fshg | 9300 |
| Windsor | 3 Wilson "185" | Delta #73 | Re-Entry | 9000 |
| Windsor | 4 Wilson "188" | Delta #73 | 7290 | 9000 |

TERRELL COUNTY

| | | | | |
|---|---|---|---|---|
| Mobil | 3 Banner Est. | Brahaney #4 | 12,300 | 13,50 |
| Monsanto | 5 Bernice | Cactus #25 | 9100 | 12,00 |

TERRY COUNTY

| | | | | |
|---|---|---|---|---|
| Amoco | 16 Covington "B" | Verna #1 | TD | 8900 |
| Young | 1 Daughtery "A" | Sitton #2 | 4350 | 5000 |

TOM GREEN COUNTY

| | | | | |
|---|---|---|---|---|
| Eurafrep | 2 McGregor | Caraway #2 | 6813 | 7100 |
| Florida Gas | 1 West Pate | Tucker #3 | 5810 | 6500 |
| John H. Hill | 1 Field | Fortune #3 | 6425 | 7400 |
| Tucker | 1 Harper | Tucker #8 | 5793 | 6800 |

UPTON COUNTY

| | | | | |
|---|---|---|---|---|
| Burns | 1 McElroy | Halliday #2 | 8750 | 14,000 |
| Cotton Pet. | 4 Halff | Sone Sledge #4 | 5420 | 10,100 |
| Gulf | 282 Crier-McElroy | Tom Brown #2 | 3022 | 3900 |
| Gulf | 993 McElroy | Tom Brown #19 | 1983 | 3900 |
| Gulf | 995 McElroy | Tom Brown #19 | 3200 | 3400 |
| Knox | 4 Turner | COP #1 | 6925 | 6950 |
| North American Royalties | 1 Arco Fee | Halliday #1 | 3450 | 10,500 |
| Texas Oil & Gas | 3 Damcon | FWA #11 | "TIGHT" | |

VAL VERDE COUNTY

| | | | | |
|---|---|---|---|---|
| C&K | 1 Mobil-Mills | Burt #4 | 14,210 | 15,500 |
| Chevron | 1 Bassett Mineral "46" | Rowan #7 | 19,150 | 20,000 |
| Mobil | 2 Morrison | Dual #19 | 468 | 14,500 |
| Resources Investment | 1 Mills "18" | Delta #4 | 4250 | 15,500 |

WARD COUNTY

| | | | | |
|---|---|---|---|---|
| Amoco | 5 Postelle | Hillin #4 | "TIGHT" | 8800 |
| BTA | 1 Stallings | Cactus #1 | 15,980 | 17,000 |
| Forrest | 1 Golden State | Ard #8 | 800 | 20,000 |
| Gulf | 1 J. W. Cadenhead | Sharp #59 | 9100 | 18,150 |
| Gulf | 3 T. B. Pruett | Thompson #7 | 17,100 | 19,800 |
| Gulf | 2 State "OA" | Johnn #4 | 5500 | |
| HNG | 1 Lee "128" | Parker #58 | TD | 22,000 |
| HNG | 124 Middleton "C" | Tom Brown #17 | 3674 | 6750 |
| Monsanto | 1 Rodgers | Parker #87 | 9100 | 19,500 |
| Shell | 148 Scaly-Smith | Verna #16 | 3100 | 6700 |
| Texaco | 1 State Gas Unit "D" | Thompson #1 | 15,445 | 20,390 |
| Union Texas | 1 Scaly "58" | Marcum #5 | 5780 | 17,500 |
| Clayton Williams | 2 Avary | Norwood #3 | TD & RU | 6800 |
| Clayton Williams | 4 Thompson Est. "A" | Capitan #2 | 5900 | 6700 |

WINKLER COUNTY

| | | | | |
|---|---|---|---|---|
| Amini | 1 Scaly-Smith "13" | FKA #1 | 7900 | 9200 |
| Exxon | 2 Haley "17" | Thompson #3 | 14,875 | 18,500 |
| Gfrd, Mtchl, Wsnbkr | 1 Capitan | W. H. Smith #55 | 1900 | 3200 |
| Gfrd, Mtchl, Wsnbkr | 1 Little Wolf | Roy Smith #55 | 1900 | 3300 |
| Gfrd, Mtchl, Wsnbkr | 1 Dull Knife | Parker #39 | 16,984 | 22,500 |
| Gfrd, Mtchl, Wsnbkr | 1 Roman Nose | Parker #86 | 4510 | 22,500 |
| HNG | 2 Haley "19" | Parker #74 | 20,374 | 18,500 |
| Hilliard O&G | 1 Amburgy | Gene Hodge #2 | 8700 | 9300 |
| Shell | 150 Scaly-Smith | Warton #5 | 8599 | 9800 |
| Tahoe | 1 Hendricks "A" | Red Bic #4 | 3500 | 4200 |

YOAKUM COUNTY

| | | | | |
|---|---|---|---|---|
| Shell | 4224 Denver Ut. | Verna #6 | 4240 | 5320 |
| Shell | 5411 Denver Ut. | Verna #2 | 4210 | 5250 |
| Shell | 1716 Denver Ut. | Verna #9 | 5250 | 5300 |
| Shell | 1717 Denver Ut. | Verna #9 | Spud | 5300 |
| Texaco | 2127 Roberts Ut. | Cactus #52 | 3934 | 5300 |
| Texaco | 3217 Roberts Ut. | Cactus #67 | 2320 | 5300 |
| Texaco | 3326 Roberts Ut. | Cactus #51 | 4206 | 5300 |
| Texaco | 4222 Roberts Ut. | Cactus #67 | 2320 | 5300 |
| Texas Pacific | 274 Bennett Ranch Ut. | D-B #9 | TD | 5500 |

CHAVES COUNTY

| | | | | |
|---|---|---|---|---|
| Shell | 8 Amoco Federal | Cactus #68 | 3850 | TD |
| Yates | 1 Tom Tom | Capitan #7 | 3497 | 4700 |

EDDY COUNTY

| | | | | |
|---|---|---|---|---|
| Anadarko | 1 Federal Com "2" | Warton #6 | 6412 | 12,000 |
| Antweil | 1 Mesa Arriba | Morenco #7 | 6880 | 11,600 |
| Antweil | 1 Rio | Morenco #8 | Logging | 12,000 |
| Atlantic | 372 Empire Abo "I" | Empire #1 | 2582 | 6400 |
| Atlantic | 381 Empire Abo "I" | Empire #1 | TD & Logging | 6300 |
| Atlantic | 183 Empire Abo "E" | Empire #6 | 6180 | 6400 |
| Atlantic | 91 Empire Abo "M" | Empire #6 | Spud | 6400 |

EDDY COUNTY (Cont'd)

| | | | | |
|---|---|---|---|---|
| Atlantic | 1 State "BU" | Ard #2 | 10,888 | 10,90 |
| Bennett & Ryan | 1 Penasco | McVay #4 | 6305 | 9000 |
| C&K | 1 Carlsbad "12" | Sharp #37- | 8840 | 12,00 |
| Exxon | 1 Laguna Grande | Delta #3 | 1260 | 12,00 |
| Exxon | 2 Laguna Grande | Delta #1 | 3612 | 12,00 |
| Exxon | 1 NM "CU" State | Marcum #3 | 3684 | 10,50 |
| Gulf | 1 North Shugart | McVay #9 | 9786 | 12,00 |
| HNG | 1 Valdez "5" Com. | Warton #4 | 8412 | 13,50 |
| Moncrief | 5 Lechguilla Canyon | Ard #6 | 7890 | 11,00 |
| Monsanto | 1 Myers | Cactus #24 | 1180 | 9000 |
| Penroc | 5 Ross Draw | Morance #5 | 8520 | 8500 |
| Southland | 1 Featherstone State | Hondo #3 | 1655 | 11,30 |
| Texas Pacific | 1 Glenn Farmer | Ard #1 | 6384 | 8100 |
| Western | 1 Bass | McVay #8 | 1684 | 11,50 |
| Yates | 3 Box Canyon | Ard #7 | 8460 | 8600 |
| Yates | 1 Dinkus State | Morance #9 | 8912 | 8900 |
| Yates | 4 Williamson "BC" | Morance #2 | 3788 | 11,60 |

