

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON MONOPOLY

OF THE

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

NINETY-FIRST CONGRESS

SECOND SESSION

ON

PRESENT STATUS OF COMPETITION IN THE
PHARMACEUTICAL INDUSTRY

PART 16

FEBRUARY 24, 25; MARCH 3 AND 4, 1970

ORAL CONTRACEPTIVES (VOLUME TWO)



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COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition In the Pharmaceutical Industry)

TUESDAY, FEBRUARY 24, 1970

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

The subcommittee met, pursuant to notice, at 9:35 a.m., in room 4221, New Senate Office Building, the Honorable Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson, Javits, Dole, and Hatfield.

Also present: Benjamin Gordon, staff economist; Elaine C. Dye, clerical assistant; James P. Duffy III, minority counsel; and Dennison Young Jr., associate minority counsel.

Senator NELSON. We will resume hearings at this time. Our first witness this morning is Dr. Francis Kane, Department of Psychiatry, University of North Carolina Medical School, Chapel Hill, North Carolina.

Dr. Kane, we are pleased to have you take the time to appear this morning. Did you submit to the committee some biographical data?

**STATEMENT OF DR. FRANCIS J. KANE, JR., ASSOCIATE PROFESSOR
OF PSYCHIATRY, DEPARTMENT OF PSYCHIATRY, UNIVERSITY
OF NORTH CAROLINA SCHOOL OF MEDICINE, CHAPEL HILL, N.C.**

Dr. KANE. No, I was not asked to.

Senator NELSON. Would you wish to state briefly your medical credentials for the record, or, if you wish, to submit it later, whatever you wish.

Dr. KANE. I am an associate professor of psychiatry at North Carolina University Medical School. My principal job is as director of psychiatric in-patient services. I have also done research related to the area upon which I am going to comment for a number of years. I possess a medical degree from New York Medical College.

Will that be sufficient?

Senator NELSON. Fine. Go ahead, Doctor. Your statement will be printed in full in the record. You may present it in any way you desire. If you wish to elaborate on anything you have said in your statement or extemporize on it, feel free to do so. I assume that if

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some questions occur to the committee, you do not mind being interrupted.

Dr. KANE. Fine.

Senator NELSON. Thank you very much, Doctor.

Dr. KANE. Mr. Chairman, members of this committee, I have been asked by this committee to present a report on one of the newer entries to the "diseases of medical progress," a term used to describe illnesses newly generated by our potent therapeutic agents. The earlier studies on oral contraceptive agents, as I will document later, seem to indicate little problem in this area. However, in view of the large literature on mood and behavior alterations in relation to sexual hormone variation in women, such reactions should come as no surprise.

Psychiatric reactions, especially depression, in the early postpregnancy period are commonplace in the practice of obstetricians. We from our department recently reported that 28 percent of a group studied of normal women reported subjective symptoms of anxiety and depression in the postpregnancy period, confirmed by psychological test materials. Somewhat more surprising, however, was the fact that this figure was less than half that of the changes reported in the last 3 months of pregnancy. These are normal pregnant women. These are not psychiatric patients. While rates of psychosis among pregnant women are below those rates expected in nonpregnant women, in the early postpregnancy period milder forms of illness become less frequent and major psychoses, which many psychiatrists feel are unusual in their clinical phenomenology, dramatically increase in incidence. The fact that 80 percent of these psychotic episodes occur within the first 30 days after delivery suggests a relationship to the dramatically altered endocrine state occurring at the end of pregnancy.

The menstrual cycle is also associated with alterations in mood and behavior, especially immediately prior to and during the menses. A number of studies have documented the markedly increased incidence of psychiatric illness during this period, including suicides, suicide attempts, homicides, and admissions for acute psychosis. Some have attributed this to the decline in hormones taking place during this time. The relief of premenstrual symptomatology by the oral contraceptive agents is striking in some studies and may be related to the shortening of the period when there are low levels of hormones.

Another period of major psychosocial endocrine change for a woman is the menopause, which also is associated with a marked increase in incidence of major and minor psychiatric illness. The incidence of such illness, especially so-called involutional psychotic reactions, is more than 3 to 1 in favor of women.

The use of steroid hormones for treatment of various conditions has also been associated with notable mood and behavioral change in a certain number of people receiving these drugs. A variety of studies have reported mild to moderate euphoria and increased well-being as well as tiredness, depression, and increased irritability. Frank manic and depressive psychotic episodes with higher dosages of steroids are not unusual. Animal and human studies would also

predict alterations in sexual behavior as a result of hormone use.

I shall now review my own work and that of others bearing on the frequency and severity of emotional disturbance associated with oral contraceptive agent use. It must be borne in mind that almost all of the studies to be reported here refer to combination oral contraceptive agents with little data of a systematic kind being available on sequential hormonal agents.¹

Glick surveyed the available literature on the use of oral contraceptive agents. Nineteen studies, mostly by obstetrician-gynecologists, revealed sporadic reporting of emotional distress, with a 5 percent incidence of depression being the highest reported. There were more favorable comments reported, though these comments, like the others, were likewise largely anecdotal. A similar scattering of reports from the same clinical material showed increased "libido," increased satisfaction with sexual relations, increased control of menstrual pain, and decreased premenstrual tension. Changes of adverse kind were much less frequent, but they were reported for all except premenstrual tension symptoms. Several not following this pattern Wearing reported, with a 16-percent incidence of depression in 62 patients, and when it occurred, the depression became more prominent the longer the patient remained on drug.

Moos reported a questionnaire survey of women asked to rate a variety of symptoms separately for menstrual, premenstrual, and intermenstrual phases of their most recent cycle and for their worst cycle. He reported that almost 80 percent reported slight decrease in menstrual symptoms, while 10 percent had a significant increase and 10 percent a significant decrease in menstrual symptoms. Sequential hormone users reported more symptoms of water retention and negative feeling than the combination drug group.

Bakke reported a double blind crossover study of an estrogen-progestin mixture, estrogen, and placebo in a menopausal group. In other words, there were three groups of treatments. Each patient took each treatment, but they did not know which they were taking. Twenty of 27 women preferred either estrogen or the oral contraceptive agent, which is to be expected in this age group. Complaints of moodiness, being cross and tired, alterations in sexual drive, weight gain, edema, and insomnia were commonest in the group using the estrogen-progestin group. Twelve women reported increased sexual drive. Six women who enjoyed the increase in drive continued on the drug, while six rejected the drugs because of this same change. Scott and Brass reported their experience in the use of massive doses of norethynodrel in the treatment of endometriosis on 20 patients. Daily dose varied from 40 to 100 mg. of norethynodrel. They commented that "mood and behavior changes were noted in all patients, and three developed moderate depressions that responded to antidepressant drugs. One patient also developed a tremendous increase in libido."

Senator JAVITS. Mr. Chairman, could we ask the witness, so we can appraise what he is testifying, whether there is any standard term of use of the pill by the people about whom he is testifying? How long had they used it?

¹ NOTE.—Bibliography at end of statement.

Dr. KANE. Well, these are documented in the studies. I do not remember offhand. The Scott and Brass study——

Senator JAVITS. I am told it was 30 days or less. Is that true?

Dr. KANE. Oh, that is—I am sorry?

Senator JAVITS. That is, the use of the pill was only for 30 days or less of all of the cases that you are reporting. Is that true?

Dr. KANE. Are you talking about some of my own work or the work I am reporting?

Senator JAVITS. What you are reporting.

Dr. KANE. I have not reported any of my own work as yet.

Senator JAVITS. Will you let us know, if it is not contained in your testimony, submit a list as to how long each of the patients that you are describing had used the pill before you came to your conclusions in these cases?

Dr. KANE. You are getting sort of ahead of the game. Let me state it this way.

What you are referring to represent cold metabolic studies. To my knowledge, I think I probably studied only 10 patients, all of whom had taken it for a month. That refers only to studies on neurohormone excretion. In many of the studies which have been reported here, the patients had been using the drugs for a considerable period of time.

Senator JAVITS. All I want to know is in each case, how long was the pill used. You have already told us that in your 10 cases, it was a month, right?

Dr. KANE. Senator Javits, I think it is very difficult. I have given the references to the committee and those can be found, generally speaking, in the studies being reported, especially the clinical studies and some of the studies I will report in some detail later, generally the women were using them every month, the clinical studies. The kind of studies I was doing had a different purpose. We were really not studying it so much—we were studying biological alterations and we were not interested, really, in a number of other things.

Senator JAVITS. In the 10 cases you have described, it was a month?

Dr. KANE. The 10 cases on which certain conclusions are based only.

Senator JAVITS. That is what I wanted to know.

Dr. KANE. Yes. In these other studies I have reported, these people were using the drug regularly.

We first became interested in this when we observed a patient who had a psychotic episode upon withdrawal of a large amount of Enovid used to control endometriosis. The patient experienced relief of her psychotic behavior with drug replacement and intensification of her psychosis when we withdrew the drug once again. We have seen four additional women since that time who have suffered psychotic episodes coincident with the use of oral contraceptive agents. In two instances these were associated with the use of the combined agents and in two with the use of sequential hormone combinations. One patient noted change with both, although she became hospitalized while using the sequential agent. Three of these women gave a history of postpregnancy disturbance in the past and one was receiv-

ing psychotherapy for a character disorder. One patient tolerated sequential agents very well for a year but suffered psychotic episodes with only 1 month of combination drug use on separate occasions before and after the use of the sequential agents.

This would seem to raise a question as to whether there is not some increased risk in using these drugs in persons with known psychiatric illness. There have been two additional reports of psychotic reactions in the world literature. Idestrom reported another case of psychosis upon withdrawal of drug; in this case, norethindrone. Sturgis reports recurrence of psychosis in a patient participating in the prospective study of drug effects.

The frequency of a prior psychiatric history among those who had psychosis prompted us to undertake a study comparing normal women with psychiatric patients as regards their reactions to regular use of the pill. In this situation, we were comparing women who were regular users on a retrospective basis. We were asking them questions about their previous use.

One hundred and thirty-nine married women who had never had psychiatric care were compared with 64 women who had previous history of psychiatric care. These were private patients attending clinics at the North Carolina Memorial Hospital, while the psychiatric patients were private patients hospitalized on our wards. Among those without previous psychiatric care, 64 percent of the 139 women reported feeling different than their previous selves. Depression 34 percent, irritability 29 percent, and lethargy 24 percent were most often seen. About 10 percent of these women had increased well-being only, meaning they felt more peppy and had increased vigor. In other words, 10 percent of the users stated in some instances they felt better than they ever had before. Another 2 percent reported an increase in sexual pleasure only. Thus, 52 percent of the entire sample reported undesirable consequences of using the pill. Decreases in sexual desire or capacity for sexual pleasure were found far more often than an increase. When those with symptoms were compared with those without symptoms on a variety of background figures, factors usually associated with neuroticism, such as disability of the menses and significantly decreased frequency of sexual intercourse and capacity for sexual pleasure were found to discriminate the two groups. In other words, the people who had reactions seemed on history to be psychiatrically more loaded.

About 15 percent of these women who complained about the effects of the drug stopped the medication for this reason, while another 10 percent reported they had wanted to but had been dissuaded from doing so by their physician. Perhaps the most extreme of these was the wife of a member of the health professions who complained to her husband that she had become depressed and was having suicidal ideas. She had never felt this way before and wondered if the oral contraceptive medication might be involved. He assured her that this could not be so because such complaints were not included in the list of side effects on the package insert which accompanied the medication.

Senator NELSON. May I ask what date was that?

Dr. KANE. That was prior to the listing of these. This was in 1966 or 1967. The lady in question, her husband was a druggist. After reading the package insert, he decided it couldn't be, and she experienced relief of the symptoms when she stopped the medication.

Senator NELSON. But the package insert now includes even mental depression as a side effect?

Dr. KANE. Yes, it does.

Senator JAVITS. As I recall your figures, you spoke of 52 percent.

Dr. KANE. Right.

Senator JAVITS. You accounted for 25 or 27 percent. What happened to the others?

Dr. KANE. The symptomology is such, and this is borne out in a number of other studies. The symptoms are, in some, of fairly moderate intensity. These seemed to be the women who stopped the drug. As I will document for you later, the Swedes seemed to have somewhat the same experience. Their principal reason for stopping the drugs was psychiatric.

The others sort of say, well, they are choosing between the lesser of two evils. They would prefer feeling a little tired and a little irritable to being pregnant.

Senator JAVITS. Don't you think that has to be compared to the effects of not using the pill and getting pregnant, in terms of mental depression?

Dr. KANE. This is often so, Senator Javits, but I think it should not be compared with not using the pill or being pregnant and using another form of contraception.

Senator JAVITS. If they would use it. It also must take into account, must it not, whether or not the other would be resorted to as frequently. That is a factor, isn't it?

Dr. KANE. That is a problem, again, one of a kind of informed consent. I think as long as the patient knows she is taking risks of this type. I have talked to wives of my colleagues who have felt badly while taking the medication and they have chosen to stay on it. They have said, well, I will come back and see you if I feel worse, which I think is fine. They are making a choice for themselves based on the information there at hand. That is fine, I think. People can choose as long as they have the information.

Senator JAVITS. Now, this work that you discussed, has that been done on any preponderantly economic group, middle class or lower class? I am not trying to characterize people, just data.

Dr. KANE. Well, my own was. My own was principally, I guess you would call it, white lower to upper middle class patients in the university hospital.

The Swedish studies, I think, are more representative. One was done—both were done in university hospitals. I think again with some of the lower socio-economic groups, my experience has been, in talking with the ward patients in the hospital, that the pill has a bad name, quite frankly. I couldn't report you a study.

Senator JAVITS. That is not clinical research. Now you are talking about hearsay, is that right?

Dr. KANE. Of course. I am talking about why we don't see many of these people. I have no explanation for this.

Senator JAVITS. Well, the only reason I am asking you these questions is because I have the impression that these hearings have given the impression that this was all bad or a good deal bad and it scared a lot of people. I think that if we really want to do a responsible job in so critical an area, especially with people who really have unwanted children, and I am speaking mainly of numerous families who are the subject of poverty, I think we have to be extremely careful that we know what we are talking about. I hope very much that those who testify, and I am delighted to see that our witness from New York, Dr. Connell, who is doing precisely that, will bear that in mind. What's said here can have an enormous effect. And it is having an enormous effect. It is not just a hearing on camera. It is vitally important that a balanced picture be presented by everyone who testifies. I understand that certainly you want the truth and the facts, but we want balance, too, I should think. For men as eminent and able as the witness, it seems to me that it would be extremely helpful if they bore that in mind, that we are dealing with millions of human lives. It is very easy to scare and thus it may be very regressive, or I can see situations where it may be entirely appropriate. I think we should have a very balanced picture of social and economic status, with broad samplings, with understanding in detail of what's afoot, and not an a priori effort to prove the case.

Senator NELSON. Let me say I am the only one of the committee who has sat through all the hearings. We have called on the most distinguished witnesses we can find in the country. I think they have given their honest interpretation of the effects of the use of the pill. I do not know of anyone who has appeared who has not done so. They have their differences, but I do not see how we could have secured a more qualified list of witnesses, nor a more balanced group.

Go ahead, Doctor.

Dr. KANE. Among the psychiatric patients, frequency of morbidity was even higher. Eighty-five percent of the psychiatric patients perceived change, most of these being adverse reactions. Here again depression, irritability, and lethargy were most frequently reported. The psychiatric patients were different in that it seemed to enhance both their sexual desire and capacity for sexual orgasm. They also showed much more sensitivity to stopping the drug every month, indicating some withdrawal effects. While this figure of morbidity with the pill seemed high to us, and concerned us considerably, because this was higher than anybody else had reported before, a Swedish study reported by Nilsson and his colleagues supported our findings. They reported on a questionnaire study of 344 women who had received oral contraceptives during the year 1964 at the University department in Sweden. They had a 91-percent response to their questionnaires. Of 138 women who stopped using the medication, weight gain and emotional disturbances were the most frequently reported, 26.1 percent and 23.9 percent. Forty-nine percent reported either worsening of previously existing symptoms or a development of new symptoms. In women without a previous psychiatric history, 45 percent reported new symptoms of emotional distress. Fifteen percent of these had five to 10 symptoms. The results of their survey

suggested side effects of a psychiatric nature are almost as common as purely somatic symptoms and that in many cases the intensity of the side effects is sufficiently great to motivate earlier cessation of oral contraceptive treatment.

Senator JAVITS. Doctor, are we to assume that the pill remains the same from 1964 to date?

Dr. KANE. No.

Senator JAVITS. I mean that there have been no changes or refinements or developments, either in the administration or in the medication itself?

Dr. KANE. You raise a great problem, Senator Javits. I would not argue with it at all. We do not have enough information.

Senator JAVITS. I do not know.

Dr. KANE. There is not enough medical research. If you want to make a pitch for that, I could not agree more.

Senator JAVITS. I do not make any pitch. I want to know, is there a difference in administration or medication?

Dr. KANE. I do not know. There has not been enough research.

Senator JAVITS. But is there a different pill, is it differently administered? What's the fact?

Dr. KANE. I would say there are no studies available.

Senator JAVITS. But is it the same pill? Do they take the same thing, is it administered the same way? You should know that.

Dr. KANE. I think there are differences. I am not an obstetrician.

Senator JAVITS. Do you not think that has a very material effect on your conclusions, that they use the same thing? You are giving us a fact that you say is evidence now.

Dr. KANE. I think you are making an assumption that I think has no basis in fact.

Senator JAVITS. I am not making any assumption. I am asking you a question: Is it the same pill, is it administered the same way?

Dr. KANE. I don't think so. I think your assumption is that it is going to be different.

Senator JAVITS. I don't assume a thing, sir. I am asking you. You are a doctor. I am only a senator and a lawyer. I am not a researcher. I do not know anything about it.