LEA COUNTY

| | | | | |
|---|---|---|---|---|
| American Quasar | 2 Brinninstool | Cactus #31 | 13,089 | 14,50 |
| Atlantic | 11 Wimberly | Cactus #53 | 7277 | 7400 |
| Cleary | 1 NM Federal "E" Com. | Warton #1 | 14,348 | 14,10 |
| Getty | 1 NM "J" NCT | Hondo #7 | 6498 | 8000 |
| Gulf | 424 Central Drinkard | MGF #10 | 6558 | 6750 |
| Gulf | 1 Lea "RL" State | McVay #10 | 14,296 | 16,00 |
| Ledbetter | 2 Jay Federal | Cactus #66 | 2124 | 3700 |
| Leonard Bros. | 6 Leonard Bros. | Cactus #66 | 250 | 4000 |
| Maralo | 1 Carson Federal | Forster #4 | 9391 | 12,00 |
| Marathon | 18 Lou Wortham | Cactus #64 | 7390 | 7700 |
| Newbourne | 1 State "G" | Cactus #3 | 4590 | 13,50 |
| Oil Dev. | 1 State "9" | Hondo #5 | 11,250 | 12,50 |
| Texas Pacific | 1 Reed Federal | Cactus #54 | 3914 | 5000 |
| Tipperary | 1 State "28" | Tri-Service #6 | 9591 | 12,50 |
| Union Calif. | 1 Cinch State | Robinson Bros. #2 | 10,700 | 10,70 |
| Yates | 1 E. D. Powell "A" | Byrd #3 | TD 3750 | 3600 |

SOCORRO COUNTY

| | | | | |
|---|---|---|---|---|
| TransOcean | 1 Major SFPRR | Loffland #12 | "TIGHT" | |

The Following Rigs Are Stacked, Rigging Up, Moving, Etc.

TEXAS

| | |
|---|---|
| Tom Brown | RU on SL |
| Tom Brown #16 | Moving |
| Tom Brown #20 | Moving to Bakersfield |
| Brahaney #6 | Stacked |
| Byrd #1 | Moving for Phillips |
| Byrd #7 | Stacked for Conoco |
| Cactus #9 | Stacked in Midland Yard |
| Cactus #23 | Stacked |
| Cactus #30 | Moving |
| Cactus #60 | MI & RU for Mobil |
| Chico #4 | Moving to New Loc |
| Chieftan #1 | RU |
| Delta #36 | Stacked |
| FWA #4 | Moving to Midland Yard |
| FWA #8 | Stacked |
| FWA #17 | Stacked |
| Five P's #1 | Stacked |
| Richard Gray #2 | Stacked |
| Gulf #2 | RU |
| Loffland #227 | Moving for Monsanto |
| Norwood #1 | Moving for Aminoil |
| Thompson #4 | Stacked |
| Thompson #6 | RU for Gulf |
| Tri-Service #5 | Stacked in Midland Yard |
| Verna #5 | Moving |
| Verna #7 | Moving |
| Warton #31 | RU |

NEW MEXICO

| | |
|---|---|
| Big West #17 | Moving |
| Cactus #34 | Stacked |
| McVay #7 | Moving |
| Moranco #6 | Moving |
| Robinson Bros #4 | Derrick Repairs |
| Warton #7 | Moving |

Exhibit 2

Larry Adcock and Associates
Economic Consultants

SUMMARY

# SOCIOECONOMIC IMPACT ANALYSIS OF THE PROPOSED WASTE ISOLATION PILOT PLANT

APRIL, 1977

PREPARED BY:
LARRY D. ADCOCK
BASIL B. WEST

# STATEMENT OF EXISTING CONDITIONS

## 1.0 STUDY AREA

The proposed Waste Isolation Pilot Plant will be physically located within Eddy County. However, the impact anticipated from that plant will primarily affect both Eddy and Lea Counties. All of the following socioeconomic analysis will be limited to this primarily impacted area, Eddy and Lea Counties. The following analysis will cover the existing conditions, the expected impact and change during the construction phase, and expected impact and change during the operation phase.

Given the proximity of the plant to Carlsbad, it is expected that Carlsbad will receive 88 percent of the direct impact from the plant, both in terms of incomes and employment generated. Of those indirect impacts, i.e. those individuals and dollars connected with secondary and tertiary industries, approximately 80 percent will go to Carlsbad, 10 percent will leak off into the surrounding area inside Eddy County, and the remaining 10 percent will spread to Lea County.

## 2.0 POPULATION CHARACTERISTICS

In 1912 when New Mexico became a State, Eddy County contained approximately 9,600 people. The 1910 Census showed 9,684 individuals; by 1920 the population had dropped to 9,116, and population again rose to 15,842 in 1930. With the start of potash mining in 1931, growth between 1930 and 1940 was fairly substantial and showed an increase of nearly 9,000 persons, or a total of 24,311 persons. Between 1940 and 1960 Eddy County continued to grow principally because of the mining operations in the county. By 1960 the population had reached 50,783. However, in 1970 the activity in the mining sector decreased, and the population subseuqently dropped to 41,119. Between 1970 and 1975 this trend was reversed, and the population count of Eddy County again began to grow. The 1975 estimate released by the Bureau of the Census showed that Eddy County had grown to 42,400--an increase of approximately 1,300 people.

In 1917 Lea County was organized from parts of Chavez and Eddy Counties. By the time of the 1920 Census, the area now known as Lea County had 3,545 residents. Oil exploration began in southeastern New Mexico in 1924 which brought substantial growth to the county. By 1930 the population had increased to 6,144, and by 1940 had tripled to 21,154. Continued growth through 1960 reflected a population of 53,429 at the time of the Census. However, between 1960 and 1970 Lea County sustained a population decrease of approximately 7.3

percent. Between 1970 and 1975 the population of Lea County increased from 49,554, at the time of the 1970 Census, to 51,200 for mid-1975.

Thus, both counties sustained population decreases in the 1960 decade precipitated principally by depressed conditions in the mining sector, the basic industry supporting the economy in both counties. The decrease in the potash mining activity was caused by Canadian potash dumping on national and international markets.

Eddy County contains four municipalities: the Cities of Artesia and Carlsbad, and the Villages of Loving and Hope. The largest of these is Carlsbad which recorded a population of 21,297 in 1970. The estimates prepared for this study show that the population in mid-1976 has grown to 25,000--still below the population of 25,541 achieved in 1960. Artesia, the second largest municipality, recorded a 1970 population of 10,300. Again, this was down from a 1960 population of 12,000. Both the Villages of Hope and Loving are small. In 1970 Hope registered a population of 90, and Loving had a population of 1,192.

In Eddy County some 97.1 percent of the population is white by race, while only 2.2 percent are black by race, with an additional 0.7 percent of racial minority groups other than black. The Spanish ethnic group is fairly large; 25.4 percent of the population is of Spanish origin or descent.

Lea County has five municipalities: the Cities of Hobbs, Lovington, Eunice and Jal, and the Town of Tatum. In 1970 these municipalities had respective populations of 26,025, 8,915, 2,641, 2,602, and 982. In Lea County 93.7 percent of the population is white, while 5.3 percent of the population

is black, with 1.1 percent of minority groups other than black. The Spanish ethnic group is somewhat smaller in Lea County than in Eddy; only 10.9 percent of the population are of Spanish origin or descent.

In 1970, 76.9 percent of the population of Eddy County resided in urban places, approximately 18.1 percent of the population lived in rural non-farm settings, and 5.0 percent lived on farms. In Lea County the population was slightly more urban in distribution; 81.1 percent of the population resided in urban areas, while 15.1 percent resided in rural non-farm areas, and the remaining (approximately 3.8 percent lived on farms.

# STATEMENT OF EXISTING CONDITIONS

## 3.0 GENERAL ECONOMIC CHARACTERISTICS

There are three basic industries in the two-county area: in order of importance, they are mining, manufacturing and agriculture. Although government may be considered, in parts of New Mexico, a base industry because of heavy federal government activity, this is not the case for Lea and Eddy Counties. Most of the government activity in this area is of normal size and supportive of the area. On the other hand, the retail and services sectors are larger than might be expected from the general activity of the area. Eddy County encounters heavy tourist traffic attracted to Carlsbad Caverns; thus, the average size of the retail sector is somewhat above normal. Transportation facilities and the transportation sector within the area are well developed because of the existence of heavy-type industry activity within the area.

## 3.1 AGRICULTURE

In 1974 income figures prepared by the Bureau of Economic Analysis show that the agriculture industry's mainstay in the two-county area was meat animals and livestock. Total agricultural receipts in Eddy County in 1974 amounted to just over $31.4 million of which 59 percent was received from the animals and livestock sector. In Lea County slightly more than $20.9 million in receipts were registered from farm marketings in 1974. Of this amount

3.1 AGRICULTURE continued

62.4 percent came from meat animals and livestock. In the area of the proposed project the only agricultural activity present is that of cattle grazing.

3.2 MANUFACTURING

In 1976 there were 44 manufacturing companies in Eddy County and 47 in Lea County. Employment in manufacturing in Eddy County was approximately 930 in 1976, while employment in manufacturing in Lea County was close to 950. According to the latest information available, income from manufacturing in Eddy County in 1974 was between $8.7 and 8.8 million, while in Lea County income derived from manufacturing amounted to between $10.2 and $10.3 million. In 1974 manufacturing accounted for the second highest amount of income generated from "basic" type industry.

3.3 MINING

Mining is the major industry in both Eddy and Lea Counties. In Eddy County in 1976, mining employed approximately 5,200; in Lea County mining employed between 3,400 and 3,500. In both counties, employment in the mining sector was substantially larger than in any other identified industrial sector.

In Eddy County, potash mining is the primary mining industry; more than nine out of ten persons employed in mining work in the area of potash mining. Potash from Eddy County supplies a very large portion of total potash production in the United States. While recent figures have not been disclosed, in 1965 potash from New Mexico supplied 90 percent of total potash deliveries in the United States, Canada, and Puerto Rico. At that time point, mining employment in Eddy County was somewhat larger than it is today.

However, potash mining remains the principal basic industry in the county's economy.

In Lea County, most of the mining activity centers around the oil and gas industry, although other mining operations exist in potash, sand and gravel, rock, salt and caliche. Total mining employment in those activities other than oil and gas amounted to less than 200 individuals in 1976. Therefore, it is estimated that nearly 5,000 individuals are employed in the mining of oil and gas in Lea County.

Personal income from mining was over $36.6 million in 1974, or 21.5 percent of total personal income generated in Eddy County. Personal income from the mining sector in Lea County amounted to just over $59.7 million in 1974--26.7 percent of total personal income. This is, by far, the largest industrial sector in the county.

3.4 TRADE AND SERVICES SECTORS

The latest available information listing the total number of dollars and number of establishments in the two-county area in retail trade appears in the 1972 Census of Business. This Census shows a total of 1,068 retail outlets in the two-county area--454 of these located in Eddy County, and 614 of these located in Lea County. Within Eddy County the majority of the locations, some 281, are located in the City of Carlsbad.

Total sales volume for all 1,068 outlets in 1972 was about $185.9 million, or just over 8 percent of the more than $2.3 billion in retail sales throughout the State of New Mexico. Although no information is available after 1972, it is obvious that retail sales in the area have increased substantially.

3.4 TRADE AND SERVICES SECTORS continued 8

Employment in both wholesale and retail trade has increased from an average of 2,500 in 1972 to approximately 3,000 in 1976 in Eddy County alone. In Lea County, 1972 employment in both wholesale and retail trade was just under 3,600. In 1976, employment in this sector moved close to 4,400 people. Thus, the trade sector in the two-county area has shown substantial increase since 1972.

There were 835 establishments operating in the area of services--hotels, motels, barber shops, advertising, business services, repair shops, etc.--at the time of the 1972 Census of Business. In that year these establishments were doing an annual business of just over $32.6 million. The 835 establishments represented just over 10 percent of the total 8,273 such establishments throughout the State. However, their volume of about $32.6 million was only about 4.3 percent of the total volume of such establishments in New Mexico. Therefore, the average size of these businesses is somewhat below the state average. As in the trade sector, activity in the services sector has increased substantially since the 1972 Census of Business. In 1972 service sector employment in Eddy County was just less than 1,900. Preliminary estimates for Eddy County in 1976 put that employment at approximately 2,500, a substantial increase during the four-year period. In Lea County service sector employment is somewhat smaller than that in Eddy County. In 1972 that employment was slightly less than 1,800. Nevertheless, preliminary estimates for 1976 place employment in that sector at approximately 2,300 individuals, a substantial increase.

Analysis of the trade and services sectors indicates a steady increase in overall economic activity in Eddy County during the last three or four

years. This suspected boost in economic activity is also supported by information from the Employment Security Commission which shows 311 reporting establishments for retail trade in Eddy County through the second quarter of 1976. In the second quarter 1972 the reporting number was 300. The average number of employees per establishment has increased from just under 7 to over 8 in the four-year period.

In wholesale trade, the number of establishments reporting employment increased from 59 in 1972 to 70 in 1976. The average number of employees per establishment in wholesale trade increased from 6½ to almost 8 in the four-year period.

In the services sector, the number of establishments reporting employment has increased only slightly from 275 in the second quarter 1972 to 279 in second quarter 1976. Those establishments reported that the number of employees has increased from an average of 6.3 employees in 1972 second quarter, to 8.7 employees in 1976 second quarter.

## 3.5 FINANCIAL RESOURCES

In Lea and Eddy County combined there are a total of eight chartered banks--four of which hold state charters, and four national charters. Five of these eight banks are in Eddy County--three state banks and two national banks. As of December 31, 1976, these five banks reported assets totaling about $173 million and total deposits of nearly $161.6 million. In addition to the main offices, there are four branch locations. The main banking offices are located in the two major municipalities in Eddy County--Artesia

and Carlsbad. Carlsbad has three banks--two state and one national--with assets totaling close to $104.3 million, and total deposits of just over $98.6 million.