Dr. KANE. Fine.

Senator JAVITS. All right, go ahead.

Dr. KANE. Among the individual symptoms, those of a neuroses—fatigability, emotional lability, irritability—or depressive character—feelings of depression, sleep disturbance, inferiority feelings, difficulty in starting work—were the most commonly encountered. The frequency of psychiatric side effects is not related to age, parity, marital status, or social class. Those more likely to develop problems of an emotional nature with oral contraceptive agents were: (1) women with a previous history of psychiatric symptoms; (2) women who have experienced emotional problems or severe nausea or vomiting in earlier pregnancy; (3) women who were significantly overweight prior to the start of treatment, which is in itself usually associated with an underlying susceptibility to psychiatric illness. Impaired sexual desire was reported by 25 percent of those using the pill, while almost 50 percent reported their sexual

adjustment to be improving. Eighty percent of this total related to an increasing security regarding pregnancy rather than an increased sexual desire. Actually 10 times as many women reported decreased sexual desire. In this study, as in our own, 9 percent reported only beneficial effects and fewer symptoms of emotional disorder. In 1968, Nilsson and his colleagues reported a prospective psychiatric and psychological investigation of 169 women during pregnancy and the postpregnancy period, comparing 54 women who were prescribed oral contraceptives during the postpregnancy period with 104 women who used other contraceptive methods. There were no differences between the two groups with respect to psychiatric symptoms and psychological or social factors before medication.

Senator NELSON. May I ask, during the Nilsson studies, were they using a sequential or not?

Dr. KANE. No, as I commented earlier, almost exclusively what I am reporting are the use of combination agents. Senator Javits raised the question as to whether sequential agents do not make a difference. I think there is no information. There simply is no research in this area and there are no answers.

Senator NELSON. So these were all fixed combination?

Dr. KANE. Right. Almost everything I say has to do only with combination agents. There is simply no information on sequentials.

Senator NELSON. Did you recite, did you identify in your bibliography the Nilsson study? What was the date of that?

Dr. KANE. 1967 or 1968. You have the bibliography. I do not have mine here.

Senator NELSON. Did they identify the brand of drug they were using?

Dr. KANE. I think they did.

Senator NELSON. So then if they identify the brand, anybody can find out how many micrograms of estrogen are in the drug?

Dr. KANE. Right; that is correct.

Senator NELSON. Then, of course, that identifies the synthetic agents and how many micrograms—

Dr. KANE. Correct. That is all contained in the body of these references.

Senator NELSON. The studies would reflect the effect of that drug, whether it be 100, 75, or 50 micrograms, and everybody would know that it was that level of estrogen content that was involved in the study and not another level?

Dr. KANE. Yes; correct.

In this study during the postpregnancy period, a significantly higher frequency of psychiatric symptoms was found in the oral contraceptive group as regards both the total number of psychiatric symptoms and individual symptoms of a neurotic and depressive nature. They felt these to be related to the medication.

In June of 1969 another study was reported by Lewis and Hoghugh in the *British Journal of Psychiatry*. This was a study of 50 pill-takers in a working class general practice in England. Of the 62 women who were known to be taking oral contraceptives, 50 were agreeable to answering questions. A clinical assessment to their mood/state was made by a psychiatrist, and objective rating scales of

depression were also used. Information about previous depressive episodes and previous mental illness were also collected. They were compared with 50 married women of childbearing age who had not used oral contraceptives. There was no difference in socioeconomic status and very little difference in age. While there was no difference in history of past depressive episodes in either group, the clinical assessment of depression revealed that 14 of the pill sample, or 28 percent, had depression of mild to moderate proportions, while only three of the control group reported this. A comparison of the depression rating scores showed the pill sample to have distinctly higher scores, meaning greater depression than the non-pill-takers. As with the other studies reported, when the intensity of depressive symptoms were analyzed, scores for the pill groups were particularly high for guilt, self-absorption, and loss of energy, but sleep disturbances were not noticeable. Two suicidal attempts in the pill sample were found, which had not been disclosed to the general practitioner. Since completing the study, another depressed pill-taker had made a serious suicidal attempt. They comment, and this is my experience also, that while many of these women were aware of the depression as a side effect, they were prepared to tolerate it rather than risk further pregnancies. Loss of interest in sex was very general in both groups. Their data also showed that those with a history of previous depressive illness had much higher scores on the depression test than those who did not have a positive history of emotional illness. In other words, the results strongly suggest that women predisposed to depressive breakdown react more adversely to any psychiatric side effect the oral contraceptive may have. There is also a trend toward higher scores with lengthening periods of medication and with increasing progestin content of the steroid.

This latter comment here may answer, at least in part, one of the questions Senator Javits raised, which was, "Is there any evidence that there may be less or more with other kinds of pills?" There is some suggestion from this study and one other that if you decrease the progestin in the pill, this may have a lesser effect on depression. However, there have been no clinical studies that I know of, and the area remains one for research.

Again, as I said in my paper, unfortunately, when I asked my colleagues about this, the sequential agents are in low repute as antifertility agents. I report that only as again being a factor that bears upon this.

Mr. GORDON. Dr. Kane, why is that?

Dr. KANE. They just don't feel it is as effective as the other drugs, there is more risk of pregnancy with these and they are reluctant to use it for other reasons.

Again, this is out of my area of expertise. I am not an expert in this. But just in asking my colleagues about their responses and what their impression had been, this is what they told me, that they would prefer to use the combination drugs still, themselves.

In an attempt to elucidate further the mechanism underlying these changes, we have studied 10 experimental subjects to date, especially with reference to neurohormone metabolite excretion in urine. In addition to behavioral changes similar to those reported in

other studies (fatigue, tiredness, lethargy, mild to moderate depression, and loss of sexual desire), there has also been an alteration in neurohormone metabolite excretion. There also seems to be some variation in neurohormone excretion relative to size of dose of the pill. Again, I think, this would bear somewhat on the question Senator Javits made. At the present time, these studies are very preliminary, and number of patients studied must be increased before we may draw very many final conclusions from the data available. In another very interesting study, Morris and Udry demonstrated that the general physical activity level of women taking oral contraceptive pills is lower than that of women not taking pills, as measured by the use of a pedometer, which was used daily for a 90-day period. Dr. Morris commented in this study that these women did not complain of depression and had not had a great deal of difficulty with the pills. He pointed out that if there were any bias in the study, it would be on the side of women who had experienced the least side effects. Now, this is very similar to the running activity, depression of running activity that one sees in animals, and this is precisely why they did the study this way, a general lowering of the physical activity of animals, if you study them in running cages.

In summary, the studies I have discussed in some detail with you are in substantial agreement on a number of points. First, there is a considerable incidence of mild to moderate psychiatric morbidity associated with the use of combination oral contraceptive agents. The principal manifestation of this morbidity is in the form of feelings of depression, sleep disturbance, feelings of inferiority, and difficulty in starting work. Neuresthenic symptoms in the form of fatigability and increased emotional lability and irritability are also extremely common. In three of the four studies, there seems to be agreement that those who have required psychiatric care in the past will be more at risk for the development of morbidity, including psychosis. One study also suggests that there may be some increase in depth of illness the longer the medication is taken. The study of Doctors Morris and Udry with regard to the decline in activity would also seem to be in support of the clinical picture described. This would also seem to be compatible with the clinical phenomena generated when other drugs which affect neurohormone metabolism are used. These agents, too, have been associated with a 10- to 15-percent incidence of depression serious enough to warrant discontinuance of medication. These medications would be anti-hypertension agents such as Rauwolfia drugs and so on.

The clinical phenomena accompanying the pseudopregnancy induced by the pill are similar in kind and frequency to those seen during normal pregnancy. There is one significant difference, however, and that is the length of the pseudopregnancy may be much longer than the natural event.

The psychotic reactions seen after withdrawal of medication also resemble the clinical phenomena seen in the psychotic reactions at the termination of pregnancy.

With regard to the effects of combination oral contraceptives on sexual functioning in the human, the expression of sexuality is less closely tied to hormones, but the evidence does indicate that there is

some general relationship between the two. The agreement on changes in sexual desire and capacity for orgasm are less well agreed upon by all the investigators. There does seem little doubt that it impairs the desire and capacity for sexual pleasure in 10-15 percent of women who use these medications for any significant period of time. A somewhat smaller percentage seem to have an increase in desire and capacity for pleasure; and this seems especially marked in psychiatric patients, which, I think, underscores the inner relationship between biological and psychological factors in this area. There have been two reported cases of nymphomania, one of whom I saw. From the patient's subjective report and the medication she was using, my guess is that she was responding to this as to a male hormone testosterone, to which the medication she took is related chemically. The clinical picture was very similar to that seen with women who have used male hormones for treatment of other conditions. One problem we became aware of in trying to assess changes in sexual behavior in women taking the pill was that the women often did not notice it themselves, but their husbands commented on it. This phenomena has been noted by other investigators, but has not been fully exploited from a research standpoint.

While the research available in this area with reference to the emotional problems generated by hormone use is not inconsequential, I think all investigators would agree there is much to be done. There are not, as I have told you, any studies of any consequence on sequential hormone users. There has been extremely little in the way of research done on the possible mechanisms underlying these emotional changes in the human. For example, our longest study involves only 1-month use of drug. While we were able to demonstrate change during this period of 1 month, we do not know whether there is a return to normalcy with prolonged use in some women, while others who become depressed may not so change. For example, our longest study involves only 1 month of drug use.

Senator NELSON. You say there have not been any study of any consequence on sequential pills?

Dr. KANE. In reference to behavior.

Senator NELSON. Have you reviewed all the published literature on the psychiatric effects or depression effects of the use of—

Dr. KANE. I think I am pretty current.

Senator NELSON. Do you have a bibliography?

Dr. KANE. I have submitted to you, I think, the salient bibliographic items you would need, which refer to—

Senator NELSON. Referring to the studies that you include in your statement.

Dr. KANE. Right.

Senator NELSON. How many studies have there been, offhand, on this subject? And when did they start?

Dr. KANE. There are actually only four studies that are really at all systematic in their evaluation of behavioral change. The bibliography I presented to you has to do with the—

Senator NELSON. I see the earliest one appears to be Keeler and Daly and Kane, "An Acute Schizophrenic Episode Following Abrupt Withdrawal of Enovid," and so on—1964. Then the next one appears to be 1966, the next one 1967—

Dr. KANE. The latest is 1969.

Senator NELSON. 1967, 1968, and 1969. This bibliography pretty well covers the published literature?

Dr. KANE. That is right.

Senator NELSON. So in fact, the scope of the study is pretty well limited?

Dr. KANE. Very modest, very modest.

There are many women who pay a certain price for their infertility and know it. They realize they feel somewhat less well than they did before and may be more irritable and tired, but feel that this price is not too much to pay for avoiding another pregnancy. We do not know at the present time whether continued use of medication in this situation has ultimate deleterious effects. We also do not know what the long term effects of these drugs are, and in this respect the situation is much like it is for the evaluation of cancer. It will be some time before we know whether women who use these medications for years at a time run any greater risk of psychosis than those who use other methods of birth control, even though these may be somewhat less effective. It is only by large-scale epidemiologic studies that these data can be generated.

(The attachment to Dr. Kane's statement follows:)

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Senator NELSON. Are any long-term studies under way at the present time that you are aware of?

Dr. KANE. I really do not know. I have heard Dr. Hertz speak when he was at the NIH of studies with the Kayser group. I do not know whether they are looking into behavior very systematically. They were monitoring for cancer mostly. Whether there are systematic studies of this sort behaviorally, I do not know. I am not aware of any, but that does not prove anything. The National Institutes of Mental Health could probably furnish you this information.

Senator NELSON. Would you know whether all, none, or part of these studies were underwritten by NIH?

Dr. KANE. I do not think any of them were.

Senator NELSON. You do not think any of them were?

Dr. KANE. No. The two Swedish ones were not, mine was not, and neither was the British study.

Senator NELSON. Do you consider it important that such studies be conducted, sponsored by NIH and—

Dr. KANE. I do not think there is any question about it. I think it should have been done when the pills came out. At some point, we ought to do a prospective study with some of the new drugs, at least now, much in the model of the Swedish study, and compare these with other contraceptive agents, because this is the only meaningful comparison we can have.

Senator NELSON. Thank you very much.

Senator Dole, do you have questions?

Senator DOLE. Do I understand perhaps in summary that there has been no real valid conclusion reached. Do I interpret correctly, that there are certain areas where there is considerable evidence of mild neurotic psychiatric morbidity associated with the oral contraceptive? But are there any other areas in which you have reached a valid conclusion? These seem to be very inconclusive.

Dr. KANE. I think the clinical studies are in very good agreement. I think where I would be very hesitant is to look, say, at the metabolic studies we have been doing, because these are based only on 10 patients. I think the fact that all four of the other clinical studies pretty much agree that about half the women feel poorly—

Senator DOLE. You are referring to mental depression?

Dr. KANE. Right. I am referring only to behavioral effects. There is fairly good agreement that somewhere between 20 and 50 percent of the women are adversely affected and that 10 to 15 percent of the group are going to discontinue medication because of it, I think this can be agreed upon. Whether this will change with other medications, we do not know, because there is simply no information. The information we have clearly indicates that the combination agents, as specified in these studies, and they were specified, do provoke this.

There is some evidence suggesting that lower levels of progestin in the pill will give you less trouble. I think again, that remains to be seen. I think more study has to be done. As these pills come along, they must be evaluated for this. I am prepared to be convinced that this will change.

For instance, when the steroid hormones came out originally, they had a great deal of trouble because excessively large doses were used.

When they scaled the doses down, they had less trouble. I am prepared to suggest this for this, too, but we do not know.

Senator DOLE. Since the hearings started—about a month, now, since the last hearing—there has been some stirring in the air that perhaps we may have caused more problems than we are going to solve. But I would like, Mr. Chairman, at this point in the record, to put in some stories in the Washington Post, the New York Times, and the Wall Street Journal which indicate the alarm among thousands and perhaps millions of women in America resulting from some of the statements made here.

Dr. KANE, the point is, after reviewing all these studies, what conclusion can be reached about the pill itself? Do you think the risks or the behavioral symptoms would indicate that the pill should not be taken, or—

Dr. KANE. I certainly think that there is an indication that patients with a history of prior psychiatric illness should use the pills with caution and should be observed by a psychiatrist or somebody for possible adverse effects. It seems clear from all the studies that psychiatric patients are most at risk. Unfortunately, there are probably a fair number of users among this group because of the stresses of pregnancy and what have you.

Senator DOLE. The risk of taking the pill, is it greater for those people than, say, an unwanted pregnancy?

Dr. KANE. The comparison can't be with an unwanted pregnancy. You are assuming they are going to become pregnant. There are acceptable other modes of contraception. I think it should be compared with other means of contraception.

Senator DOLE. Are you familiar with other studies?

Dr. KANE. There is only one, the Swedish study. That indicates that there is more psychiatric morbidity among those using the pill than using other contraceptives.

Senator DOLE. But you have done none yourself?

Dr. KANE. No, that is the only one that has ever been done.

Senator DOLE. How many people participated in that study?

Dr. KANE. 169, something of that order.

Senator DOLE. You did indicate in your last sentence that perhaps without a long-range study, there is no conclusion that can be relied upon by those who should be making a decision.

Dr. KANE. I think there are some things, yes. Psychiatric patients are more at risk, that anywhere from 30 to 50 percent of the women are going to feel different and they should be aware of this.

Senator DOLE. Does that mean they should not take the pill?

Dr. KANE. I did not say this. I say they should be aware why they are feeling different and if they do feel different, they should talk it over with their doctor, and he should be aware of this so if the symptoms get worse, he should discontinue the pill. Some women tolerate these things reasonably well, but they ought to be observed a little more carefully. I say those who are going to become depressed should be observed a little more carefully. Perhaps they should take two medicines, a birth control pill and an anti-depressant pill, rather than becoming pregnant. I think that could be their choice so long as they know this is going on.

Senator DOLE. With reference to your own study, that involved 10 women?

Dr. KANE. That is quite a different order of business. We were trying to look at the underlying mechanisms, the changes in neuro-hormonism, which I think must be studied. There are changes which seem to vary pretty much with dosage. Beyond that, I think we still have a lot of work to do.

Senator DOLE. Thank you, Mr. Chairman. If there is no objection, I would like to insert in the record these stories that I have referred to.

Senator NELSON. Sure, we will be glad to have them in the record. (The news articles referred to follow:)

[From the Wall Street Journal, Feb. 2, 1970]

THE PILL ON TRIAL: ADVERSE REPORTS LEAD MANY WOMEN TO SWITCH BIRTH-CONTROL METHODS—NO FRESH MEDICAL EVIDENCE SEEN IN SENATE HEARINGS, BUT USERS EXPRESS ALARM—IUD'S, DIAPHRAGMS IN DEMAND

"It's horrible," says a Pittsburgh obstetrician-gynecologist. "The phone has been ringing off the wall. Even people who aren't our patients have been calling."

Something like that has been happening in a number of doctors' offices. The callers are anxious women with questions about "The Pill." Via newspapers, television or word of mouth, they have learned of health hazards attributed to the oral contraceptive in Senate subcommittee hearings called by Sen. Gaylord Nelson, Wisconsin Democrat.

The publicity has been intense. Interviews in the past few days with gynecologists and other practitioners in several major cities confirm that many of the approximately 8.5 million women using the birth control pill are alarmed and distraught.

The interviews suggest that a sizable proportion of women are asking their physicians hard questions about the pill and its hazards, and a number of them are changing to other methods of contraception. But there is evidence that many women who genuinely worry about side effects of the pill are determined to continue using it nevertheless.