In Lea County the only chartered state bank is located in Hobbs. One of the national banks is also lcoated in Hobbs, and the remaining bank has main offices in Lovington. In addition to the main offices, there are 13 branches located throughout Lea County. Total assets for the three banks combined are slightly less than $236.9 million, while total deposits are slightly more than $218.9 million.

In addition to the banks, other financial institutions within the two-county area include four savings and loan institutions, and three credit unions. Three savings and loan institutions are mutual associations located in Eddy County, and the one capital stock savings and loan institution is located in Lea County. All four have combined assets of almost $114.7 million. Total savings within the institutions amount to approximately $103.8 million. The three mutual savings and loan institutions in Eddy County have combined assets of more than $95.8 million and total savings of more than $87.1 million. The savings and loan capital stock institution located in Hobbs (Lea County) has total assets of more than $18.8 million and about $16.7 million in total savings.

Of the three credit unions in the two-county area, two are located within Eddy County. Both of these credit unions are insured by the National Credit Union Administration. The credit unions in Eddy County are for school employees--one in Carlsbad and one in Artesia. They have combined assets of

more than $1.8 million, and combined shares and deposits of about $1.5 million. The credit union located in Lovington (Lea County) is insured by the New Mexico Credit Union Insurance Corporation. It has total assets of slightly more than $1 million, and total shares and deposits of $.9 million.

Twenty-one small loan licenses are doing business in the two-county area, 11 of which are located in Eddy County and 10 of which are located in Lea County. Distribution of the small loan operations are as follows: Carlsbad, 6; Artesia, 4; and Lovington, 1; and in Lea County, Hobbs, 7; Jal, 1; and Lovington, 2.

## 3.6 PERSONAL INCOME

Combined total personal income in Lea and Eddy Counties was listed by the Bureau of Economic Analysis as $394.4 million in 1974 (the latest available information). Of this amount, residents of Eddy County received $170.4 million and the residents of Lea County received $224 million. The combined two-county area accounts for about 6.3 percent of total personal income generated in the State of New Mexico. Total personal income in Lea County has been showing steady, but gentle, increases in recent years. However, Eddy County has not been as fortunate because of declines in activity of the potash industry in the middle and late 1960s. Eddy County sustained a decrease in total personal income in 1968, and in 1969 barely achieved the level established in 1967. However, since 1968, the total personal income in the county has been increasing--a small gain in the 1970-1971 period, and more rapid gains in the periods since 1971. While recent information is not available, trends in the area and the State would

indicate that total personal income has been increasing at slightly over 10 percent per year since 1974.

In both counties mining is the base industry generating the most total personal income. In Eddy County potash mining is the major component, while in Lea County, mining is centered around the oil and gas industry. In 1974 Eddy County's mining sector contributed between $36.6 and $36.7 million to total personal income, or about 21.5 percent of all income generated in the county. In Lea County, mining accounted for more than $59.7 million--nearly 26.7 percent of the total.

In both counties the second major sector contributing a total personal income is retail and wholesale trade--generally viewed as a "non-basic" sector. Other activities which may be identified as basic industries are agriculture and manufacturing, but these contribute very small amounts compared to mining, and retail and wholesale trade.

Per capita income in the two-county area varies between the counties. For example, Lea County's per capita income in 1977 was $4,480, or approximately 8 percent above the $4,139 registered statewide level. In Eddy County, however, the income was near the state average at $4,109, or about 1 percent below the state level. In Eddy County per capita income increased 37.2 percent between 1970 and 1974, while in Lea County per capita income increased 44.7 percent during the same period. The statewide level also increased 34 percent during the same period; thus, the per capita income for the two-county area is increasing slightly faster than the statewide average.

The Bureau of Economic Analysis reported that statewide per capita income grew more than 11 persent in 1975 and preliminary indications are that it is continuing to rise at a healthy rate. Given the trends in Eddy and Lea Counties, it can be assumed that per capita income in these two counties has also grown by at least 11 percent in each of the last two years.

3.7 TOURISM

It is important to note that tourism is a substantial portion of the economic activity in Eddy County. While outdoor recreation in the area centers around activities such as hunting, four-wheel driving, camping, etc., the nearby parks--Guadalupe Park, Living Desert State Park, the President's Park in the City of Carlsbad and others--also attract recreationists and tourists. The main tourist attraction in the area is Carlsbad National Park. In 1976, the total number of visitors to Carlsbad Caverns was 876,490, or more than 43 percent of all visits throughout the State to all 11 national parks and monuments.

The effects of these visits and the tourism in the area can readily be seen in the Employment Security Commission statistics for the area. Retail trade and selected services are most affected by tourism. For example, employment in eating and drinking establishments (a part of retail trade) more than triples in the three summer months throughout the county. In the area of services, employment in lodging will increase 60 to 70 percent during the summer months more than employment in the winter months. Additionally, other secondary and tertiary types of services impacted by

tourism also show substantial increases.

Therefore, tourism is one of the major economic sectors in Eddy County. However, it is highly seasonable due to the nature of visits at Carlsbad Caverns. Such visits fluctuated in 1976 from a high of 185,750 in July to a low of 25,160 in November. This variation illustrates the seasonality of the tourism industry in Eddy County. To support this tourist industry, the City of Carlsbad has a total of 18 motels and hotels with over 900 rooms. While additional facilities are found throughout the county, it is obvious that Carlsbad, due to its proximity to the Caverns, receives the major portion of the impact from this national park.

STATEMENT OF EXISTING CONDITIONS

## 4.0 LABOR FORCE

Labor force is defined by the Department of Labor as those persons who are employed and those persons who are unemployed and actively seeking employment. The combined total labor force in Eddy and Lea Counties is approximately 40,700. The annual average labor force in Lea County in 1976 was approximately 22,700, while in Eddy County the labor force was about 18,000. In 1976 total employment in the two-county area was 38,500.

The combined unemployment rate for the two counties was just over 5.3 percent. However, the unemployment rate varies significantly between the counties. Since 1973, when the economy of both Eddy and Lea Counties began to pick up, the total labor force has grown approximately 13 percent, or by roughly 4,700 individuals in the three-year period. Thus, the annual average growth rate in the labor force has been approximately 4 percent. The overall growth of employment in the area for the three-year period was 11.6 percent, which indicates an annual average growth rate in employment somewhat less than 4 percent. Therefore, the number of persons unemployed and the unemployment rate have been steadily increasing for the last three years.

## 4.1 EMPLOYMENT

Examination of employment by sector in the two counties shows that mining is, by far, the largest employer of the identified sectors. Manufacturing and agriculture, other basic sectors in the area, appear to have

approximately the same amount of employment. Accurate figures on agricultural employment are difficult to obtain and are normally out of date. The latest available credible information on agriculture shows that between 1,900 and 2,000 people were employed in agriculture in the two-county area in 1974. Agricultural employment in the area has been decreasing. Between 1973 and 1974 alone, the number of people working in agriculture dropped by over 5 percent. Today in the two-county area it can be estimated that between 1,700 and 1,900 people are presently employed in the agricultural sector. The manufacturing sector incorporates approximately 1,900 individuals within the two-county area. In Lea County approximately 925 individuals are employed in manufacturing, while in Eddy County figures indicate nearly 975 persons. Therefore, the manufacturing employment is fairly equally distributed between the two counties. Those non-basic sectors in the two-county area include contract construction; transportation utilities; trade; finance, insurance and real estate; and services. Additionally, the government accounts for a significant amount of employment.

In the two-county area it is estimated that by-sector employment distribution is as follows: agriculture, 5 percent; mining, 23 percent; manufacturing, 5 percent; construction, 7 percent; transportation utilities, 9 percent; wholesale and retail trade, 21 percent; finance,insurance and real estate, 4 percent; services, 15 percent; and government, 12 percent.1/

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1/ Total does not add to 100 percent because of rounding.

4.2 UNEMPLOYMENT

Unemployment is relatively low in the two-county area. By the end of 1976, the average unemployment rate in Eddy County was 6.7 percent, while in Lea County 4.3 percent was recorded. Unemployment varies significantly from month to month. Higher unemployment rates are generally recorded during the month of June each year, and lower unemployment rates are generally recorded in the late spring or late fall.

A review of those individuals applying for work through the New Mexico Employment Security Commission revealed a large number of technical occupations available in the area. Many of these occupations were directly connected with construction or with mining--the two occupational categories needed for the construction of the WIPP project. Additionally, this information showed a large number of clerical and secretarial skills available in the area.

4.3 UNDER UNEMPLOYMENT AND DISGUISED UNEMPLOYMENT

The unemployment rate computed by the state and federal governments is based upon those individuals actively seeking employment. In some cases, an area may experience a defined unemployment rate and have a significant amount of underemployment. Underemployment refers to occupations or jobs that do not take full advantage of an employed individual's potential. Also, disguised unemployment may exist in which case many individuals are not actively seeking employment but would take a job if a job were available in the area. These concepts are difficult to measure, particularly at the sub-

county level where no information is provided by the various Department of Labor programs.

Areas with significant underemployment can be identified by considering labor statistics in relation to wages. However, quantification of this relationship remains difficult. A review of the labor statistics and wages in the two-county area indicates that some underemployment may exist due to seasonality, but it does not appear to be significant in the labor market.

Disguised unemployment is also difficult to measure. However, a review of labor force participation rates by age groups indicates whether or not an area is experiencing disguised unemployment. In the two-county area the labor force participation rate of males is higher than the state average. On the other hand, it appears that the labor force participation rate for females is lower than the state average. It is assumed that not all females who are willing to work are actively seeking employment and that the labor force availability for females may be greater than the current labor force statistics would indicate.

STATEMENT OF EXISTING CONDITIONS

## 5.0 HOUSING AND LAND USE

### 5.1 HOUSING PROFILE

Vacancy rates for housing in Carlsbad are relatively low due to inactivity in new construction because of population losses experienced between 1960 and 1970. Since 1970, this trend has been reversed, and by the mid-1970s 200 to 250 new residential units are being produced each year in the City of Carlsbad. The estimated vacancy rate of 2.9 percent implies 263 available units to support new population growth.

### 5.2 LAND USE PROFILE

The zoning ordinance for the City of Carlsbad identifies eight zones for residential and business activity. Except for lands used for multi-family dwellings, development in the area has proceeded in accordance with the zoning classifications used. There are substantial nonconforming uses within the multi-family zone.

Substantial vacant land exists within the city for all zoning classifications. For example, it is estimated that 1,446 acres zoned for single-family dwellings is currently available.

STATEMENT OF EXISTING CONDITIONS

## 6.0 CARLSBAD COMMUNITY FACILITIES

Review of existing conditions on community facilities includes existing conditions for education, ground water, municipal water systems, waste water systems, electrical production, fire protection, law enforcement, medical and dental care, library facilities, communication services, and sports and recreation.

### 6.1 EDUCATION

The Carlsbad school district is served by 15 schools at all levels. There are ten elementary, two junior high, one mid high, one high and two private schools. Current enrollment is estimated at 6,812, and capacity is estimated at 9,638 students. This indicates that the school system could absorb an additional 2,826 students at all grade levels.

### 6.2 GROUND WATER AND MUNICIPAL WATER SYSTEMS

The City of Carlsbad currently draws its water supply from Capitan Reef. The reef aquifer is allocated 22,128.51 acre feet of water rights per year. Carlsbad has been exceeding water right withdrawals from the reef aquifer for the last two years. However, Carlsbad has acquired an additional 1,000 acre feet of water per year. Production and transportation systems must be built to exploit these water rights.

6.3 MUNICIPAL WASTE WATER SYSTEMS AND TREATMENT FACILITIES

The City of Carlsbad currently has a collection and treatment capability of approximately 4.5 million gallons per day of waste water. The existing trickling filter treatment system is undergoing improvements which will result in a design capacity of 6 million gallons per day and substantial improvement in the quality of treated effluent.

6.4 ELECTRICAL SERVICES

Electrical services are provided by the Southwest Public Service Company. Current service area demand totals approximately 60 to 80 megawatts serving 10,667 residential customers, 1,213 commercial customers, and 30 special contract customers. The company requires approximately six months lead time to provide services for a subdivision. Adequate power appears to be available to the service area for anticipated growth.

6.5 FIRE PROTECTION

Fire protection services are provided by both city and county governments. The city mans and operates a 24-hour fire protection operation, whereas the county fire services are provided by volunteer departments. The Insurance Service Organization recommends two firemen on a 42- to 56-hour work week per 1,000 population. Carlsbad currently has a ratio of 0.67 per 1,000 population.

6.6 LAW ENFORCEMENT

Law enforcement in the City of Carlsbad and Eddy County is provided by local city and county governments. The City of Carlsbad operates its

police department with 41.5 persons; the county government provides law enforcement services through its sheriff's department which employs 23 personnel. The FBI guide to manpower requirements recommends 2.5 officers per 1,000 population. Carlsbad had a ratio of 1.1 per 1,000 population.

6.7 MEDICAL AND DENTAL CARE

A regional medical center consisting of a 124-bed hospital is located in the City of Carlsbad. There are currently 30 M.D.'s with various specialties and 10 dentists serving the community. There is a 134-bed full-service hospital under construction. The national average of physicians per 1,000 population is approximately 1.53. The City of Carlsbad has a physician per 1,000 population ratio of 1.2.

6.8 LIBRARY FACILITIES AND SERVICES

The city government in Carlsbad operates a municipal library with 37,271 volumes. The American Library Association standards recommend two volumes per capita; Carlsbad currently has approximately 1.5 volumes per capita.

6.9 GARBAGE COLLECTION AND DISPOSAL

The City of Carlsbad provides solid waste collection and disposal services. Collection services are provided by rear-loading packers and the land fill is a daily trench and fill operation. A refuse collection vehicle in Carlsbad has a production capability of approximately 450 households per day.

## 6.10 TRANSPORTATION FACILITIES

There are no mass transit systems serving the general population in Carlsbad. However, transportation services do exist to serve specialized needs. For example, an industrial bus service transports workers from the community to the potash mines and operates on a daily basis. There are approximately 28 buses with a capacity of 40 passengers each which make these daily trips to the mines.

A survey of traffic counts at high volume intersections within the City of Carlsbad indicates that substantial excess capacity exists within the street system.

## 6.11 COMMUNICATION SERVICE FACILITIES

Telephone communication services are provided by GTE. There are approximately 21,450 telephone instruments in service including 1,547 business and 9,316 residential main lines. GTE is presently implementing an expansion of services in the Carlsbad area which will provide for installation of 1,800 new lines. The planning period for installing the new lines is approximately 18 months.

## 6.12 SPORTS AND RECREATION

It has been estimated that approximately 1.8 million visitors come to the Carlsbad area each year. These visitors enjoy a variety of recreational activities including fishing, swimming, boating, hunting, and visits to Carlsbad Caverns and the Zoological Botanical State Park.