IRRITATED MD'S

A number of physicians are irritated about the furor. They say that the hearings haven't elicited any new medical evidence. There are charges that the subcommittee witnesses have included a disproportionate share of pill foes. Most physicians queried had made up their minds long ago about whether or not to prescribe the pill, and the hearings haven't changed their minds. Some, however, are taking new pains to inform patients of the pill's possible hazards.

The controversy reflects a problem common to many drugs. "There's no perfect way to thwart nature," says a general practitioner in Cleveland. "Whenever you alter the natural process, there is some hazard." The decision as to who uses the drug becomes a complex one involving the patient, the physician and the Government.

The Federal Food and Drug Administration, which passes on the safety and efficacy of drugs and certifies them for marketing, indicated last Wednesday that it was considering unusual measures for the pill. The agency said it might require pill makers to include in each package of pills printed matter outlining the possible health hazards. But the FDA said it wouldn't move to take the pill off the market.

ANXIETY QUOTIENT

What concerns Dr. Milton Perloff, a general practitioner in Philadelphia, is the anxiety that the health reports have created. "Most of my patients have gotten quite apprehensive," says this physician.

"Women like the pill," Dr. Perloff says. "It gives them control over a function they think should be under their control in the first place. Most are seriously interested in restricting family growth. Now they're told the pill is

dangerous, and even though the family doctor thinks it's safe, they're left with question marks. They end up with an underlying worry and anxiety about whether taking the pill is right, and this is sure to be reflected in their everyday life."

The hearings produced testimony associating the pill with above-average incidence of blood clots and strokes, and one witness said that hormones used in the pill can cause malignancies in laboratory animals when given in large dosages. There also was evidence that use of the pill might speed the development of some existing malignancies.

Dr. Mabel Brelje, a Denver gynecologist, thinks that most of the testimony at the Nelson hearings so far "is based on inadequate documentation and sometimes outright misrepresentation." The scientific debate continues—the hearings are to resume later this month—but the evidence that many women already have responded sharply to the testimony is widespread.

ONLY HALF AS MANY

The Planned Parenthood Center of Pittsburgh tallied its calls during the first few days of the hearings. On the first day, there 34 callers expressing concern about the pill, and about 25 daily for several days thereafter. More than that, there has been a change in the preferences of the women asking for birth-control help.

"In the past several days, only half as many women are choosing the pill as had made that choice prior to the hearings," says Mrs. Ellenjane Donahoe, an official of the center. The women shunning the pill are choosing intrauterine devices (IUDs) and diaphragms instead, she says.

Many of the callers, Mrs. Donahoe says, "are seeking reassurance." Many physicians find that to be the case with the vast majority of patients who have inquired. Dr. Alfred L. Vassallo, a Dallas gynecologist who sees more than 5,000 women a year, says that only one of each 200 using the pill has asked to be switched to other methods.

Dr. Clinton Hathaway, another Dallas gynecologist, finds many patients determined to continue taking the pill despite the uncertainty. "Most of my patients are younger women who just tune out on the criticism," he says. "They handle the emotional conflicts the best way they can."

When a woman in turmoil calls him, Dr. Hathaway says he tells her, "Look, you've had no complaints about the pill, you're having no side effects.

"I try to equate the dangers," he says. "It's safer taking the pill than having a baby every year."

Other physicians who prescribe the pill use equally basic reasoning to reassure their patients. "I ask them if they drive a car," says one Cleveland gynecologist. "They say yes. I say it is dangerous, and of course it is."

The anxious callers aren't always the females taking the pill. "I'm getting all kinds of calls from mothers asking whether their daughters ought to continue on the pill," says Dr. Abraham Rakoff, a Philadelphia gynecologist. Dr. Robert C. Stepto of Chicago says one of his patients recently switched from the pill to an IUD, at the insistence of her husband.

Dr. John Arey, a gynecologist in Concord, N.C., offers a reminder that there always have been side effects associated with birth-control pills. He has made a point of explaining them. "I still follow the same procedure I always have," he says. "I tell the patient both sides of the issue and let her make up her own mind."

Several other physicians indicated that they now plan a new emphasis on having patients make up their own minds. Dr. Perloff, the Philadelphia GP, says, "It's hard to tell a patient the pill is safe with this controversy going on."

He now deals with his patients in this fashion: "I explain that they're only getting one side of the story and that there are many competent physicians who believe the pill's benefits greatly outweigh its dangers. I also tell patients that there is no medication that is without some inherent danger but that in this case the potential danger is relatively small."

Dr. Sang B. Rhee, a Cleveland gynecologist, says recent information about the pill and its side effects has caused him to be more selective about prescribing it. "I'm more careful of family history and background now," he says. "I don't give it to any patient where there's a history of blood clot or stroke."

Another Cleveland practitioner has a new worry. "I don't like the medical-legal aspects of this thing," he says. "This is the thing that's going to catch up with all of us." This physician foresees a growing number of malpractice suits from women who suffer serious illnesses. "And they're apt to find a lay jury pretty sympathetic," he says.

Some physicians prescribing the pill now limit prescriptions to six months. Then they require the woman to stop taking the pill for a monthly cycle or more. "By making the patient go off the pill for a month, you allow normal body processes to return to an undepressed state for a while," says Dr. John Isaacs, a Skokie, Ill., physician. "It's like starting afresh. The prolonged use of any drug without interruption is more dangerous than using it with periodic interruptions."

The minority of physicians who have staunchly opposed use of the pill since its introduction are more firm than ever now in their opposition. "I'm switching women from the pill when I can," says a doctor in Cleveland, "and the adverse publicity has made it easier."

There have been other related developments. The Planned Parenthood Center in Pittsburgh reports an increasing number of calls inquiring about vasectomy. This is a relatively simple operation for male sterilization in which sperm ducts are closed off.

Some druggists are hurrying to broaden their inventories of birth-control devices. For instance, Speices Drug Store in Chagrin Falls Ohio, discontinued the sale of diaphragms two years ago, for lack of customer interest. Now the store stocks them again.

[From the New York Times, Feb. 15, 1970]

PREGNANCIES FOLLOW BIRTH PILL PUBLICITY

(By Jane E. Brody)

Doctors across the country say they are beginning to see the first round of unwanted pregnancies among women who stopped using birth control pills after adverse publicity in the last few months.

"I'm now looking for some one to abort a 14-year-old who panicked," said a New York obstetrician who specializes in family planning among the poor.

Another New York physician, a Park Avenue obstetrician, said a patient of his who dropped the pill after reading a "scare report" is in London this weekend to get an abortion.

In California, Dr. R. Elgin Orcutt, president of the San Francisco Planned Parenthood Association, reports that "many are coming in for therapeutic abortions, many are going to England and many others are getting criminal abortions."

These women, who stopped the pill in a panic and are now trying to deal with an unwanted pregnancy, are experiencing "the most serious side effect," Dr. Orcutt remarked.

Dr. Orcutt and about a score of other birth control experts interviewed last week said that they expect the number of unwanted pregnancies to soar in the next few weeks and months among women who have recently given up the pill in favor of less effective contraceptive methods and, in some cases, no contraception at all.

"We regularly see a crop of unwanted pregnancies—a disturbing number of them—after each batch of bad publicity," commented Dr. Selig Neubardt, a New Rochelle obstetrician who is the author of "A Concept of Contraception," a popular book on family planning.

A Gallup poll taken during the first week of this month for Newsweek magazine, revealed that largely because of recent reports of suspected health hazards, 18 per cent of women have stopped taking the pill and 23 per cent more said that they were giving serious consideration to doing so.

Most of the adverse reports on the pill grew out of the Senate hearings on oral contraceptives held last month by the monopoly subcommittee of Senator Gaylord Nelson, Democrat of Wisconsin.

Testimony at the hearings linked the pill to a long list of disorders, including blood clots, strokes, heart attacks, diabetes, high blood pressure, cancer and arthritis.

Many physicians in the family-planning field have charged that the hearings were heavily stacked in favor of pill critics who overemphasized the health hazards that are at best speculative.

Just prior to the hearings, the long-simmering debate about the pill's safety became intensified with the publication of several books and lay articles and the presentation of broadcasts proclaiming the pill to be dangerous.

SOME REACTIONS TO REPORTS

"Unfortunately," Dr. Orcutt said, "many women who heard and read these reports stopped the pill without calling their doctors and without using any other form of contraception."

Interviews with obstetricians in various parts of the country disclosed that, of the women who did call their doctors, many decided to stay with the pill after being told that the Senate hearings had produced no new evidence of health hazards.

But a far greater number of women, these physicians said, were so disturbed and upset by the reports that they decided to switch to other methods of contraception.

Many doctors reported "a run on diaphragms" and, to a lesser extent, on intrauterine devices (IUD's). A check of pharmacies in and around New York disclosed a small but significant increase in the sales of contraceptive foams, jellies and creams and condoms, and a definite falling off in sales of oral contraceptives.

Dr. Nathan Chaste, a Providence, R. I., urologist, said he has had a tripling in requests for male sterilization procedures (vasectomies) since the Senate hearings.

Several doctors interviewed said that the turn away from oral contraceptives would not cause too many problems among middle-class and upperclass women who, for the most part, are highly motivated to use other contraceptive methods effectively and who could support another child or obtain an abortion should an unwanted conception occur.

"But among clinic patients, who cannot afford another child and cannot back up a contraceptive failure with abortion, the defection from the pill to less effective methods could be disastrous," a spokesman for Planned Parenthood of New York said.

Dr. Edwin Daily, director of the city's Maternal and Infant Care program, said that the percentage of new patients who requested and received oral contraceptives dropped from 68 per cent in December to 47 per cent during the last week in January.

Dr. Daily pointed out that, except for sterilization, the pill is the most effective contraceptive currently available.

[From the Washington Post, Feb. 21, 1970]

BAD PUBLICITY AND "THE PILL"

(By Whayne Eisenman)

NEW YORK.—Druggists across the country say recent testimony against birth control pills has alarmed many women but sales of the pill have not lagged significantly yet.

Some pharmacists reported, however, that demand for other contraceptives is up.

Results of an Associated Press sampling indicate it may be too early to assess the impact of scientists' claims before a Senate subcommittee last month that oral contraceptives may be harmful to health.

"Most women buy three-to-six-month supplies, so we wouldn't see an instant drop," noted a spokesman for a Los Angeles pharmacy. The pill usually comes in batches for a month or more.

"We've had no decline . . . but people have been asking whether or not the pill is safe," said a Little Rock, Ark., pharmacist in a typical comment.

Some druggists reported a decline in new prescriptions for the pill since the subcommittee hearings. But they said most women who were taking the pill before the hearings continued to refill their prescriptions.

The pill was named at the hearings as a possible factor in blood clots, cancer, heart disease and other ailments. Robert H. Finch, secretary of health, education and welfare, advised doctors to alert women to possible risks but he also cautioned against "over reacting."

Last Sunday Surgeon General Jesse Steinfeld said a growing amount of evidence would indicate other forms of contraception would be safer for some women.

However, he said, "I think the pill has saved more lives than it has cost."

To some women, he indicated, the possible risk of taking the pill may be less than complications such as miscarriages and hemorrhages.

Some doctors say they have noticed an increase in unwanted pregnancies which they attribute to women forsaking the pill.

Meanwhile, big money hangs in the balance. Some nine million women last year bought \$100 million worth of oral contraceptives.

Will the sales eventually decline?

A Gallup poll shows that 18 per cent of women surveyed who used oral contraceptives in the last three months have stopped using them, largely because of the adverse publicity from the hearings.

But two-thirds of the 895 women between 21 and 45 years of age surveyed believe the advantages of the pill outweigh the risks, the poll said.

Many druggists questioned by the associated Press reported concern among pill users.

"Some customers seem very upset," said Dick Berg, owner of the Loop Pharmacy, one of the largest in the Minneapolis-St. Paul area.

Berg checks with doctors before refilling old prescriptions and of those he said he had talked to since the hearings, not one had withheld a prescription, he said.

Obstetricians interviewed in Albany, N.Y., said they are being asked to recommend alternatives to the pill more frequently as a result of adverse publicity.

One said 10 to 15 per cent of his patients on the pill have requested other forms of contraceptives.

"We are selling more intrauterine devices in the last two months than we ever have," said J. Vinson Riley, manager of four drugstores in various sections of Atlanta.

"The pills have dropped by a small amount . . ."

Senator NELSON. I might say that as to the concern of people around the country hearing different things, I would guess that the fact is that if the doctors had told them in the first place, what are the known side effects and the contraindications, then they would not have been frightened when they heard it. As the Newsweek article stated, two-thirds of the women in the country had heard nothing about the side effects and when they read it in the paper, they became disturbed about it. That is not the fault of the testimony here, that is the fault of the physicians in not advising the patient, and the press failure to publish the FDA committee reports.

Thank you very much, Doctor.

Senator Hatfield?

Senator HATFIELD. Dr. Kane, in most studies of this type their validity is related directly to the number of people involved and the time over which the study is made. These two are factors in judging the merits of the study. What do you believe to be the time factor necessary to draw conclusions from such a study as yours and what number do you think is a sufficient base for making such studies? I know you alluded to this, but I would like to have you reiterate it at this point.

Dr. KANE. There are two kinds of studies one could do. One involves the prospective studies comparing use in large populations—

comparing, say, a pill-using group with a non-pill-using group; in other words, people who use other forms of contraception—and merely studying other rates of incidence of mental illness in the entire group. The other is a more retrospective thing. That is comparing rates of psychosis in hospitalized patients who have used drugs for a long period of time; in other words, an *expose facto* type of study.

I think probably there are people—I have not been involved with studies of this kind and I am sure you could get better experts than I from, say, the National Institutes of Mental Health to give you information on this.

Senator HATFIELD. Let's take your study. Has the prospective study been based upon what you would call a sufficiently broad patient population?

Dr. KANE. Probably not. The two Swedish studies were excellent.

Senator HATFIELD. You do not feel, then, that your study actually had sufficient numbers to make their application—

Dr. KANE. Their numbers are not important. Their randomness is the critical factor. Mine was not an entirely random population.

Senator HATFIELD. As a layman, may I interrupt? Correct me if I am mistaken. We are told by certain experts, according to the testimony in this hearing, that, taking breast cancer as an example, we have a Corfman-Siegel report that indicated that in order to get an accurate projection of a twofold increase, let's say, in breast cancer, they would have to have a number of 80,000 cases or 80,000 people. There is a relationship here between numbers and validity of study or what you can draw as conclusions from such a study.

Now, going back to your study, what's the number or what's the basis upon which we can draw certain conclusions from your study?

Dr. KANE. There are two things here. I think perhaps psychosis is similar to cancer. We have symptoms here, for instance—you can draw conclusions from 10 patients, studied very carefully, about acutely occurring symptoms. In other words, if you give them a medicine or a blank and compare their reaction on this, you will then be able to gauge their reaction to the medicine for even a 1 month period. We have done this. They are balanced studies.

Senator HATFIELD. You can draw a medical fact from that?

Dr. KANE. Oh, yes, you can, for certain kinds of things, certain kinds of acute symptoms. If you give, for example, LSD, the changes you would expect from LSD, at least behaviorally, would be mainly occurring within a 2- to 4-hour period from certain doses. I think you can have that study.

Then you can have the longer term study for, say, effects of hormones on genes over a longer period of time.

Senator HATFIELD. Let's come back to your study again. Do you feel that your study and the conclusions that you have drawn have incorporated sufficient numbers of people that we can draw a medical fact from them?

Dr. KANE. Yes, with regard to the more acute changes, I think so. With regard to the risks for development of psychosis, I think there is much less information. I think that is in the same ballpark as the figures for cancers. You must have large numbers.

Senator HATFIELD. So we really have to focus upon what we can draw as conclusions from your study and that which we cannot draw.

Dr. KANE. Right.

Senator HATFIELD. Let me ask about the time factor. We are told by many that there are certain effects that are going to appear in the first 30-day usage, but then some of these will level off at a certain point and reduce. What about the time factor in your study and its relevance to this matter of short-term and long-term use?

Dr. KANE. Well, again, with regard to the neurohormone studies, there was only 1 month and I think one can draw a 1 month conclusion there. With regard to the others, these were questionnaire types where people had been using the drugs for a certain time, 6 months, a year. So these were not acute changes. Almost all the studies reported, my own included, involved people who had been using the drugs for 6 months to 2 years. In other words, these were fairly chronic differences that they noticed in themselves.

Senator HATFIELD. In other words, those conclusions you draw from a 30-day study would not necessarily be the same conclusions you would draw from the same group of people perhaps over a 60-, 90-, or perhaps 120-day period or longer?

Dr. KANE. We simply do not know.

Senator HATFIELD. We should be careful in this committee, should we not, between drawing conclusions from short-term use and what might be long-term side effects and such?

Dr. KANE. I do not think there is any information on long-term side effects.

Senator HATFIELD. We should not apply the short-term to possible long-term, should we? We cannot ignore the time factor, can we?

Dr. KANE. No, I think it is an area for further research. This sort of thing, the fact that psychoses seem to occur at all, it seems to me, is something we ought to be concerned about. The question of how many in other words, I think we do not know the answer to the question, if a woman takes a given pill for 2 or 3 or 4 years, is she somewhat more at risk statistically to develop a psychosis at that time. We do not know the answer to that one.

Senator HATFIELD. Even for some of those who might develop this psychosis characteristic in the first 30 days, is there not a possibility that they might, too, level off and not have an intensity of such a thing after 30 days?

Dr. KANE. I would be unprepared to risk that. I think they should try something else.

Senator HATFIELD. Then turning it round, shall we assume that because they have such characteristics during the first 30 days, should we assume they will retain those over the longer period?

Dr. KANE. No, there would be every expectation that they would recover if you stopped the medicine.

Senator HATFIELD. How about if you continued to use it?

Dr. KANE. I know of no one who would suggest such a course.

Senator HATFIELD. In other words, there could be a differentiation drawn between those who use them for 30 days and others who use them for 60 days?

Dr. KANE. I don't think you will ever find out.

Senator HATFIELD. Why can't you, if you have such a controlled group as you can develop in this study—

Dr. KANE. If they develop psychosis, who is going to be willing to continue the drug?

Senator HATFIELD. But you indicated these were patients who already primarily, in their own makeup, were probably aggravated or accentuated or drawn out by the use of the drug, if I understand your testimony.

Dr. KANE. At least in part.

Senator HATFIELD. Then I understood you to say that, perhaps with long-term usage, there could be differences or changes that occurred in a person's characteristics from that of the 30-day period alone.

Dr. KANE. Well, now, I think you are extrapolating something from where it does not belong. I was referring really to metabolic changes and this, you know, is a speculation. I think if someone did develop psychosis while taking the pill, they probably would not take it again.

Senator HATFIELD. Well, then, retrospective studies do not have the medical validity of prospective studies, is that correct?

Dr. KANE. Oh, absolutely, yes. And there is only one of those.

Senator HATFIELD. And you could not say we could generalize from 10 women to apply, say, to 10 million?

Dr. KANE. No, but I think you can generalize from 169 women.

Senator HATFIELD. To apply to 10 million?

Dr. KANE. Yes.

Senator HATFIELD. How many more than 10 million?

Dr. KANE. Again, I think more important, perhaps, than numbers here, would be different kinds of pills. I think the point Senator Javits raised is a good one: Are there some pills that are safer to use than others. I think I would rather approach it that way. You could certainly have larger numbers and that would be nicer, but I do not think they would give you much difference in the way of data.

Senator HATFIELD. Dr. Kane, one last subject. You are familiar with the 12 primate centers we have in the NIH across this country?

Dr. KANE. Yes.

Senator HATFIELD. And you are aware that some of them are devoted exclusively to the subject of reproductive physiology. Are you aware of the studies that are going on or what kinds of studies could be conducted in any of these primate centers relating to the effects or side effects of the pill?

Dr. KANE. I think that people at Emory are doing something of this sort. I know there was one chap there who was looking at the behavioral effects of the pill on chimpanzees, I think. I have never seen any of his data published, but I think he is doing something on this.

Senator HATFIELD. Do you think that where they can accelerate the generational effect on the use of drugs of particular kinds in the strain, particularly the rhesus, that there could be, say, some benefits derived from such studies within this strain of monkeys?

Dr. KANE. I think animal studies are fine. They can allow you to do certain kinds of things, for instance, but there are certain kinds

of animal studies we have planned that can only be done in animals. However, looking at these effects on behavior, I would prefer to see it done on humans, because they are not naturally occurring in humans. My preference would be for human studies.

Senator HATFIELD. Does it need to be "either or"?

Dr. KANE. As I say, there are some things that you can do better in animals—for instance, studying brain mechanisms, how many changes can you get in the metabolism of the brain. I don't think you are going to get many humans.

Senator HATFIELD. Especially the study of generational effects over a period of time, as different from human generations?

Dr. KANE. I would say yes, I think so.

Senator NELSON. Thank you, Doctor.

Our next witness is Dr. John McCain, in the private practice of obstetrics and gynecology, Atlanta, Ga.

Dr. McCain, we are very pleased to have you appear to present your view.

Your statement will be printed in the record, or you may proceed in any way you desire.

STATEMENT OF DR. JOHN R. MCCAIN, IN THE PRIVATE PRACTICE OF OBSTETRICS AND GYNECOLOGY, ATLANTA, GA.

Dr. McCain. Senator Nelson, Senator Dole, gentlemen: Just by way of introduction, I took my medical school training at Emory University, my residency training at the Grady Memorial Hospital in Atlanta. I have the academic rank of clinical professor in the Department of Gynecology and Obstetrics at Emory University. I might say my view is personal and not representing the view of the department, which may be different from my own.

Senator NELSON. Which school is that?

Dr. McCain. Emory.

Senator NELSON. Do you teach at the department now?

Dr. McCain. The clinical professor title means that you teach without pay.

Senator NELSON. Go ahead.

Dr. McCain. The development of the oral contraceptive pills has been one of the major achievements of modern medicine. The availability of the contraceptive pills and the publicity associated with them have stimulated a concern for the worldwide population explosion. The pills have also provided a method by which this rapidly increasing problem can be controlled.

As one considers the use of the oral contraceptive pills in private practice, it is well to remind ourselves as physicians that our prescriptions of pharmaceuticals to patients are usually for the treatment of specific illnesses. Virtually all medications, even those as simple as aspirin, carry the possibility of danger to some individuals. Physicians are accustomed to evaluate the risk of the medication against the risk of the disease and then to decide whether or not the drug should be prescribed. The usual woman who does not desire children does not have any disease. If the contraceptive pills do carry some risk to the patient, the physician should prescribe them

with caution to the individual woman. If the contraceptive pills do involve risks, the physician should be even more cautious in advising their use on a population wide basis.

On the other hand, the risks of an unwanted, unplanned pregnancy must also be considered. Even though the patient herself may have no illness, she is exposed in such a pregnancy to all of the risks it involves. The infant, all too frequently, faces major socioeconomic problems which will seriously limit a child's development in our society. It is my opinion that the risks of such a pregnancy are definitely greater than the risks of the oral contraceptive pills. If the patient does not find other methods of contraception acceptable on the basis of economic, social, moral, or religious reasons, I believe that she should have the contraceptive pills prescribed for her protection, and I have done so. The theoretical ideal must be balanced against the practical reality.

Just to illustrate this point, back some 5 years ago, when I was first becoming interested and was preparing to speak on the subject of the oral contraceptive pill, around the Sunday dinner table, I made the comment that I was preparing to give a talk about the oral contraceptive pills. My 84-year-old father said, "you know, the best oral contraceptive is 'No'." My wife immediately answered, "But that is not practical." So I think it would be that the remainder of my statement will attempt to consider both the ideal and also the practical.

For the usual private patient a considerable range of contraceptive procedures is available. Through the years I have found for my private patients that the use of the condom by the husband or of the diaphragm by the wife have been effective and satisfactory methods of contraception. During the 20 years of my private practice I do not believe that I have had over a dozen patients become pregnant if they were using a diaphragm as directed. Needless to say, pregnancies have occurred among those who occasionally omitted the diaphragm at coitus.

As I initially considered the use of the oral contraceptive pills, I was concerned regarding their possible effects upon the anterior pituitary gland. The contraceptive pills are potent steroid hormones. Alterations of the anterior pituitary function are produced by them. Investigations have been made regarding the effects upon the anterior pituitary, but the potential endocrine and systemic disturbances are almost unlimited. The effects produced through the anterior pituitary may be so indirect that years may elapse before a correlation is established between the abnormality and the administration of the contraceptive pills.

In May 1964 I encountered two patients whose complications were so dramatic that my theoretical concern regarding the potential complications of the pills changed. Since that time I have tried to record all of the complications occurring in my patients which appear to be related to the use of the contraceptive pills.

A patient whom I saw on May 1, 1964, was a 26-year-old woman with the findings of an acute surgical abdomen. At operation the only pathology which could be found was the presence of two free appendices epiploicae in the cul-de-sac. Appendices are small finger-

like projections of fat attached to the colon. The cul-de-sac is the lower portion of the abdominal cavity, the only explanation which would be reasonable for such a finding is that the vascular supply to the appendices had become thrombosed, followed by a separation of them from their attachment to the colon. The patient had been on Enovid for 6 months as a contraceptive measure.

On the next day, May 2, 1964, a 32-year-old patient telephoned me that for over a week she had been dreaming of killing herself and that she was terribly afraid she would commit suicide. She had been on Enovid, 10 mg. daily, for 14 days in an attempt to control a menstrual irregularity. I advised that she omit the Enovid.

After the two patients omitted the contraceptive pills, they have had no additional problems.

At about the same time one of my colleagues in Atlanta had a patient die shortly after being placed upon a contraceptive pill. The death occurred in a 20-year-old patient who had been in apparently normal health before she was placed upon Ortho-Novum as a contraceptive.

I might state that I am using the trade names. This, of course, is technically, perhaps, not correct, and mention will be made later that there is no particular implication of one versus another as far as my experience has been concerned.

She had taken Ortho-Novum, 2 mg. daily, for 7 days but was then advised to discontinue the pills because of nausea and vomiting. The nausea persisted and a mild diarrhea developed the next day. The patient became acutely ill on the 12th day after she had begun the Ortho-Novum and died in 4 hours. The only specific pathology found at a complete autopsy, including the brain, was the presence of intracardiac mural thrombi of recent origin. No emboli were found.

Since May 1, 1964, I have seen patients with 52 complications which seem to me to be significant and which may be related to the contraceptive pills. I prescribe the pills for contraceptive purposes to relatively few patients, but I do advise them fairly frequently in the treatment of dysfunctional uterine bleeding.

Many of the patients included in this study were advised to use the pills by other physicians and I saw them later. All of the patients were taking the pills on a cyclic basis. The complications have been arranged according to the type of the abnormality which developed. (The frequent complaints of patients taking pills, such as breakthrough bleeding, mild-to-moderate nausea and vomiting, or fluid retention are not included as complications.) For the past 2 years, my record of complications have been curtailed. My association with the complications as a pill have been somewhat publicized and I am afraid has probably influenced the patients that I see in practice.

So, in fairness, I do not think the patients that I see would be on an unselected group with regard to the complications of the contraceptive pills.

Complications: The emotional or psychiatric problems are listed in table 1.¹

¹ See information beginning at p. 6480.

The emotional or psychiatric problems are the complications which seem to me to have the most serious potential danger. Three patients have stated that they were desperately afraid that they were going to kill themselves. Two of them had been on the pills 14 days or less. The third patient lived out of town and later told of her depression and fear of suicide beginning 4 months after she started taking the pills. These three patients are the only ones in the author's experience who have ever told so dramatically of their fear of suicide. After the pills were omitted, the depression and suicidal fears of the three patients disappeared, as did the depression of the other patients in table 1.

Now, rather than go through the points of the report that I gave, which do not deal specifically with the emotional or psychiatric problems, skipping over, then, to the discussion on page 8 of the report which I submitted formally:

A study of the complications of the report indicates that it might be possible to make suggestions regarding the use of contraceptive pills in selected types of patients as well as some general suggestions.

Suggestions for specific patients: The possibility of depression or of other emotional disturbances suggests that caution would be advisable if contraceptive pills are to be prescribed for individuals who already have these conditions. Such patients should be kept under close observation for a possible aggravation of their disturbance if they are to be given the pills. All physicians prescribing the pills should be aware that emotional disorders can occur and persist until the pills are discontinued. Similar precautions should be observed in prescribing the pills for patients with conditions such as migraine headaches, or with symptoms such as vertigo. Just for example, one patient that is not included in this study called me at 12:30 a.m. Sunday. She had had previous psychiatric therapy, had been placed on a contraceptive pill for gynecological reasons, had had them omitted during the preceding week because of an aggravation of the psychiatric disturbance, had called seeking some emergency sedation for an acute emotional reaction. So I have not included all of the complications which I have seen in the last 2 years.

Skipping on then to page 11 with regard to general suggestions:

The emotional or psychiatric changes seen in some of the patients of this report suggest that additional study should be given to such complications. If the patients reported here were willing to discuss their problems without any invitation to do so, one is concerned regarding other patients who may not have discussed similar problems. It is disturbing to consider the patients on the pills whose depression may have ended in suicide and/or homicide with no recognition of any association with the contraceptive pills. Investigations would seem advisable to determine the possibility of such a correlation. Personality changes could be a factor in other conditions such as automobile accidents and divorces. It is my opinion that the changes that one encounters on an emotional basis correspond rather closely to those that are associated and described as premenstrual tension. The correlation is probably not absolute, but I think

there is a great similarity and the risks involving emotional and psychiatric disturbances for prolonged, continuous use, in my opinion particularly with the combination drugs, carry a greater risk of involvement of the emotional disturbances.

Investigations are desirable to determine the possible correlation of the contraceptive pills with the individuals involved in these circumstances.

This report includes 16 major complications—they are listed in the last table of this report. I will not go over them individually. They should be classified as major ones associated with the contraceptive pills (table VIII). Through the years the author has attempted to keep accurate records on his patients. A system of IBM punchcards has been used during his practice to analyze and cross-index the records of the gynecologic and of the obstetric patients. The 16 major complications associated with the contraceptive pills are considerably more numerous than have been encountered from all of the other medications combined which have been prescribed during the time of the report. In considering the complications of the pills it is also possible that additional problems may develop in these and in other patients from as yet unrecognized abnormalities produced by altered anterior pituitary gland functions or by other endocrine or systemic changes.

If satisfactory contraceptive methods are available which do not carry the possible risks of the contraceptive pills, they deserve consideration. If other methods of contraception are not available or acceptable for the patient, the pills are valuable contraceptives, especially if given under careful medical supervision.

The patients for whom the pills may be the contraceptive method of choice will include those who find other methods unacceptable for moral, religious, social, or economic reasons. The indigent patients constitute a fairly large group of individuals for whom the pills may be the advisable contraceptive. The husbands of these patients do not use condoms reliably. The medical facilities for the patients may not permit the individual fitting of diaphragms and individual directions as to their use.

The medical care available for the indigent patients in our country is in the process of considerable modification. It appears that, under the title XIX of the Social Security Act, perhaps by 1975 all indigent patients will have medical care available for them by the private physicians on the basis of the physician's usual and customary charges. If this change takes place for the indigent patients, all patients will then have available the methods of conception control which are now available from private physicians by the individual instruction of each patient.

The most important factor in the success of almost any of the recommended contraceptive methods is the motivation not only of the patient but also of the physician. The enthusiasm of the physician for the specific contraceptive method which he is recommending will determine to a large degree the patient's and her husband's acceptance and utilization of the method. The physician's enthusiasm is important for the success of the contraceptive method whether he is advising it for a private patient or for the women of a large clinic

for whom he is responsible. From a practical standpoint, from a knowledge of my colleagues and their opinions and relationships in practice, from a practical standpoint, I do not believe that most physicians will take the time to effectively instruct their patients in the use of the diaphragm or of condoms. I am not sure that these physicians can motivate their patients adequately for a diaphragm or for condoms to be used successfully.

By way of conclusion, then:

1. No method of contraception at the present time is completely safe and at the same time practical as determined by popular acceptance and utilization.

2. The population explosion is of overwhelming worldwide importance. It threatens the very foundations of national existence. Unless the explosion is moderated, radical methods of population control, rather than family planning, may be required.

On the basis of my best judgment, in the light of these two statements, I should like to recommend as effectively as I can:

1. That the Government proceed as rapidly as possible to provide effective methods of family planning to all who desire them. The best methods of contraception now available, as determined by their safety and by their practicality, should be employed. The program should have fully adequate funds for its effective operation. On a dollar for dollar basis, the funds appropriated for family planning will produce far greater social and economic benefit than can be achieved by any other investment of money.

2. That the Government intensify the research being undertaken to develop safer and more effective methods of contraception.

(The complete prepared statement of Dr. McCain and attachments follow:)

STATEMENT BY JOHN R. MCCAIN, M.D., IN THE PRIVATE PRACTICE OF
OBSTETRICS AND GYNECOLOGY

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On the other hand, the risks of an unwanted, unplanned pregnancy must also be considered. Even though the patient herself may have no illness, she is exposed in such a pregnancy to all of the risks it involves. The infant, all too frequently, faces major socioeconomic problems which will seriously limit a child's development in our society. It is my opinion that the risks of such a pregnancy are definitely greater than the risks of the oral contraceptive pills. If the patient does not find other methods of contraception acceptable on the basis of economic, social, moral or religious reasons, I believe that she should have the contraceptive pills prescribed for her protection and I have done so.

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After the two patients omitted the contraceptive pills, they have had no additional problems.

At about the same time one of my colleagues in Atlanta had a patient die shortly after being placed upon a contraceptive pill.

The death occurred in a 20-year-old patient who had been in apparently normal health before she was placed upon Ortho-Novum as a contraceptive. She had taken Ortho-Novum, 2 mg. daily, for 7 days but was then advised to discontinue the pills because of nausea and vomiting. The nausea persisted and a mild diarrhea developed the next day. The patient became acutely ill on the 12th day after she had begun the Ortho-Novum and died in 4 hours. The only specific pathology found at a complete autopsy, including the brain, was the presence of intracardiac mural thrombi of recent origin. No emboli were found.

Since May 1, 1964, I have seen patients with 52 complications which seem to me to be significant and which may be related to the contraceptive pills. I prescribe the pills for contraceptive purposes to relatively few patients, but I do advise them fairly frequently in the treatment of dysfunctional uterine bleeding. Many of the patients included in this study were advised to use the pills by other physicians and I saw them later. All of the patients were taking the pills on a cyclic basis. The complications have been arranged according to the type of the abnormality which developed. (The frequent complaints of patients taking pills such as breakthrough bleeding, mild to moderate nausea and vomiting, or fluid retention are not included as complications.)

COMPLICATIONS

The *emotional or psychiatric problems* are listed (table I.). They are the complications which seem to me to have the most serious potential danger. Three patients have stated that they were desperately afraid that they were going to kill themselves. Two of them had been on the pills 14 days or less. The third patient lived out of town and later told of her depression and fear of suicide beginning 4 months after she started taking the pills. These three

patients are the only ones in the author's experience who have ever told so dramatically of their fear of suicide. After the pills were omitted, the depression and suicidal fears of the three patients disappeared, as did the depression of the other patients in Table I.

The *central nervous system symptoms* (table II.) of severe vertigo, headache or nausea and malaise have been encountered in four patients. The symptoms were disabling until the pills were omitted. Since then the symptoms have subsided.