# ANTICIPATED IMPACT OF THE WIPP CONSTRUCTION AND OPERATION

## 1.0 GENERAL ECONOMIC IMPACTS

The construction phase for the Waste Isolation Pilot Plant (WIPP) is expected to begin in 1979 and end about May of 1983. During that time, substantial increases in the number of construction workers within the labor market area are expected. In addition to these construction workers, a below-ground construction phase--similar to a mining operation--will also take place concurrently with the above-ground construction phase.

As a result of the construction and mining-type activities, those industries serving the population (generally secondary and tertiary industries) and those industries which service other businesses (basically, some manufacturing, service and wholesale operations) will also experience substantial increases in activity (i.e., dollar volume and need for additional employees).

The location of the Waste Isolation Pilot Plant is within Eddy County; however, the socioeconomic analysis assumes that the primary impact will be spread over two counties--Eddy and Lea Counties. The survey of existing patterns indicates the following: approximately 88 percent of the direct impact connected with the plant will go to the City of Carlsbad; 11 percent of the impact will go to areas within Eddy County, but outside of Carlsbad; and approximately 1 percent of the impact will go to Lea County.

In terms of indirect impact, 80 percent was allocated to Carlsbad, 10 percent was allocated to areas outside of Carlsbad within Eddy County, and the remaining 10 percent was assumed to spread into the Lea County area. The

operation phase for the Waste Isolation Pilot Plant is expected to begin in 1983. However, the impact from the operational phase is expected to be below average in 1983; it is not until 1984 that the near-full impact of the operational phase will be felt in the two-county area.

During the construction phase nearly $222 million will be directly expended on the two-county economy. In addition, indirect, or spin-off, effects of an additional $117 million will occur. On an annual basis, the greatest amount of economic activity during a single year is expected to be below $90 million which will occur sometime during the period 1980-1982. As the Waste Isolation Pilot Plant construction phase ends and the plant becomes operational, the impact upon the community is expected to change significantly.

Beginning in 1983, as the construction is completed during the first four months of the year, operation activity will take over. It is expected that at least $15 million in operating expenditures will occur during 1983. During 1983 indirect impact from the operation phase will amount to just over $8.1 million. Thus, total direct and indirect impact from operation in 1983 will be $23.1 million.

Beginning in 1984 some $40 to $52 million in expenditures will be made for the operation phase. However, only about 80 percent of the actual operation cost ($40 million) plus $2 million for continuous construction, will flow into the Carlsbad economy directly. This amounts to some $34 million dollars annually, after full operation phase begins in 1984. It is anticipated that beginning in 1984, and for an additional 23 years, the economic impact of the operation, both direct and indirect will amount to $55.7 million annually ($21.7 million indirect expenditures).

1.1 EMPLOYMENT AND POPULATION 3

During 1979--the first year of the construction phase--direct employment due to the construction of the Waste Isolation Pilot Plant above ground will result in just over 400 additional construction jobs. While the above-ground construction phase is being completed, the below-ground operation--very similar to potash mining operation--will also be occurring which will employ just less than 200 individuals. The nature of the Waste Isolation Pilot Plant requires an additional 19 individuals because of equipment sophistication and construction preciseness in the area for engineering and inspection. Therefore, a total of approximately 619 individuals will be directly employed during the first year of construction in 1979.

During the approximate three-year period following 1979, until May 1983,* an average of 529 individuals will be employed in the above-ground construction phase, and 193 workers will be employed in the below-ground operation phase. The inspection and engineering crew will remain at approximately 19. Therefore, an average employment of 741 individuals will be directly attributable to the Waste Isolation Pilot Plant during the years of 1980, 1981, and 1982. Approximately 56 percent of the direct employment during the construction phase will be individuals not now residing in the area; the remaining 44 percent is assumed to be drawn from the labor force in Eddy County, with a few coming from the Lea County area.

Indirect job impact associated with the first-year construction of the Waste Isolation Pilot Plant is estimated to be 1,172 jobs. From 1980 through the end of 1982, it is expected that an annual average of slightly over 1,400

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*Phase-down is assumed during the first 4 months of 1983; thus the average of 529 employees may not be met.

jobs will be an indirect result of the construction of the Waste Isolation Pilot Plant.

Of those jobs created as an indirect result of the construction phase of the WIPP project, it is estimated that some 46 percent will be filled by newcomers to the area who are attracted by new employment opportunities.

During the first year of construction, approximately 1,600 new individuals will migrate to the area. In 1980 an additional 1,300 will be attracted to the area; in 1981 the impact of the construction phase is expected to be complete with an additional 400 migrants. Thus, in 1982, the final full year of construction, the impact of the Waste Isolation Pilot Plant on the area should be static, with 3,300 total new individuals attracted to the two-county area.

It should be noted that during the years of plant construction, the unemployment rate is expected to drop substantially--to an overall rate of approximately 3.5 percent for the combined two-county area. This, however, is not an unusual unemployment rate for these counties. In 1976, Lea County experienced monthly unemployment rates as low as 3.1 percent and an overall average of 4.3 percent for the year. During the 1960s when economic conditions were somewhat depressed in the two-county area, the unemployment rate in Eddy County never rose above 6.9 percent (1963) on an annual basis, and was as low as 4.6 percent (1960). In Lea County during the 1960s the unemployment rate was 3.8 percent in 1963, and as low as 2.8 percent in 1968. However, a level of 3.5 percent will essentially constitute an area of labor shortage, given today's unemployment rates and conditions throughout the State and the Nation.

1.1 EMPLOYMENT AND POPULATION continued 5

The following table shows the population for Eddy and Lea Counties, the municipality of Carlsbad, and the Carlsbad School District. Population projections are presented for the area with and without the Waste Isolation Pilot Plant. The population figures end in 1985, since it is assumed that the operational phase will be static in terms of impact by that time.

The most significant population impact will be felt by the year 1981 when approximately 2,700 individuals will have been added to Carlsbad's population due to the construction of the plant. The impact on the school district is expected to be 2,900 individuals, while throughout Eddy County an additional 3,100 people are estimated.* In Lea County by 1980 an additional 200 people will be added to the population. After that time, it is assumed that impact of the plant will be essentially static until 1983.

As the operation phase begins and construction is completed, population and employment characteristics will change significantly. For example, the number of people required during the construction phase is substantially greater than the work force in the operation phase. During the construction phase total employment is expected to be approximately 741 people during the most active years; by 1984 employment directly connected with the operation will total only 427 individuals. Most of these, slightly over 300, will be directly connected with the general operation of the plant, while between 75 and 80 persons will be working on continual mining operations, and approximately 40 individuals will be employed in maintenance and additional construction work. In addition to these jobs directly created by all operation activity, there will be between 950 and 1,000 jobs indirectly created by the operation phase.