An *alteration of menstrual function* after the pills have been omitted has been reported occasionally by other authors. Five patients with this complication are included (table III.). (One of the five patients is listed on a later chart with miscellaneous complications.) Four of the five patients have had a return to apparently normal menstrual function after intervals of up to 6 months. The patient with persisting metrorrhagia is a 20-year-old individual with no history of previous menstrual irregularities. She had taken Enovid-E for 6 months. Since she omitted the medication she has had metrorrhagia for 1 to 2 weeks before her menses for 24 months. So far she has not returned for any specific diagnostic or therapeutic studies.

The *infections* of the vagina and of the vulva have been encountered fairly frequently. The most frequent infection has been a monilial vulvovaginitis. In this report 11 patients are listed (table IV.). The monilial infection has been seen so often that no attempt was made to record all of the cases. All of the infections, including the nonspecific vaginitis and the furunculosis, responded rapidly to treatment after the pills were omitted.

The most frequent *change in the pelvic organs* (table V.) has been that of a pseudodecidual reaction of the cervix. The reaction has been encountered so often that the cases listed here represent only a few of the ones which have been seen. The reaction of the cervix has been so severe in some patients that the gross appearance simulated that of a malignancy. The benign nature of the lesion can be proven by a Papanicolaou smear and cervical biopsies. It has not been possible to clear the pseudodecidual reaction by local therapy as long as the pills were continued. The cervical changes cleared, or responded readily to treatment, after the pills were omitted.

The two patients with leiomyomas had the uterus enlarge to twice its previous size during the 6 months of treatment with the pills. After the pills were discontinued the leiomyomas and the uterus decreased to approximately the size which had been present before the pills were prescribed.

It is possible that unexpected pelvic pathology may be associated with pill therapy. The endocervical polyps were removed by curettage. The pathologist at his examination suggested that the polyps may have developed as a result of the Enovid stimulation. Another unexpected finding was that of a patient with recurring attacks of cystitis. After the contraceptive pills were omitted, the bladder infection was cleared by the same medication which she had been using previously.

The *vascular accidents*, together with the emotional or psychiatric changes, have been the most serious complications in my experience (table VI.).

The patient with the three pulmonary emboli was a 37-year-old woman, 62 inches tall, weighing 121 pounds, who had been placed upon cyclic therapy with Ortho-Novum, 2 mg. daily, for dysmenorrhea with mild pelvic endometriosis. She was in good general physical condition. As she began her third cycle of Ortho-Novum in November 1965, she developed the first pulmonary embolus, apparently from her pelvic veins, with no other clinical evidence of disease. In the next 2 weeks, in spite of anticoagulant therapy, she developed two more pulmonary emboli. After her recuperation from the emboli, she has had no other abnormality develop.

The subarachnoid hemorrhage occurred in a 31-year-old patient who was apparently normal and who had been prescribed Enovid-E as contraceptive pills. After three cycles, the patient developed a subarachnoid hemorrhage. A rupture of an aneurysm of an anterior cerebral artery was suspected but could not be identified in spite of carotid artery angiography performed twice. The patient's findings slowly cleared and she now has no neurologic residual.

The two patients of special interest among the *miscellaneous complications* (table VII.) are the patient with the visual disturbance and the patient who twice attempted the criminal abortion. The patient with the visual disturbance

was diagnosed as having vitreous bodies in the posterior chamber of the eyes. The visual change developed 6 days after she had begun C-Quens. The vitreous bodies still have not cleared 6 months after the pills were omitted.

The patient who twice attempted the criminal abortion was an unmarried girl who had an amenorrhea for 3 months after omitting the pills. After she missed her second period she was told by her family physician that she was pregnant and was referred to an abortionist. A French catheter was inserted into the uterine cavity on two occasions, but no bleeding occurred. The patient was referred to the author because of her lower abdominal and pelvic pain. The examination revealed a moderate pelvic cellulitis but no evidence of any pregnancy. The cellulitis cleared on antibiotic therapy. The patient had a fairly normal menstrual period 4 months after she omitted the pills.

DISCUSSION

The material presented in this paper has included information regarding the type of the contraceptive pill and regarding the duration of its use before the onset of symptoms. The frequency with which one type or another of the contraceptive pills is included in the study probably indicates the relative frequency with which it has been prescribed in the Atlanta area. The study probably does not indicate that one preparation is either more or less dangerous than another.

The length of time varied widely from the start of the contraceptive pills until the appearance of the complication. Some of the dramatic complications began within a few days. Other patients had apparently uneventful courses for several months before the onset of the complications. The menstrual irregularities did not appear until after the pills were discontinued.

The complications cleared completely and did not recur for almost all of the cases. The exceptions include the patient who died, the patient with persisting visual difficulties and the patient with persisting metrorrhagia.

A study of the complications of the report indicates that it might be possible to make suggestions regarding the use of contraceptive pills in selected types of patients as well as some general suggestions.

Suggestions for specific patients: The possibility of depression or of other emotional disturbances suggests that caution would be advisable if contraceptive pills are to be prescribed for individuals who already have these conditions. Such patients should be kept under close observation for a possible aggravation of their disturbance if they are to be given the pills. All physicians prescribing the pills should be aware that emotional disorders can occur and persist until the pills are discontinued. Similar precautions should be observed in prescribing the pills for patients with conditions such as migraine headaches, or with symptoms such as vertigo.

The menstrual abnormalities which were observed in some patients when the pills were discontinued suggest the possibility that a major disturbance of the menstrual pattern can occur in an occasional individual. Such a change would be especially unfortunate if the patient were a young person who might later want to have children. For the young patient it seems advisable to omit the pills at fairly frequent intervals for two to three months to be sure that normal menstruation resumes. For the older patient who has completed her family the pills might be continued for longer intervals of time.

Some of my colleagues have told me that the menstrual irregularities after omitting the pills seem to be more severe if the menstrual pattern had been that of dysfunctional uterine bleeding before the pills were prescribed. If these patients are to be given the pills, it would also seem wise to omit them fairly often for two to three months to permit the resumption of normal menstruation.

If a period of amenorrhea develops after the pills are omitted, it does not necessarily indicate that the patient is pregnant. It is true that pregnancy is the most frequent cause of secondary amenorrhea, but, as illustrated by the patient who twice attempted a criminal abortion, pregnancy is not the only cause of secondary amenorrhea.

The menstrual irregularities after omitting the pills are not as serious a problem now as they were in the past. Since clomiphene citrate (clomid) has been released for use, adequate treatment is now available for most patients who have an infertility associated with the menstrual irregularity.

The monilial vulvovaginal infections have been very difficult to clear in many patients as long as they continue the pills. The monilial infections seem to be more frequent in my experience among patients taking the combination type pills than among those using the sequential type. Either type of pill should be prescribed with caution if a patient has an existing medical disease, such as diabetes mellitus or a cardiac lesion requiring continuous chemotherapy, which is more favorable for the development of a monilial infection.

Other types of vulvovaginal infections may be associated with the pills. The most frequent of these is a trichomoniasis. The trichomonas infections have not been a significant problem, however, because of the effectiveness of metronidazole (Flagyl) in their treatment. Occasional non-specific types of vaginal infections may be associated with the pills. The non-specific infections in this study have cleared if the pills were omitted.

The pseudodectidial reactions of the cervix have been encountered very frequently with the combination type of pills and somewhat less frequently with the sequential type. At times the gross appearance of the lesion may be disturbing from the standpoint of a malignancy. The maintenance of the cytologic changes at the external os of the cervix suggests on a theoretical basis that it might predispose the area for a later malignant change. The theoretical dangers are probably more than offset by the close observation given patients who are taking the pills. The recent "Survey of Experience with Oral Contraceptive Pills" by the American College of Obstetricians and Gynecologists in October 1967 reported that 98.9 percent of the patients on the pills were being re-examined at least once a year.

It is advisable to prescribe the pills cautiously to patients with leiomyomas of the uterus. If the leiomyomas enlarge or become symptomatic, the pills should be omitted. The possible relationship of endocervical polyps and other pelvic pathology to the pills should be remembered. If abnormalities occur, consideration should be given to the omission of the pills.

Vascular accidents in association with contraceptive pills have been reported with relative rarity. Two patients in this study had serious vascular accidents and two had less serious ones. The frequency is disturbing.

The only ophthalmologic complication has been the one with vitreous bodies in the posterior chamber of the eyes. It is slowly clearing since the pills were omitted but it has been a considerable problem for the patient so far.

General suggestions: The emotional or psychiatric changes seen in some of the patients of this report suggest that additional study should be given to such complications. If the patients reported here were willing to discuss their problems without any invitation to do, one is concerned regarding other patients who may not have discussed similar problems. It is disturbing to consider the patients on the pills whose depression may have ended in suicide and/or homicide with no recognition of any association with the contraceptive pills. Investigations would seem advisable to determine the possibility of such a correlation. Personality changes could be a factor in other conditions such as automobile accidents and divorces. Investigations are desirable to determine the possible correlation of the contraceptive pills with the individuals involved in these circumstances.

This report includes 16 complications which should be classified as major ones associated with the contraceptive pills (Table VIII.). Through the years the author has attempted to keep accurate records on his patients. A system of I.B.M. punch cards has been used during his practice to analyze and cross-index the records of the gynecologic and of the obstetric patients. The 16 major complications associated with the contraceptive pills are considerably more numerous than have been encountered from all of the other medications combined which have been prescribed during the time of the report. In considering the complications of the pills it is also possible that additional problems may develop in these and in other patients from as yet unrecognized abnormalities produced by altered anterior pituitary gland functions or by other endocrine or systemic changes.

If satisfactory contraceptive methods are available which do not carry the possible risks of the contraceptive pills, they deserve consideration. If other methods of contraception are not available or acceptable for the patient, the pills are valuable contraceptives, especially if given under careful medical supervision. The patients for whom the pills may be the contraceptive method

of choice will include those who find other methods unacceptable for moral, religious, social or economic reasons. The indigent patients constitute a fairly large group of individuals for whom the pills may be the advisable contraceptive. The husbands of these patients do not use condoms reliably. The medical facilities for the patients may not permit the individual fitting of diaphragms and individual directions as to their use.

The medical care available for the indigent patients in our country is in the process of considerable modification. It appears that, under Title XIX of the Social Security Act, perhaps by 1975 all indigent patients will have medical care available for them by the private physicians on the basis of the physician's usual and customary charges. If this change takes place for the indigent patients, all patients will then have available the methods of conception control which are now available from private physicians by the individual instruction of each patient.

The most important factor in the success of almost any of the recommended contraceptive methods is the motivation not only of the patient but also of the physician. The enthusiasm of the physician for the specific contraceptive method which he is recommending will determine to a large degree the patient's and her husband's acceptance and utilization of the method. The physician's enthusiasm is important for the success of the contraceptive method whether he is advising it for a private patient or for the women of a large clinic for whom he is responsible.

CONCLUSION

No method of contraception at the present time is completely safe and at the same time practical as determined by popular acceptance and utilization.

The population explosion is of overwhelming world wide importance. It threatens the very foundations of national existence. Unless the explosion is moderated, radical methods of *population control*, rather than *family planning*, may be required.

On the basis of my best judgment, in the light of these two statements, I should like to recommend as effectively as I can:

(1) That the Government proceed as rapidly as possible to provide effective methods of Family Planning to all who desire them. The best methods of contraception now available, as determined by their safety and by their practicality, should be employed. The Program should have fully adequate funds for its effective operation. On a dollar for dollar basis, the funds appropriated for Family Planning will produce far greater social and economic benefit than can be achieved by any other investment of money.

(2) That the Government intensify the research being undertaken to develop safer and more effective methods of contraception.

TABLE I.—*Emotional or psychiatric problems*

Complications:	Cases
Severe depression:	5
With fear of suicide:	
(Orthonovum, 2 mg./d., for 8 days)	1
(Enovid-E for 9 months)	1
(Enovid, 10 mg./d., for 14 days)	1
With personality change (Enovid for 6 months)	1
"On verge of nervous breakdown" (Enovid for 3½ years)	1
Severe hysteria with psychiatric treatment for 2 years (Enovid for 3½ years)	1
Divorce (proceedings instituted 2 months after patient began Enovid) ..	1
Loss of libido (on Enovid)	1
Total	8

TABLE II.—*Central nervous system symptoms*

Complications:	Cases
Severe vertigo:	2
With hospitalization for 1 week:	
(Enovid, 5 mg., for 5 months)-----	1
(Enovid, 5 mg., for 1 cycle)-----	1
Severe headache (Orthonovum, 2 mg., for 4 months)-----	1
Severe nausea and malaise (C-Quens for 10 days)-----	1
Total-----	4

TABLE III.—*Altered menstrual cycle after omission of pills*

Complications:	Cases
Metrorrhagia for 5 months (Enovid for 29 months)-----	1
Metrorrhagia for 24 months (Enovid-E for 6 months)-----	1
Oligo-amenorrhea for 3 months (Enovid for 9 months)-----	1
Amenorrhea for 6 months (Enovid for 3 years and then C-Quens for 6 months)-----	1
Total-----	4

TABLE IV.—*Infections*

Complications:	Cases
Vaginal:	
Monilial vulvovaginitis resistant to treatment until pills omitted (Enovid, 8 pts.; others, 3 pts.)-----	11
Membranous vaginitis (C-Quens for 4 months)-----	1
Nonspecific vaginitis (Enovid for 3½ years)-----	1
Systemic: Furunculosis, severe (Enovid for 14 months)-----	1
Total-----	14

TABLE V.—*Abnormal changes in pelvic organs*

Complications:	Cases
Pseudodecidual reaction of cervix (Enovid 8 pts., Norlestrin 1 pt.)--	19
Enlarging leiomyomas of uterus-----	2
(Enovid, 5 mg., for 6 months)-----	1
(Orthonovum, 2 mg. for 6 months)-----	1
Multiple endocervical polyps, pathology report suggested "as a result of Enovid" (Enovid, 5 mg., for 18 months)-----	1
Repeated episodes of cystitis (Enovid for 3½ years)-----	1
Total-----	13

TABLE VI.—*Vascular accidents*

Complications:	Cases
2 free appendiceal epiploicas found at surgery (Enovid for 6 months)--	1
3 pulmonary emboli (Orthonovum, 2 mg., for 2 months)-----	1
Thrombosis of vein of vulva (Oracon for 18 months)-----	1
Subarachnoid hemorrhage (Enovid-E for 3 months)-----	1
Total-----	4

¹ This change was seen in many additional patients not included in this table.

TABLE VII.—*Miscellaneous*

Complication:	Cases
Chloasma.....	2
(Enovid, 5 mg., for 6 months).....	1
(C-Quens for 9 months).....	1
Peptic ulcer, radiologically clear 2 months after pills omitted (Enovid for 3½ years).....	1
Vitreous bodies in posterior chamber of the eyes beginning 6 days after onset of pills (eyes still not clear 6 months after pills omitted) (C-Quens for 2 months).....	1
Attempted criminal abortion twice when 3 months amenorrhea occurred after pills omitted (Enovid for 6 months).....	1
Total.....	5

TABLE VIII.—*Major complications associated with the oral contraceptive pills*

Type:	Cases
Emotional or psychiatric problems.....	7
Central nervous system symptoms.....	4
Vascular accidents.....	3
Ophthalmologic changes.....	1
Attempted criminal abortion.....	1
Total.....	16

Senator NELSON. Thank you, Doctor.

What's your view of the question of informed consent?

Dr. McCAIN. This, I think, is almost impossible to give in a satisfactory manner. If one were to take virtually any medical therapy and were to go down the list of all of the possible complications that can be involved, from even as we mentioned in the first of the paper, even such a simple thing as aspirin, we cannot fairly say a patient carries no risk. I can give what in my opinion would be a generally satisfactory explanation to the patient of the risks involved. However, I think that virtually any such statement can be challenged, and perhaps successfully, as not being satisfactory informed consent in the various courts of the country.

Senator NELSON. Would you agree that the situation is somewhat different in the case of a patient suffering from serious disease of some kind or other which would indicate the use of some potent drug in which the doctor has to make a judgment whether a patient is better off taking the risk of some side effect or not take any drug at all? In other words, this is a medical judgment about a situation involving a disease. Does that not differ from the situation in which, for the first time in history in this country, 81½ million healthy people, with some exceptions—a small percentage—are receiving a very potent drug? Are not those two situations quite different?

Dr. McCAIN. I think you are right. I think there is a difference. I was giving what I would consider an overall opinion of informed consent. Variations are certainly quite in order. I think, in giving a statement to a patient: and I will be frank in my statements here, that when I am speaking with doctors, I will give a little different interpretation of my opinion regarding the risks of contraceptive

pills than when I am speaking to indigent patients. I think this is fair. The indigent patient has circumstances and situations such that I think if one considers the overall risk involved, the choice of contraceptives as compared with the risks of pregnancy puts that individual in a separate category. From the standpoint of attempting to determine medical complications on a medical background, I think that the physicians should be cautious and concerned about relatively infrequent complications unless the situation justifies the use of this specific medication.

Senator NELSON. Well, you referred to indigent patients. Of course, I think you would agree that there is as high a percentage of indigents with the capacity to understand as well as those who inherited some money. If a person could understand, would you consider it a responsibility of the physician to explain the various alternative methods of contraception and the risks that are involved in each, and the side effects that may occur from each of them, including the oral contraceptives?

Dr. McCAIN. I think that there are limits. I was speaking of the indigent as one particular group. Obviously, there is no real group. Obviously, there are individuals in all economic walks of life for whom this can fairly apply as well. But there are social, I suppose, would be maybe a better word—there are social areas in which one can anticipate that contraceptives of a mechanical nature can be, will be utilized inadequately by a husband or by a wife or by both. For that reason, then, one is not saying that the oral contraceptive is more dangerous than the mechanical method of contraception. One has to compare the risks of the oral contraceptive against the unwanted pregnancies that will occur if that mechanical method is not uniformly employed.

Senator NELSON. What I am getting at is should the user be told anything?

Dr. McCAIN. Yes, I think so. But the point that I was trying to make is how much should one tell? Now, you see, I am enthusiastic again for the mechanical methods of contraception. I enjoy teaching. To me, I consider it somewhat of a challenge to be able to present the advantages of the mechanical methods of contraception. The actual number of patients for whom I prescribe the oral contraceptives initially is about three tenths of 1 percent of my gynecological practice. I do prescribe it, as I have indicated here. With the information that I give, the motivation which I would hope I could stimulate within the patients whom I treat, they can utilize the mechanical methods very effectively. From the standpoint of other physicians who do not have this motivation that I might feel with regard to the field, I do not believe, as I have indicated, that they will effectively motivate their patients. As to where one draws the line, there is the responsibility for information for the patient, there is the responsibility on the doctor for the outcome of unwanted pregnancies and all that they carry for the physicians.

As to where one draws the line, it is a responsibility. It is a most difficult responsibility as far as the—I am speaking as the clinician, the person who is a clinician. For the person who is caring for the individual patient, it is a most difficult responsibility for the care of the individual patient as to what can be done.

Senator NELSON. Well, if the user is going to use the oral contraceptive, should the user be told that if you experience certain reactions, side effects, migraine headaches, swollen legs or erythema, should not the patient be told the various signs to watch for which are listed in the package insert so that, if she discovers this kind of a reaction, she would then have enough information to realize that she ought to consult her doctor? Should she be told that?

Dr. McCAIN. This is very difficult to give a completely satisfactory answer. Now, you see, as I am motivating the patient to utilize mechanical methods, I like to take a Physician's Desk Reference, which has nearly a page of—well, really, it is about 2 pages, I believe, of all the information that is required by the Food and Drug Administration listed in the Physician's Desk Reference. There is about one column in that of the complications and to visualize all the risks involved, this is effective to the patient. Whether this can be done effectively to the patient who does not have the background, or the physician who does not have the motivation that I feel I have, I am not sure.

Then there is also the question of the suggestion to the patient of the possibility of complications and the concern of the patient then for even the slightest little bit of difficulty or discomfort that she may experience, which may be entirely unrelated to the pill itself. For example, just an ordinary sinus headache, for example, will be a matter of grave concern, perhaps, and it would be, to many patients if the physician had cautioned her against the possibility of headache, had I listed in detail the complications that are listed in the Physician's Desk Reference.

Senator NELSON. You do not think, then, that if a person is on the pill, she should be told that if she experiences a very strong headache, migraine, temporary loss of vision, swelling of the legs, she should get in touch with you? You do not think you dare tell them that so they will call you and consult with you? Are you saying that on balance, they are better off to suffer the possible risk of thromboembolism or something else than they would be to call the doctor and consult?

Dr. McCAIN. No, the question is how far down the list of complications—I have not counted them. There must be 75, I suppose, that are listed. It is a long column of complications that are listed in the Physician's Desk Reference. As one takes the ones that would be perhaps the most serious, and you have listed the ones, I believe, that would be the most serious, it would be very fair to go over with the patient these individual precautions.

Senator NELSON. This is the point I am getting at. There seems to be quite a division in the profession. The Commissioner of the FDA sent out a letter dated January 12, 1970, to 318,000 doctors. It says:

In most cases, a full disclosure of the potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risks associated in this method.

Do you disagree with Dr. Edward's letter to the medical profession?

Dr. McCAIN. Of course, you cannot disagree.

Senator NELSON. Well, you can.

Dr. McCAIN. Well, I mean I could, but it is not feasible to disagree with the director in such as that, because complications might happen and you would be in a very difficult position to say I am disagreeing with the statement that has come out in that manner.

But from the standpoint, you say, of full disclosure—what's meant by full disclosure? This is where I initiated my comments at the onset. What is meant by full disclosure? How full does it have to be to be classified as full disclosure?

Actually, if you took one single complication and really gave full disclosure, this would involve the essentials of a course in medicine and of a residency training and of the experience, in my case, of some 25 years of practice.

Senator NELSON. Do you think that is what Dr. Edwards meant?

Dr. McCAIN. I don't think so. But the interpretation is what does "full" mean? I think I might, and I do go into considerable detail as I talk with the individual patient that I see. But from the standpoint of how full it is going to be with actual use of these preparations and the large number of the patients that are being seen by family planning that is involved, this is where the difficulty arises.

Senator NELSON. I am satisfied that you conscientiously go into great detail. Your statistics on your patients run counter to all the rest. I think there are about $8\frac{1}{2}$ million on the pill and about one million on the IUD. Interestingly enough, in Dr. Hellman's clinic—Dr. Hellman was chairman of the FDA's Advisory Committee on Obstetrics and Gynecology—around 55 percent use the IUD and about 40 percent use the pill, which indicates that some educational process is going on.

I happen to be very concerned and would endorse the statement you made about population. I think the most critical matter facing humankind is the overpopulation of the planet. I have friends who feel that way and think, therefore, you had better not tell anybody about the side effects because one of the benefits of the risk-benefit ratio includes the question of overpopulating the planet. I have never understood that to be the responsibility of the physician, to make a sacrifice of a patient for purposes of some wider sociological gain. But this is the attitude of many people who have talked to me, including many of the doctors that I have talked to. Their position is that disclosing the concern of the profession and the facts about the pill threatens the cause of birth control and limitations in population growth. They apparently feel, and some of them have in fact conceded to playing the part of "Big Brother" to all the rest of the women in the world. They conclude that population control is so important that no one should be informed about the pill for fear they will not use it. I think that is a very dangerous posture to assume and defend. But that is the position that many of them do take.

Let me ask you this question: It has been suggested by Dr. Ley. I think it is under consideration by the Food and Drug Administration now. It has been suggested by a number of witnesses here and elsewhere that there ought to be some informative, understandable piece of literature inserted in the package that the user gets, which is simple and direct and indicates circumstances under which they

ought to consult the doctor, and tells them something about the pill.

Would you agree or disagree with that?

Dr. McCAIN. I think that would be a fine idea. May I make a comment with regard to your previous statement about the problems of world population and the risks that are involved in the pill?

I became initially concerned because of the fact that there was no statement being made with regard to the fact that pills had any risks. I believe that it has been established that there are risks that are present. The question is how much. I would hope that, certainly from the investigation that is being made here, from the information that is available, intensive research, or the research can be intensified regarding not only the risks of the pills that are currently available, but additional methods of contraception that can carry less risk or preferably no risk. This is tremendously important.

Senator NELSON. Let me say I certainly agree with you. That is one of the reasons for having the hearings. The fact is we have been unable to get the kind of research support for studies in all methods of contraception and moneys for family planning, which are very important. The battle has been fought for years with hardly any progress. My own view is that, as a result of these hearings, we are going to see a substantial increase in the research moneys allocated for the improvement of the oral contraceptives, and research into other methods of contraception.

I think all those I have talked to who have been working in the field would agree that the oral contraceptive now on the market is a sort of crude, first generation contraceptive and that we have not done enough research including dose response studies, we do not know whether 25 micrograms of estrogen would inhibit pregnancy or 10. We just know that if we give pills containing 100 or 75 or 50 micrograms of estrogen in the tablet, they are effective. We have not made studies to find out how far we can go. We have not made adequate studies to find out how much the reduction of the use of these agents reduces the side effects. So I am hopeful that out of all this, we will get a substantial increase, as I think we will, in research funds.

On the question of what people know and are aware of, and in reference to the news stories and the attacks on the hearings on the grounds that people are being frightened by the truth, I doubt whether there is one person, one doctor in a thousand in this country who is aware that Dr. Louis Hellman himself, as the chairman of the FDA study, said, "Now, in discussing the chairman's report, the second report to the committee, I said to them that a more forthright statement has to be made. We cannot just hide behind rhetoric. We are going to have to say something, and we have an option; that these are not safe, and then the Commissioner might have to take them off the market if he believes this. We can say these are safe and our scientific data did not really permit that kind of statement."

Yet Dr. Hellman was quoted in the media and in a large number of articles distributed widely to doctors that the oral contraceptives are safe, period. The FDA report did not say they were safe, period. It said they were safe within the FDA's present interpretation of

the meaning of the law, which was a law passed in 1938 and did not contemplate this sort of situation where a potent drug is widely prescribed for a healthy user. But the fact that this is disclosed to the public, the truth of what the chairman of the committee said, upsets all kinds of people. I happen to be one of those who believes that we lie in a free country and that if we give people all the facts, they will make the right decision and if they do not, it is better than having somebody take the responsibility to decide what people should know or should not know.

Any questions, Senator Dole?

Senator DOLE. Dr. McCain, on the bottom of page 1 and on page 2, you indicate that the risks of a pregnancy are definitely greater than the risk of the pill, and also that you have prescribed the pill for protection in your practice. You have practiced for about 25 years. I do not know how many patients you have had in that period of time. How many patients have you seen in the 25 years—of course, you have not had the pill that long. How many patients have you prescribed the pill for? You have said three-tenths of 1 percent?

Dr. MCCAIN. This would be the patients within the child-bearing years. As one matures, our patients grow older also. It would run about 1,000 women a year. They would be gynecology patients within the reproductive years.

Now, it is hard to modify what one must feel with what's considered generally immediately acceptable. Patients who have been placed on the pills by other physicians, unless they ask my opinion, and unless they are having complications, I do not volunteer the interruption of their method of contraception which has been selected by medical advice. Of these individuals, about 10 percent of the patients I see are continued on contraceptive pills. I have about 10 percent of the patients that are on the contraceptive pills for gynecologic purposes, not contraceptive purposes. In other words, that makes about 12 percent of my patients that I place on them, 12 and a fraction percent.

Senator DOLE. For how many do you prescribe the pill for contraceptive purposes?

Dr. MCCAIN. That I prescribe them for, about three-tenths of 1 percent, which would run—that would be about three or four a year, something like that. That I initiate the prescription for, for contraceptive purposes.

Senator DOLE. On these case studies which you have referred to, you have a total of what, 16 different major complications? What are we talking about in numbers? You have seven cases of emotional or psychiatric problems, four of central nervous system symptoms, attempted criminal abortion, one. Are these all patients of yours?

Dr. MCCAIN. Most of these were patients that have been put on them by some other physician. For example, the attempted criminal abortion was one that had been seen in another State and the abortion had been attempted in another State. Then she was seen by me in Atlanta as a result of the complications which are described.

Let me come back to your comment about the first page there. My statement that the risks of pregnancy are definitely greater, that was

not an unqualified statement. This was the concluding statement of this paragraph. It is my opinion that the risks of such a pregnancy—in other words, these are the patients who have an unwanted, unplanned pregnancy, and the risks that the infant faces, the socioeconomic situation in which the patient may find herself. Now, in such a pregnancy, under those circumstances, under those economic conditions, I think the risk of a pregnancy for mother and for infant carry a definitely higher risk than the pills would have been in that particular individual. It is not an overall endorsement.

Senator DOLE. I understand that.

As far as your own judgment is concerned, then, based on your own practice, your own experience and your own observation, the pill has a very low priority?

Dr. McCAIN. It does. But yet I know my colleagues pretty well, too, and their response to the figures that are presented is not the same as mine, obviously. With 8½ million women on it, obviously it is not the same.

Then one tries to consider what's really fairest for the patient, for the women of our country. As one weighs what I know the sentiments of the medical profession are, what I know as far as my own interpretation of risks are concerned, my conclusion would be the points that I made there.

Senator DOLE. On page 11, under the heading of "General Suggestions," you say, "It is disturbing to consider the patients on the pills whose depression may have ended in suicide and/or homicide with no recognition of any association with the contraceptive pills." I am not certain I understand what you are saying.

Dr. McCAIN. This is one of the things that is very disturbing. How many people that see a murder that is, where the woman is a murderer, check to see whether or not she has had the pill? How many studies have been made of women who have killed themselves? Is she taking the pills?

Senator DOLE. Are you saying there is some relationship?

Dr. McCAIN. There may be. When I have seen these patients who have come in and without any hint or question on my part tell me of their depression, these three patients very specifically of their suicidal impulses, then one gets to be, if you are going to be fair, it seems to me, you should be very concerned about studies that would really investigate suicides, homicides, divorces, automobile accidents—all of these involve emotional disturbances and no studies are made. It would have to be done fairly, because with the number of women that are on the pill, obviously, many of these would be on the pill, but not necessarily the result of the pill.

Senator DOLE. You do think there may be some relationship between the taking of the pill and driving off a cliff somewhere?

Dr. McCAIN. I do. At least, I am disturbed about the possibility that there may be, and there is no study undertaken at all with regard to this possibility.

Senator DOLE. You base this conclusion on conversations with patients and what they have told you about the pill and the depressing effect it has had, but are you speculating here or stating a conclusion based on evidence?

Dr. McCAIN. Well, now, for example, on this patient that I quoted specifically about the divorce, she told me that she was getting ready to separate from her husband. She had been on the pill. I told her, why don't you try leaving off the pill? She said, I am not about to. She would rather be divorced than stop taking the pill. Well, was it really because of the pill? I am not prepared to say.

On the documentation regarding premenstrual tension, and all the things involved, in the criminal institutions, some 62 percent of all women who are in criminal institutions had their crime committed during this stage of premenstrual tension.

Senator DOLE. They were not all taking the pill?

Dr. McCAIN. No, but this is by way of inference. I mentioned in my discussion that it seems to me that the emotional reaction of the patients while they are on the pill correlates very closely with what we have always been accustomed to recognize as premenstrual tension. Now I am taking the emotional problems of premenstrual tension and their wide range of applicability and implying then that it should not be ignored. It may not be this severe, but I am afraid that there may be some correlation.

Senator DOLE. You are suggesting, then, that there be some investigation to see if there is a correlation. When a woman runs a stop sign, you do not ask her, "Are you taking the pill?," but somewhere in the course of investigation, you raise this question to see if there is any relationship based on this medical point which I do not understand clearly.

Dr. McCAIN. I am not sure that I do, but at any rate, the investigators ought to work it out and work it out exactly.

Senator DOLE. Thank you.

Senator NELSON. Senator Hatfield?

Senator HATFIELD. Dr. McCain, I would like to go back a little bit to try to understand more clearly in my own mind what kind of profile we are trying to draw from these tables that you have presented to us. I assume that table 8 is an extrapolation of the first seven tables?

Dr. McCAIN. That is correct, the cases that I would consider the major complications.

Senator HATFIELD. But they are all part of 52 that I believe you referred to in the first part of your testimony?

Dr. McCAIN. That is correct.

Senator HATFIELD. This is 52 out of how many?

Dr. McCAIN. This is why I have not reported this as a strictly scientific report. This is my experience in private practice. This is the difficulty that it does not bear up as far as it being a scientifically accurate paper. This is my personal experience. I can give you some estimate, as I have done, about the patients that I have seen on the pills, but some of these, you see, I did not have on the pills. I did not prescribe the pills for them. I saw them as a result of their complications. So it is not a fair presentation.

Senator HATFIELD. So you are not really presenting these figures to us as a scientific investigation?

Dr. McCAIN. This is my concern based on my experience, actually, from 1964 through 1967.

Senator HATFIELD. Could you indicate to us the number of patients you have seen who are not on the pill who have had some of these same side effects that you list for us in these seven tables?

Dr. McCAIN. Probably the one that would be the most frequent that we encounter is with regard to the vascular accidents. Now, I have seen three patients in the period—actually, this carries on up from 1964 to the present time, so it is really no longer that the period that is involved in the report, who had thrombophlebitis. These three patients, two of them were postoperative within 2 weeks, one of them was postpartum within 1 week, this is the time or interval in which we fairly frequently encounter this, but this was not because of any medication. This is one of the hazards of surgery or delivery, as I would interpret it.

Senator HATFIELD. So in a period of time, you had three cases which were not on the pill and you had four cases which were on the pill from which you drew these conclusions relating to table 6, is that right?

Dr. McCAIN. That is correct.

Senator HATFIELD. What about infections? In table 4, you list various complications resulting from infections. I assume it is possible for women to have these infections who are not on the pill?

Dr. McCAIN. Actually, the correlation of a monilial vulvovaginitis—this is commonly called a yeast infection, it is called Thrush in babies and infants—is far more frequent than I have indicated here. It is so frequent that I did not even count the tabulation of the cases because of the changes, apparently, in the physiology of the vaginal secretions, making them more favorable as changes are true in pregnancy and it is a very common complication of pregnancy. It is a nuisance. If it is combined, as is indicated in the part of the paper that I did not read, with diabetes or with cardiac conditions requiring the use of continuous antibiotics—either of those two conditions make the monilial infection much more frequent.

To add to that, then, the increased likelihood under the pills, should be borne very specifically in mind. It is a very frequent problem.

Senator HATFIELD. But it could happen in nonpill users?

Dr. McCAIN. Oh, it does.

Senator HATFIELD. In other words, table 8, then, is it possible for all of these effects that you have observed in pill users to take place in nonpill users on listings of table 8, the more complicated ones?

Dr. McCAIN. This is true, except that these that are listed are ones who were treated with the ordinary methods of treatment and failed to respond until the pills were discontinued, and then improved and cleared rather quickly under the same treatment that they had been on previously.

Senator HATFIELD. I accept the fact that you have identified this as a nonscientific study, but in a scientific study, would it not have to be in juxtaposition to what might be a profile of nonusers?

Dr. McCAIN. It would have to work out in considerably more detail with a considerably large number of cases to make it valid from a statistical standpoint.

Senator HATFIELD. Are we then, as laymen on this committee, merely to draw from this testimony that you have a question as to whether certain problems might result with the use of the pill, but you do not really present us with any basic scientific study to prove it?