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* Figures are for concentric geographic areas, and are not additive.

| BASELINE POPULATION WITHOUT WIPP PROJECT | POPULATION | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1970[1] | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 | 1984 | 1985 |
| Eddy County [1,2] | 41,119 | 42,400 | 43,400 | 44,300 | 45,300 | 46,200 | 47,200 | 48,100 | 49,400 | 49,800 | 50,700 | 51,600 |
| Carlsbad [1,3] | 21,297 | NA | 25,000 | 26,000 | 27,000 | 27,900 | 28,700 | 29,400 | 30,300 | 30,600 | 31,100 | 31,700 |
| Carlsbad School District [1,3] | 25,498 | NA | 28,400 | 29,400 | 30,400 | 31,300 | 32,100 | 32,800 | 33,700 | 34,000 | 34,500 | 35,100 |
| Lea County [1,2] | 49,554 | 51,200 | 53,000 | 54,100 | 55,200 | 56,300 | 57,400 | 58,800 | 60,200 | 61,700 | 63,100 | 64,500 |
| POPULATION WITH WIPP PROJECT [4] | | | | | | | | | | | | |
| Eddy County [4] | | | | | | 47,700 | 49,900 | 51,200 | 52,500 | 52,500 | 52,800 | 53,700 |
| Carlsbad [4] | | | | | | 29,200 | 31,100 | 32,100 | 33,000 | 33,000 | 33,000 | 33,600 |
| Carlsbad School District [4] | | | | | | 32,700 | 34,700 | 35,700 | 36,600 | 36,500 | 36,500 | 37,100 |
| Lea County [4] | | | | | | 56,400 | 57,600 | 59,000 | 60,400 | 61,900 | 63,200 | 64,600 |

1 1970 Census of Population data.
2 1975-1985 data, modified BBER, University of New Mexico projection, April, 1976.
3 1975-1985 data, new data for this report.
4 1979-1984 data, new data for this report.

Therefore, the total number of jobs both directly and indirectly created through the operation phase will be about 1400. This increased job-level is expected to be achieved during 1984. Between 1982 (the last full year of construction) and 1984 (the first full year of operation) employment adjustments in the quantity of people directly connected to the project, and the types of occupations required by the project will have to take place. During the construction phase some 529 jobs, on an average annual basis, were created directly by construction activity. The continual construction activity in the operation phase is expected to employ only 40 people. Therefore, a loss of slightly less than 500 positions is expected in construction-related trades.

The mining effort runs concurrently with the construction phase and the operation phase of the WIPP project. However, during the construction phase 193 persons will be employed in that effort while only about 75 people will be employed in the mining effort during the operation phase.

Under the operation phase the types of occupations and skills required may dictate that from 150 to as high as 170 jobs will be filled by individuals not currently in the area. The shuffling of population due to losses of construction jobs, mining jobs and increases of operation jobs, will result in a net population decrease of those individuals directly and indirectly connected with the Waste Isolation Pilot Plant project.

It is expected in 1983 that the out-migration of slightly more than 400 individuals will occur because of the construction-to-operation shift. In 1984 it is estimated that just less than 300 individuals will migrate out of the area who were either directly or indirectly connected with the Waste

1.1 EMPLOYMENT AND POPULATION continued 7

Isolation Pilot Plant construction. It is interesting to note that during the 1982-1984 period the population figures for Carlsbad will remain constant at approximately 33,000, while the other areas within Eddy County will continue a slight growth pattern due to natural increase and other activities in the area. The effect on Lea County of the change from the construction to operation phase is expected to be a net loss of approximately 100 individuals.

1.2 PERSONAL INCOME

During the 1979-1982 construction period, it is expected that a total of more than $43.1 million will flow directly into wages and salaries from the construction of the plant. In addition to this amount of money, slightly more than $31 million will be derived in wages and salaries from those businesses indirectly affected by the construction.

Personal income derived from interest, dividends and rent is expected to increase nearly $16.4 million during the four-year period. A total of about $90.6 million is expected to be derived both directly and indirectly in the private sector, due to the construction of the WIPP Project during the 1979-1982 period with some spillover into 1983. In the public sector, nearly $11 million in personal income will be derived because of the increased activity in the area and additional government employment required for support. Thus, total personal income added to the area during the construction phase of the WIPP project is expected to be $101.6 million spread

over a four to five year period. However, net loss from transfer payments will decrease this total to $97.0 million.

Carlsbad will receive approximately $82.5 million of the additional personal income; other areas inside Eddy County, but outside Carlsbad, will receive nearly $10.3 million; and additions to total personal income in Lea County will amount to $4.2 million. During the construction period, it is anticipated that personal income will flow in the following manner: just over 15 percent will be derived in 1979; just less than 25 percent will be derived in 1980, 1981, and 1982; and nearly 11 percent will be derived during 1983, the final partial year of construction.

The personal income to be derived from the operation of the WIPP project will be significantly different from that derived in the construction phase. The amount of money flowing directly into the economy during a normal year of operation will be approximately $34 million, but this figure may vary depending upon expenditure patterns in the operation of the plant. This study uses a constant figure of $34 million as direct expenditures of the plant. This figure is significantly different from total direct expenditures of nearly $52 million annually during the period in which the major portion of construction will be completed.

The $34 million estimated annual flow of dollars directly associated with the operation of the plant will mean that: 1) approximately $9.4 million will be allocated to wages and salaries of those individuals connected directly with the plant; 2) wages and salaries derived from the indirect effect on businesses within the area will amount to $5.8 million;

3) government expenditures brought about by additional activity and flowing into personal income will total between $2.2 and $2.3 million per year; 4) new dividend interest and rent is estimated to create approximately $3.4 million in personal income; and 5) just over $0.9 million will flow out of the area via transfer payments for social security. The net result, therefore, is an increase in total personal income on an annual basis of approximately $19.9 million.

During the transition between construction and operation in 1983, the total personal income being derived from the operation phase will be substantially less than income during the construction phase. However, in addition to the income generated by the operation phase, the construction phase will continue during the first four months of 1983. Approximately, $7.2 million in total personal income will flow from the operation phase, both directly and indirectly, and an additional $10.4 million will flow from the remaining portion of the construction phase. Therefore, in 1983, total personal income from both the construction and the operation phases (i.e., the transition period) will amount to $17.6 million.

When the operation phase reaches its full impact, approximately 83.4 percent of the total personal income generated both directly and indirectly from the plant will go to the Carlsbad area; approximately 10.6 percent will flow to areas outside of Carlsbad, but inside Eddy County; and, the remaining 4.0 percent personal income increase will flow into Lea County.

ANTICIPATED IMPACT OF THE WIPP CONSTRUCTION AND OPERATION

## 2.0 HOUSING AND LAND USE

### 2.1 HOUSING

A total of 2,963 units of housing of all types will be necessary if WIPP locates in the Carlsbad area. If the WIPP project does not locate in Carlsbad, it is estimated that 2,283 housing units of all types will be necessary. The impact of the WIPP project on housing totals 680 units.

Timing of delivery and type of demand for housing (i.e., mobile homes, single-family detached, multi-family) varies over construction and operation time periods. For example, the demand for mobile home units reaches a peak of 453 units in 1982 with the WIPP project. In 1985 the demand for mobile home units totals 285 with the WIPP project.

The following impacts were identified: 1) An increase in construction capability must occur. It is estimated that the construction industry can produce approximately 75 percent of the housing required over the term of the project. 2) The demand for housing, by type, is expected to shift over the time period and some types of housing will be oversupplied. This is particularly the case for mobile homes. 3) There are identifiable time lags which may vary from six months to one year for housing production. These time lags are associated with processes required by local ordinances such as obtaining proper zoning, drainage plans prepared by engineers, street design plans prepared by engineers, and utility installation necessary for construction to begin.

2.2 IMPACT FOR LAND USE 11

The analysis of impacts on land use with and without the WIPP project, included determining: 1) total new land required for residential development; 2) total new land required for multi-family dwellings; 3) total new land required for mobile home parks and subdivisions; 4) total new commercial land required; 5) total new industrial land use; and 6) total new land devoted to public rights-of-way.