Dr. McCAIN. This would be true. Now, as I mentioned during one of the moments of the discussion, at the time this was begun, the general opinion was that there was no risk involved associated with the use of the contraceptive pill.

Senator HATFIELD. You were talking about the necessity of long-term studies, and I certainly would agree with you. In fact, I have felt for a long time that we ought to have long-term studies on all drugs. You mentioned the question about the possibilities, because of a lack of study to prove otherwise, of a relationship between pill users and various violence or homicides and so forth and so on. Are there such studies, or could we draw a correlation between that and, say, other uses of drugs such as—

Dr. McCAIN. Tranquilizers would be one of them.

Senator HATFIELD (continuing). Fluoridation of water? I mean these are certain things that are used. Should there be such studies in relation to other uses of other drugs?

Dr. McCAIN. You are out of my field in fluoridation. I would have to say only what my opinion is as I have understood from the expressed opinion of the American Dental Association and from the American Medical Association, from those whose opinions I respect, that they have found no trouble.

Senator HATFIELD. Well, the John Birch Society and other groups certainly raise some questions about this, but they are not the Dental Society.

Dr. McCAIN. I raise some question—certain studies should be borne in mind, and long-range studies, when one is considering health hazards, because it is true, the immediate recognized dangers should be considered. But there are long-range possibilities and fluoridation would be—well, for that matter, chlorination of the water, too. This would be a very fair consideration. Any time that we are adding a chemical to our environment, it should be kept under—

Senator HATFIELD. You are not singling out, necessarily, the pill, but you would apply this same concern to all drugs that people take that might have some impact, either short-term or long-term, for the human physiological system?

Dr. McCAIN. Well, I would carry a concern, but not the same concern.

Senator HATFIELD. Because it is outside your specialty?

Dr. McCAIN. No, because I think that from my experience and from the reports which I have encountered, which I think are valid, there is significantly more risk involved in the use of this particular medication as compared with some of these others. All medication carries some risk and should not be accepted without consideration. On the other hand, the amount of concern, I think, would have to be evaluated against the evidence of risks that are being encountered.

Senator NELSON. Thank you very much, Doctor.

Dr. McCAIN. Thank you.

Senator NELSON. We appreciate your taking the time to come here.

Our next witness is Dr. Philip Ball, an internist from Muncie, Ind.

Dr. Ball, we are pleased that you took the opportunity to come here today. Your statement will appear in the record. If you desire to read it or simply to submit it and speak extemporaneously, you may do so.

**STATEMENT OF DR. PHILIP BALL, SPECIALIST IN INTERNAL
MEDICINE, MUNCIE, IND.**

Dr. BALL. Mr. Chairman, Senator Dole, Senator Hatfield, this statement comes from the original grassroots, President Nixon's heartland of the United States, the ultimate sampling community, the statisticians' paradise, the standard of American town life, the hub of mid-America; a place semi-out in the boondocks, the typical American city, the Middletown of Lynd's famous sociology work, namely, Muncie, Ind.

I am 28 years in the business of doctoring, first in Chicago's giant Cook County Hospital, later in the Navy three wars back; in private general practice; and in the Mayo Clinic and in a small clinic; and by myself in solo practice of internal medicine in my hometown.

The letters sent out by the Food and Drug Administration to physicians in the United States dated June 18, 1968, and January 12, 1970, list some 40 to 50 adverse reactions that may be caused by contraceptive pill administration. I have seen most of them—and others not listed by the FDA letters.

Several near-tragic examples of thromboembolism caused me to slow up my prescribing of contraceptive medication 6 years ago, and finally to cease totally prescribing the birth control pill some 4 years ago.

Even though I have not prescribed the medication in some years, a procession of symptomatically unhappy women taking birth control pills continues to flow into my office.

I have seen women with thrombophlebitis, skin pigmentation, edema, weight gain, nausea, irritable bowel syndrome, backache, cancer of the breast, rheumatoid arthritislike syndrome, monilial vaginitis, uterine fibroids, erythema nodosum, temporary and alarming hypertension, and women with abnormal thyroid and liver function tests.

But more than any other problems, I have seen women who are chronically tired, or depressed, or lacking in libido, or complaining of frequent migrainelike headaches, often of incapacitating nature. These symptoms may occur singly or apparently rather frequently together in the same woman. I wrote an article concerning some of these cases in 1966 and after rejection notices by three or four medical journals, the article was first published in January 1968, in *The Journal of the Indiana State Medical Association*. I summarized my experience with these "side effects of depressive symptoms, malaise, fatigue, tension, lack of libido, acceleration of vascular-type headaches during the administration of these pills" and stated that I

thought these problems were more common than usually believed and pointed out that they should be looked for and warned that the symptoms could be incapacitating and symptomatically severe. I also stated "it is not considered reasonable that there be any mortality or morbidity in a pill used purely for contraception purposes. Medical research has got to offer something better than this. Physicians will probably look back on the contraceptive pill era of the past 5 years with some embarrassment." Since writing this article, I believe I have seen at least 200 of such types of problems and every week brings one to several more to me, and I have had no reason to change or moderate my attitude toward the birth control pill.

These are adverse effects that are happening to women, that have happened, that do happen. They are not just future risks or maybe's.

One of the first of the type of patient that I have written about was seen initially on February 13, 1965. This was a 24-year-old married school teacher who complained of headaches of severe throbbing nature accompanied by nausea, vomiting, and visual disturbances. She also complained of depression and tension and difficulty with adjustment to her marriage. All of these symptoms had been present for some 3 years, i.e., the years that she had been married and been on birth control pills. This girl was advised to discontinue her birth control medication and given advice concerning a different contraceptive technique. She did these things and was seen a few months later. She stated that the depression, tension, and migrainetype headaches seemed to abate promptly when the birth control pill was stopped. She added that she had formerly felt that perhaps she had made a mistake in her marriage and married the wrong man, or that perhaps marriage was not for her, and now she was so happy. The marriage was wonderful and she had no idea that married life could be this wonderful. I have seen such newlywed problems on many occasions since and consider this one of the unkindest prescriptions of all. These unhappily newly married women do not know if it is the wrong man, the wrong town, the wrong job, the wrong year, the wrong apartment, or yet something else, when it is really many times the wrong pill.

One of the last cases of this syndrome of unhappy womanhood I have seen came into my office 2 weeks ago. This was a 25-year-old housewife with one child, aged 4. She had been married 6 years and had either been pregnant or on birth control pills all but 2 months of her married life. She complained of being increasingly depressed for several years and she stated that she had never been depressed prior to her marriage, and apparently was inclined to blame her mood on this state—that is, the state called marriage.

Her husband stated that he did not know her to be depressed prior to their marriage, but it had been increasingly a problem ever since. She complained of being tired, tense, complained of the gaining of some 40 pounds during the recent years and also complained of increasingly severe incapacitating headaches accompanied by vomiting. She also stated that she had been losing sexual desire during the past many months and in fact had been increasingly unable to achieve a climax during intercourse. Her blood pressure was found to be as high as 212/142 mm. of mercury. This compares

with what would be a normal pressure for this woman of perhaps 130/80 mm. of mercury. She was hospitalized for investigation and treatment. But with discontinuation of the birth control pills, her symptoms and problems have been rapidly subsiding within recent days.

Why can't I give you accurate statistical numbers about the percentage of patients placed on birth control pills who develop the symptoms of fatigue, depression, et cetera, that are my particular interests? First of all, I have no idea from what numbers of women on the pill in my locality my particular statistical sample comes. Furthermore, even though I keep excellent office records which are typed, chronologic and bear face sheets listing major diagnoses and drug allergies. I cannot in my solo practice of internal medicine, seeing all types of problems, set up a complex cross reference or cross indexing system. I do not specialize in birth control problems. Hence, my information about the series of problems that I have reported had to come first from a flash of insight that I was seeing a new "syndrome," and then a laborious attempt to recall from memory some past patient's names and then keep a list of new patients seen with these problems. Don't ask me or most solo physicians for statistics regarding symptoms, disease or problems that they see in their office practice.

I take time out to congratulate Dr. McCain on having IBM punchcards. This is, I am sure, unusual in most practices.

Many of the women that have come to me with problems resulting from birth control pill administration had the pill prescribed by a gynecologist, or I should say any one of a number of gynecologists in my community. He then has usually carefully examined the woman in reference to any pelvic problems resulting from the pill but has expressed disinterest, doubt or denial concerning any side effects not in his field of interest. The American patient is often partitioned out among his physicians and this can lead to doctors being blind to aspects of people's problems that they see which may fall into other fields. In my experience most of the women that have seen me because of adverse effects from the pill have not been warned by the prescribing doctor that the pill can cause important side effects. In fact, many have been told after their side effect symptoms began, that the pill could not do this, and in fact, their doctors have often denied the obvious evidence even when discontinuing the pill resulted in elimination of the woman's problems.

The sale and prescribing of contraceptive medication during the past 10 years or so has been a massive, double-blind, uncontrolled experiment with very little possibility of good mass statistical analysis. The doctor is blind (and also sometimes deaf and dumb); the patient is blind.

The years of administration of birth control pills to millions of women have also, I believe, been a drain on the Nation's medical dollar expenditure, by causing excessive need for medical care at a time when doctors have been in short supply. If all women placed on birth control pills are checked as carefully and as often as present regulations and prudence advise, there might not be enough doctors to get the job done. These women should actually have careful,

expert interrogation for all possible side effects, and complete physical examination, with very careful examination of the breasts and pelvic organs, and Pap smear at least every 6 months. This would be an extremely expensive package of medical care if done for all women on the pill. Also then, inasmuch as in my experience, many of these women are going to be ailing after the pill is started with any one of a variety of symptoms—they are going to be utilizing a lot of doctors' time for the care of their side effect problems. I find that many of the women on birth control pills have had prescribed to them multiple medications needed to counteract the adverse effects of the birth control pills. These women may have additional prescriptions given by other physicians for appetite depressants, or diuretic fluid eliminators, or hypertension medication, of antidepressant medication, or tranquilizers, or drugs to soothe gastrointestinal side effects or antimigraine medications, or ordinary headache pills, vaginal suppositories and creams to stop itching, et cetera, et cetera. All of these medications are costly, of course, in terms of dollars and many of them have their own side effects that must in turn be looked for. I have found it easier to suggest to women that they stop birth control pills and let their side effects disappear spontaneously.

The birth control pill has been held almost sacred, or at least until the past year or so, it has been held sacred. Why is this? There are many reasons. The medical profession hates as a group to admit that it has been wrong. But we have been wrong. We were wrong in the 1950's in widely using cortisone for very simple cases of rheumatoid arthritis. We eventually stopped this. Now we use it only in exceptional cases. We have been wrong, I think, in widespread use of appetite depressants, and their use is not so popular now. And I think we have been wrong about birth control pills.

Further, because it is so simple for a doctor to prescribe it, the pill has been popular. But if a doctor carefully instructs his patients in the side effects and dangers and makes the checking exams that are necessary, the birth control pill is not so simple. Another sacred thing about the pill has been its presumed 100-percent effectiveness if used properly and continued. But it is really not accurate to say it is 100 percent effective in mass use, because many women do not continue with these pills over long periods of time for various reasons. Hence, if only 60 percent are taking the pill at the end of 2 years, the pill is really only 60 percent effective. Furthermore, a woman that becomes ill because of the pill is 100 percent ill. The pill also has been held sacred because it has been the fad or "in" thing to do—that is, for both patient and doctor, I believe. The sacred birth control pill has also had the halo of being the drug that would control the massive social problems of a burgeoning population. It could be used on the poor, ignorant, illiterate woman who scarcely knew what birth control was all about. Doctors' reluctance to leave the birth control pill also comes because, having once prescribed the holy vision of 100 percent effectiveness, what doctor likes to turn around and offer his patient only a 90 percent to 95 percent technique?

I believe that we physicians are so used to administering very potent medications to very serious disease problems, we have not really yet learned it is a totally different circumstance to administer

powerful but nonessential drugs chronically to healthy young women, as is done in contraceptive pill administration. It is of no relevance to say that the pill causes less trouble than cigarette smoking—doctors do not prescribe cigarettes. In fact, I take women off tobacco also. It is not sensible to say that birth control pills are safer than pregnancy—we don't prescribe pregnancy. The question is simply, are the pills safer than the diaphragm or safer than the foams or rubber prophylactics? And the answer is clearly no.

We have had much talk in our land about preserving our environment or improving our quality of life or preventing pollution of our country. The administration of birth control pills, in my opinion, prejudices a woman's internal environment. It may be termed an internal pollution by chemicals and it will sometimes definitely interfere with a woman's quality of life.

Is there perhaps a sexual double standard or sex discrimination that works in this seeming insistence of our medical profession to force the pill on women rather than men? Is the pill safe enough for women but a male contraceptive pill is not safe enough for men? The simple fact that women have the babies should not mean that they should be discriminated against by being the only ones subjected to chemical contraception. Is there anyone here that would guess how many men would take a male sterility pill if the list of possible side effects were made known in advance, and this list equalled 40 or 50 items, and the frequency of periodic exams were explained to the men?

My recommendation is a declared moratorium on all birth control pills for some 5 years. During this period of time women leaving the pill would be able to see what chronic symptomatology they might have slowly fading away. Doctors would find out which of their birth control pill patients no longer needed their medical services. The American physicians could try to come up with an honest retrograde evaluation of the pill era—and carry out further testing of the women who were on the pill in the 1960's to see what yet unknown problems they may develop. And the American health professions could start a concerted effort to find a new means for birth control. Certainly if all the time and money and words and thoughts and minds that are now spent on arguing the safety or danger of birth control pills were put into constructive new avenues of research, it is probable that a solution could be found for the problem of a cheap, safe, simple, casually usable, esthetically acceptable contraceptive technique.

Thank you, Mr. Chairman.

Senator NELSON. Thank you very much, Dr. Ball. I was glad to see your endorsement of the idea that we certainly need to expand our research substantially in the field of family planning and improving whatever contraceptive devices we can, or discovering new ones. I think it is necessary and a critically important step that we could be asked to take.

Did you have any questions, Senator Dole?

Senator DOLE. Senator Hatfield has to leave. Maybe he would want to ask some questions first.

Senator HATFIELD. Mr. Chairman, I just want to ask Dr. Ball a question or two.

I have before me the Indiana State Medical Journal of January 1968, entitled, "Some Apparently Common Problems in Patients taking the Pill," which I believe you authored. Again, I am bothered by perhaps a problem of semantics. Let me quote from one paragraph of introduction to your case reports:

This article was based on an unscientific sample of some 30 cases recalled "out of thin air" from an internist's office practice. The symptoms concerned were intangible enough that they would not be well identified in a mass survey, particularly if this were of a population of a backward test country or a population group that was only casually or superficially surveyed. It is also true that the symptoms are common enough in any case so that perfect truth of relation of symptoms to contraceptive medication is not easy. The author has also seen several cases of—

I do not know if I can pronounce this—

thromboembolic—

Dr. BALL. You are doing wonderfully so far, Senator.

Senator HATFIELD (continuing):

thromboembolic disease and erythema—

Is that right?

Dr. BALL. Very good.

Senator HATFIELD (continuing):

nodosum, on contraceptive pills and feels these are infrequent problems compared to those which are of concern here.

My basic problem is that I appreciate your frankness, both in testimony here this morning and in this article which you have published in the Indiana State Medical Journal.

I would like to ask you this question, Dr. Ball, again as a layman. We are here trying to come to some kind of conclusions or some sort of generalizations. I think the question is, "are these valid to do other than raise danger signals," these observations of yours? Because you say they are nonscientific. Secondly, if they are only to raise danger signals, what do we do in terms of getting to the real heart of the matter in reference to the scientific base of data on which we could, perhaps, make recommendations?

Dr. BALL. Well, sir, I thank you for reading my words from my article, and I agree with the words as heartily now as I did when I wrote that article, which was, I think, $3\frac{1}{2}$ years ago.

I am not a statistician; hence, I cannot give you accurate information as to how to carry that out. But I feel that evidence presented today by Dr. Kane bears out my initial warning, and that is what I stated this was, a warning. I felt that it had not been adequately warned about.

I felt that I was seeing a large number of these women, at that time, 30, before I finished compiling my lists and I kept a list for a while, perhaps for 6 months after that article and I had 70 on the list. Since that time I have estimated 200. My secretaries told me I am wrong, it is probably 400.

These are common problems in my practice. I do not have accurate statistics. The British studies indicate 30 percent, Dr. Kane as much as 50 percent. These are not adequately warned about. It is

implied that it is uncommon, or maybe it happens, or maybe it does not. But I say it happens and it happens commonly, and I feel that the statistical boys who have done work on this, particularly the British, perhaps, agree that it is one of the most common problems—depression, fatigue, lack of energy, lack of motivation—these problems.

Senator HATFIELD. Do I understand that you draw certain medical conclusions from these observations which lead you to say in your testimony today pretty strong words about getting off the pill?

Dr. BALL. These are observations of mine—as I say, I have had no reason to change my viewpoint. Further evidence in the literature, American literature, British literature, further evidence that I have had in my practice has convinced me that these observations are as factual today as they were then.

Senator HATFIELD. So for the purists in our society who think all things are done on a scientific basis, with scientific data, this does not necessarily follow, does it?

Dr. BALL. Right.

Senator HATFIELD. There are other conclusions drawn from observations, as you indicate, that may not be drawn from things that are scientific but may lead you to draw conclusions?

Dr. BALL. Right.

Senator HATFIELD. Would you suggest others should draw such conclusions based on your observations—I gather you suggest that here today?

Dr. BALL. That others would?

Senator HATFIELD. That others should.

Dr. BALL. I feel they should.

Senator HATFIELD. Thank you.