Based on the analysis of these types of demand it was determined that 604 undeveloped acres would be placed into use. There is adequate undeveloped acreage within the City of Carlsbad for all types of land use required except mobile home parks and mobile home subdivisions. An additional 45 acres must be zoned for mobile home parks and an additional 15 acres must be zoned for mobile home subdivisions if the WIPP project locates in Carlsbad.

ANTICIPATED IMPACT OF THE WIPP CONSTRUCTION AND OPERATION

## 3.0 PRIVATE SECTOR

The private sector is strong in both Lea and Eddy Counties. However, the economic base in the private sector is rather narrow. Most of the economic activity centers around the mining industry. In Lea County, the oil and gas industry generates more economic activity than any other industrial sector, while in Eddy County, potash mining is the most active sector. In addition to these two basic industry sectors, retail trade and services (normally non-basic sectors) may be considered to be partly a basic industry in Eddy County. This is brought about by heavy tourism traffic in the area of Carlsbad Caverns. The direct impact from this tourist traffic is felt through the retail trade and services sectors.

Other basic industries in the area such as agriculture and manufacturing have substantially less activity than the mining sector. Fertilizer production, i.e., manufacturing of chemicals, is significant in the two-county area and accounts for a significan amount of employment in the total manufacturing sector.

### 3.1 INDUSTRIAL ACTIVITY

During the construction phase of the WIPP project, certain currently existing industries within Eddy County are expected to receive a substantial

increase in activity. Because of the nature of construction of the WIPP project, and the needs for specific and highly technical equipment, a significant amount of the construction materials and probably most all of the technical equipment will be purchased outside of the area. However, basic materials going into the construction, such as sand and gravel, rock, certain electrical products, concrete, etc., can be purchased in the area. It is anticipated that during the total construction phase approximately $17.5 million in new business will flow through the manufacturing sector in the two-county area.

As the Waste Isolation Pilot Plant project moves from the construction phase into the operation phase, the effect on the various economic sectors within the two-county area is expected to change significantly. The operation phase of the WIPP project will be very similar to the warehousing operation, with two exceptions: 1) the mining operation will continue, and 2) at the same time approximately $2 million annually in maintenance construction is expected.

Under the operation portion of the project the impact upon local manufacturing is expected to be minimal. However, those entities that would experience some impact are paints and chemicals, rubber and leather products, and machinery manufacturing. As a result of plant location in the area, impact may be felt indirectly in the food products area of manufacturing. Impacts to other areas of manufacturing will be minimal. Because the operation phase does not produce a product, but in a technical

sense stores a product previously produced, the estimated amount of spinoff to the industrial manufacturing system within the county is minimal.

The effect of the mining operation may also be minimal in attracting new industry because potash mining dominates an extremely large portion of the economy of Eddy County. The mining operation of the project represents an addition to this already-existant activity, and therefore the impacts from the mining operation will flow through those industries already established for the most part.

In the construction sector, the $2 million allocated per year to the construction sector will generate some activity. However, this amount is not expected to be enough to attract new industry to the area which is directly attributable to construction.

3.2 RETAIL TRADE AND SERVICES

One of the most significantly affected sectors outside of those industries receiving direct impact, such as construction and mining, is retail trade. It is expected that the increase in retail sales during the construction period will total nearly $24 million. The heaviest impact (about $5.4 million annually) in the retail sector will come in the years 1980, 1981, and 1982 as employment -- directly and indirectly due to the construction activity -- reaches its peak. Most of this impact is created through increased buying in the household sector with some expenditures made directly by construction-related purchases. Between 15 and 20 percent of household income goes directly into the retail sector. Additionally,

businesses also purchase from the retail sector. For example, approximately 5 percent of construction expenditures are made in the retail sector.

In the services sector, substantial increases are also expected. Nearly $22 million in increased activity, both directly and indirectly, will flow through the services sector. In addition to this amount, approximately $1.7 million per year can be expected from the professional engineering portion (usually classified as a business service) of the construction activity. Thus, $22 million is an anticipated minimum flow which could increase by $6.8 million (4 x $1.7 million) during the four to five year construction period if professional engineering services are included.

As a final note, it should be pointed out that this impact assumes that the construction phase demand for goods and services takes advantage of those goods and services available in the area, and that the variety of goods and services offered in the area receives no substantial change in the construction period.

Beginning in 1984 it is estimated that the addition to retail sales in the area will amount to $3.8 million annually. This is, by far, the greatest impact on any identified sector. Therefore, much of the impact in the operation phase will flow into the secondary and tertiary industries, not into the manufacturing or basic-type industries. This is further justified by the fact that the increase in wholesale trade is expected to be approximately $1.9 million, while the annual impact going to finance, insurance and real estate is expected to be approximately $2.2 million. The services sector will enjoy a substantial increase also--just over $3.2 million per year annually.

In summary, it would appear that the private sector response to both the construction and operation phases in the two-county area will come in the form of new activity in many of the existing secondary and tertiary industries. It is expected that the operation phase will bring very few new manufacturing firms. However, it is also recognized that small equipment manufacturers and fabricated metal operations may be attracted to the area because of the maintenance and construction occurring during the operation phase and the need for certain repairs to equipment during the operation phase.

ANTICIPATED IMPACT OF THE WIPP CONSTRUCTION AND OPERATION

## 4.0 COMMUNITY FACILITIES

### 4.1 EDUCATION

Impact on the educational system was determined by estimating total student enrollment, with and without the WIPP project, for each of the years 1979 through 1985. It was determined that 1,232 students would be enrolled at the high school level with the WIPP project in 1979. This figure will exceed current high school capacity of 1,225 students. This problem is apparent only during the year 1979, and only for high school enrollment; increased enrollment at other levels can be accommodated by existing facilities.

### 4.2 UTILITY SYSTEMS

#### 4.2a Ground Water and Municipal Water Systems

Water demand, with and without the WIPP project, was estimated. It was determined that 703 acre feet of additional water would be attributable to primary and secondary population increases associated with the WIPP project. This additional water demand magnifies an existing problem; the City of Carlsbad is currently exceeding its water rights withdrawal capacity from its wellfield in the Capitan Reef. For example, the total amount of water pumped in 1976 amounted to 9,268 acre feet, 1,426 acre feet in excess of withdrawal rights. It is estimated that the City of Carlsbad will require an additional 2,295 acre feet per year on the average, should the WIPP project

4.2 UTILITY SYSTEMS continued 18

4.2a Ground Water and Municipal Water Systems continued

become a reality. This amount is in addition to current excess over withdrawal rights.

In summary: 1) The City of Carlsbad will require an additional 2,295 acre feet per year, on the average, should the WIPP project become a reality. Of this amount approximately 703 acre feet per year are directly attributable to the WIPP project. 2) The City has adequate water rights to supply additional water. 3) The City has adequate well field to produce additional water. 4) The location of water rights and well field capacity serves as a constraint for production of adequate amounts of water to serve increased population.

4.2b Wastewater Treatment

Estimates were made of the number of millions of gallons per day of discharge associated with the population increase in Carlsbad with and without the WIPP project. It was estimated that an additional flow of 0.175 million gallons per day could be attributed to the population increase associated with primary and secondary employment resulting from the WIPP project.

A major capital improvements program for wastewater treatment is anticipated. Thus, processing requirements of volumes associated with the WIPP project will not be problematic. In 1982, when the new plant is scheduled to begin operation, it will be operating at approximately one-half of capacity.

4.3 LAW ENFORCEMENT AND FIRE PROTECTION

Estimates were made of the increased personnel in law enforcement and fire protection required to maintain the existing ratio of personnel per