Senator DOLE. Has this article in the Indiana State Medical Journal appeared in other medical publications?

Dr. BALL. I believe that it has appeared in about 12 State journals and the OB-GYN News. I am not sure how many others, but in those.

Senator DOLE. I knew it appeared in the State Medical Journal and on the front page of the article there, it states that the article is based on an unscientific sampling of some 30 cases, recalled out of thin air. Do you think this is an accurate sampling? At least, it is enough for you to call off the pill in certain instances—in fact, all instances. You do not prescribe it at all?

Dr. BALL. I do not prescribe the pill, that is right.

Senator DOLE. And you have not since 1966?

Dr. BALL. Right.

Senator DOLE. Had you before then?

Dr. BALL. I had before then, yes, sir.

Senator DOLE. In many cases?

Dr. BALL. A large number.

Senator DOLE. In these same cases you prescribed the pill; then you noticed the symptoms and removed them from the pill?

Dr. BALL. The number that were my prescriptions at the time of this original article was probably high. But lately on referred patients with medical problems, problems that fall within the internists' province, the prescriptions are by other practitioners.

Senator DOLE. All the instances of who gain weight, of dizzy spells, were not totally attributable to the pill, right?

Dr. BALL. That is so. Right. But on the other hand, the evidence that I had was, here were women in large numbers ailing, coming to an internist with problems, and if you removed the pill, they were better. That is pretty good evidence.

Senator DOLE. It may very well be.

You suggest that perhaps there is a double standard for men and women. As I understand from earlier testimony, there is work being done now on a male pill but I am not certain what stage it is in.

Dr. BALL. I know no facts about it. I read in medical journals occasionally that there are such medications that are being tried out.

Senator DOLE. If there is such a pill available in say a year or two, then, of course, we can make a judgment whether we would ask men to accept the same hazard as you say we ask women to accept.

Would you prescribe the pill in any event now?

Dr. BALL. I have not, no. In fact, for treating problems like endometriosis and abnormal bleeding and so on that fall more into the gynecologist's line, the doses used are often higher and it has been my experience that the problems are greater, being somewhat dose-related.

Senator DOLE. As Dr. McCain pointed out, he places the pill in a low priority category. You do not place it in any category at all?

Dr. BALL. No category at all, that is right. But I practice very well without it.

Senator DOLE. You conclude that the risks far outweigh the benefits and therefore, you suggest a 5-year moratorium on the pill itself to discover whether the symptoms are lasting?

Dr. BALL. That is right. I feel that the vast majority of this 8.5 million women are being basically unsupervised in their taking of the pill; that is, as far as any accurate statistical analysis.

Senator DOLE. I detect from your statement that you are as critical in a proper sense of the doctors as you are of the pill. Can I infer that if doctors were well-versed in the use of the pill and they were supervising their patients as they should be, then perhaps the pill could be given with some certainty or safety?

Dr. BALL. In my opinion, this would be better than it is now.

For instance, if, as Senator Nelson suggested, perhaps a list of side effects were dispensed with the pill, this would be of some benefit—not, in my opinion, enough; but it would be of some benefit.

There is one other problem about this depression, fatigue, and so on of these women. Many times you can ask a woman and she might not either know it or say it. Therefore, to interrogate her, to question her, will do you little good. You would miss a good percentage of them. In fact, in a fair number of these women, the husband will call me separately, and say, "My God, do something about my wife, she has just turned into a bitch."

So in other words—or the mother or the mother-in-law. I never particularly listen to mothers-in-law, but these problems are often stated by other members of the family who have observed a total change in personality.

Senator DOLE. Do you have a standard response when you get those calls?

Dr. BALL. Yes, a physicians' careful courtesy—yes, yes, you know.

Senator NELSON. What do you advise the husband whose wife ends up that way and is not on the pill?

Dr. BALL. Probably refer him to another practitioner.

Senator DOLE. Dr. McCain mentioned earlier that perhaps we should start an investigation of divorces and all accidents and suicides and homicides to see if any relationship exists between ingestion of the pill and the commission of some act.

Dr. BALL. Well, that, of course, would only be a fraction of the problem, and I am not sure that would be the best way to get at it. For instance, I guess some have gone to psychiatric units and determined how many with depressions have been on the pill, and I think they have found some answers there.

Senator HATFIELD. I have another question. Dr. Ball, I presume that all of your objections are purely medical?

Dr. BALL. Yes, sir.

Senator HATFIELD. If there were no medical characteristics that you have observed over this experience of yours, would you have felt that the pills should be equally available to those who are married and those who are unmarried?

Dr. BALL. I would consider this immaterial.

Senator HATFIELD. Whether it was dispensed from University health centers or whether it was not?

Dr. BALL. To me, this is no medical consideration.

Senator HATFIELD. And you would not have any viewpoints on that particular phase of the use of the pill if there were no medical problems involved?

Dr. BALL. My antagonism is totally medical. In other words, I believe that anybody who is in the situation of needing a contraceptive should get it, but not the pill.

Senator NELSON. Let's suppose further, that if through additional research, an oral contraceptive was developed that seemed to have no significant side effects and was at the same time effective, you then would favor the use of that kind of a device?

Dr. BALL. Yes, sir. The problem is, we talked about changes in dosage over the years and so on. Each time we change the dose or the chemical, you have a whole new ball game statistically, and then a long period of time has to go by for evaluation. Again, is it going to be just this unscientific, hand-out-the-pills-and-see-who-gets-sick-business, which I say is wrong and which has been done. Each time there is a new pill, there is a new problem.

We doctors in private practice are very poor people to be evaluating this. I mean, I am talking about drug problems.

May I add one other thing? As far as statistical sampling, again, I do not want to appear to be hacking away hard at American medicine, but in the statistics on thromboembolic disease that the FDA hands out, the statistics that are considered valid, and I think about the only ones that are considered valid are from the British. In other words, a 7-fold increase over those not on the pill in the same age group.

Senator NELSON. I think the British study is seven; and I think the American study is 4.4.

Dr. BALL. Yes.

Mr. GORDON. Dr. Ball, it has been estimated that perhaps around 10 percent of the adverse actions which result from the use of drugs, pharmaceuticals, are reported.

I do not know how accurate that 10 percent is, but let us assume it is a small percentage.

Would you say the adverse reports of the pill fall into that category also?

Dr. BALL. I am sure it does. Of course, you could be very direct and say how many have I reported to the FDA. Well, when the pill was first on the market and in general use, I reported to the FDA several cases of erythema nodosum and several cases of thromboembolic diseases, one life threatening and the other can be quite an illness. So I reported those. I am an internist. The reporting of those is rather a complicated bit of paperwork and there was no feedback. In other words, the paper went in and I heard nothing back from it. So from then on, I have not reported any further on the pill.

There has been plenty of literature, there have been plenty of statistical studies, presumably going on, and in fact, I considered it a closed subject in my mind in 1966.

Mr. GORDON. You do not report the adverse effects that you see?

Dr. BALL. Since that time, no.

Mr. GORDON. So the 10 percent, as far as you are concerned—

Dr. BALL. Is wrong. It is too high. It might be like .5 percent, I do not know. But it is probably very small.

Mr. GORDON. So you really do not know the occurrence, the percentage of occurrence of thromboembolic disorders or any of the other disorders?

Dr. BALL. Out in the boondocks, we do not.

Senator NELSON. I am now looking at the experience report on the reporting form that you get. Does it have all the information necessary?

Dr. BALL. Senator Nelson, as I say, it has been several years since I made out one of those blanks, but it required a quite a bit of secretarial time. It seemed to me it was not excessive but it took time to do it. If I had reported all of these I had seen, I am afraid the paperwork for the blank would have been greater than the history form I had on the patient. It has been quite a problem, a physical problem.

Senator NELSON. Thank you very much, Doctor. So that everyone will notice the balance in the record that is talked about so much, you are the first practicing physician who has recommended abandoning the pill. We have had no other such witness; they have all been pro to one degree or another.

Our next witness is Dr. Elizabeth Connell, associate professor of obstetrics and gynecology, director of Research and Development, Family Planning Services, International Institute for the Study of Human Reproduction, Columbia University, New York City.

The committee is very pleased to have you take the time to appear here today and present your statement, Dr. Connell. You may present your statement—it will be printed in full in the record. You may present it in any way you desire.

If you wish to extemporize at any time on anything in your statement, please feel free to do so.

(The biographical sketch of Dr. Elizabeth Connell follows:)

CURRICULUM VITAE OF ELIZABETH B. CONNELL, M.D.

College: University of Pennsylvania, 1943-47. Degree: A.B.

Medical school: University of Pennsylvania, 1947-51. Degree: M.D.

Internship: Lankenau Hospital, Philadelphia, Pa. Rotating: 1951-52.

Residencies: Lankenau Hospital, Pathology and Anesthesia, 1952-53. Graduate Hospital of the University of Pennsylvania; Gynecology, 1958-60. Mount Sinai Hospital, New York City; Obstetrics, 1960-61.

Fellowship: American Cancer Fellowship, Kings County Hospital, State University of New York, 1961-62.

Board certification: Obstetrics and Gynecology, 1965.

Practice: General Practice and Anesthesia, Blue Hill, Maine, 1953-58.

Academic Appointments: Associate Professor of Obstetrics and Gynecology, New York Medical College, New York, 1962-69. Director, Family Planning Center, New York Medical College, Metropolitan Hospital Medical Center, New York, 1964-69. Associate Professor, Department of Obstetrics and Gynecology, College of Physicians & Surgeons, Columbia University, 1970 to present. Director of Research and Development, Family Planning Services, International Institute for the Study of Human Reproduction, Columbia University, 1970 to present.

Appointments: Medical Advisory Board, Planned Parenthood, New York City, 1964. Executive Committee, American Association of Planned Parenthood Physicians, 1968. National Advisory Council, Center for Family Planning Program Development, Planned Parenthood World Population, 1968. Consultant on Family Planning, New York City Department of Health. Family Planning Project Consultant, Human Resources Administration. Committee on Medical & Public Health, Executive Committee, Association for Voluntary Sterilization, Inc.

Professional societies (Membership): American Medical Association, American College of Obstetricians and Gynecologists, American College of Surgeons, American Public Health Association, American Association of Planned Parenthood Physicians, American Fertility Society, American Medical Women's Association, Inc., Medical Women's International Association, Public Health Association of New York City, The Society for Scientific Study of Sex, Inc., New York Academy of Sciences, Medical Society of the State of New York, Population Crisis Committee.

STATEMENT OF DR. ELIZABETH B. CONNELL, ASSOCIATE PROFESSOR OF OBSTETRICS AND GYNECOLOGY; DIRECTOR OF RESEARCH AND DEVELOPMENT, FAMILY PLANNING SERVICES, INTERNATIONAL INSTITUTE FOR THE STUDY OF HUMAN REPRODUCTION, COLUMBIA UNIVERSITY, NEW YORK CITY

Dr. CONNELL. Mr. Chairman, I would first like to thank you for your kind invitation to appear before you today. I fully recognize the tremendous importance to all of us of the course and the outcome of these hearings.

Upon the receipt of such an invitation, one has a moment of introspection—first, why me, and then, what should I talk about?

After much thought, I decided there were four areas in which I might possibly be able to make some small contribution based on my own personal experience. First and foremost, I am a physician. I was a general practitioner in rural Maine for 5 years and I am now a specialist in obstetrics and gynecology in New York City. It has been my privilege to care for some of the wealthiest people in our

country. I have been even more greatly privileged to care for thousands of our most grossly deprived citizens. I have delivered women of their babies under ideal circumstances—in aseptic, brightly-lit hospital delivery rooms. On a bitter, cold night, I also delivered one woman of her child by moonlight on the front seat of an ancient pick-up truck, surrounded by her distraught husband and her seven fascinated children. Having cared for many patients—men, women, and children—from all sorts and varieties of backgrounds, I hope perhaps to bring to this situation something of a clinical flavor based on a long and varied experience.

Second, I started, developed, and ran a family planning clinic in Spanish Harlem in New York City.

This led to the third area which I presume may have prompted this appearance, that of a research investigator. I have worked in the actual development of newer contraceptive techniques, have carried out studies related to patient motivation and behavior, and have been increasingly involved in programs for the training of community women.

Not only do such programs supply much needed paraprofessional help, but they also give these women an opportunity to learn, to hold responsible jobs, and to help support their families. For many of them, this is their first opportunity to get off the welfare rolls and become happy and productive members of society.

Finally, I would be naive and less than perceptive if I did not recognize that a fourth additional factor might be operative here—that I happen to have been born a female and have five sons and a daughter. Thus, I realize that I represent a group not previously heard by this committee and I certainly cannot in any sense be considered to be opposed to the perpetuation of the species. I shrink from approaching my testimony in such a highly personal manner, but after carefully reviewing the situation, it seemed to me that only in this way might my combined areas of experience be of some value to you.

In looking at a subject with as many ramifications as the oral contraceptive, all of us who deal with individual patients as well as major programs face many difficulties. On the one hand, we appreciate the obvious necessity for finding contraceptive methods which are 100 percent effective and 100 percent safe—this is not entirely the province of the academic purist. The thought that any method which we currently employ may fall short of this ideal is intensely disturbing to doctors.

At the other end of the scale, we see the tragic results of unwanted pregnancies and the growing twin horrors of overpopulation and pollution. Those of us who live and work between these two extremes understandably find ourselves in a somewhat schizoid situation. To date, these hearings have not made our lives any easier. It seems to me that much of the previous testimony has been rather like a bikini; what it has uncovered has been interesting, but what it has left concealed is vital.

To my mind, one major misfortune has been the artificial and totally erroneous creation of two camps of doctors, the pro-pill and the anti-pill. Except for a few extremists among us, such an arbi-

trary division is not only totally unrealistic but also most regrettable. I believe that I speak for the overwhelming majority of physicians when I state most emphatically that I do not belong to either group.

Senator NELSON. May I interrupt you for a moment?

Dr. CONNELL. Surely.

Senator NELSON. I would think that perhaps all but two witnesses would put themselves in your category. There may have been reports and stories written which characterized witnesses as pro-pill or anti-pill. I read one national magazine that said that this week, the hearings were loaded seven to one against the pill. I could find about four of them who did not address themselves one way or another, pro or con the pill. But the hearings have not been aimed at either camp, and I do not think that more than one or two of the witnesses who have already appeared would put themselves in the category of anti-pill.

Some of them have been pro and others have simply expressed their concern about certain aspects of it. But today, Doctor Ball was the only doctor who has testified that he was opposed to using the pill at all.

Dr. CONNELL. I was not speaking here only of physicians testifying before you. I was speaking of physicians at large who are now being classified by their patients and their confreres as being either pro- or anti-pill. This is what is happening outside of these hearings.

I firmly believe that no thinking objective doctor can be totally pro-pill or totally anti-pill. We all recognize the tremendous contribution made by these agents to medicine and society, and we use them with the same judgment and the same respect we pay to any powerful drug. In this respect, we are pro-pill.

We also recognize that there is an element of risk in all potent medications, and so for particular patients, we are anti-pill. However, to be forced daily by current pressures to declare ourselves as belonging to either the far left or the far right on this question is not only increasingly annoying but is actually incredibly destructive. Segregation of doctors into opposing camps is of value to no one, least of all the women we are all dedicated to serving.

I would like to look first at what has come out of the preceding days of testimony, as viewed by a self-styled moderate. First of all, virtually nothing has been presented in these hearings that those of us working in this field have not heard many times over. When I examined the vintage of the testimony to date, I discovered that some is relatively new, much is several years old, and a few pearls of information were in print long before I started in medical school.

It has been frequently asserted that the hearings, thus far, have been slanted, one-sided, and unfair. Objective consideration suggests that in one sense, this criticism may indeed be valid. The bias which I feel has been noticeable on previous days has been the bias of positive results. No scientist of experience would question the capability and integrity of almost all the previous witnesses. Their work has been meticulous and their results are not in question. What is disturbing is the fact that such a great percentage of time has been

devoted to two areas—first, experimental work carried out by competent men in excellent laboratories, but far removed from patient care and its implications; and second, to side effects which occur in a very small percentage of the patient population. What has been missing to date and what I think is needed to maintain an overall proper balance and perspective is a better look at the vast majority of women who can and are taking oral contraceptives safely and effectively.

As a physician who began to practice before the advent of the pill, I am constantly aware of the immense difference it has made to the lives of women, to their families, and to society as a whole. The look of horror on the face of a 12-year-old girl when you confirm her fears of pregnancy; the sound of a woman's voice cursing her newborn and unwanted child as she lies on the delivery table; the absolutely helpless feeling that comes over you as you watch a woman die following criminal abortion; the hideous responsibility of informing a husband and children that their wife and mother has just died in childbirth—all these situations are deeply engraved in our memories, never to be forgotten. Since we have had more effective means of contraception, the recurrence of these nightmares has blessedly become less frequent. The thought that we may once again be forced to face these disasters on an increasing scale because of the panic induced by these hearings strikes horror into the hearts of all of us who have lived through this era once before.

A great deal of very positive information was presented here last month. Aside from the obvious personal, social, and economic advantages of planned pregnancy, we were told of lowered prenatal loss, fewer abnormal babies, and lessened maternal risks.

Unfortunately, the general public was not always made aware of this type of information to the same degree that they were made painfully aware of the frightening speculations and the diversity of professional opinion.

Senator NELSON. Might I interrupt you for a minute?

Dr. CONNELL. Surely.

Senator NELSON. What would be your conclusions about that? That Dr. Hellman, who headed the FDA task force, should not have testified, or that Dr. Hertz should not have testified or that Dr. Davis of Johns Hopkins should not have testified? Should not what qualified doctors and scientists were saying about the pill have been made public?

Dr. CONNELL. I would certainly in no way suggest that any of this evidence should not have been given, but I would suggest that similar prominence should have been given to other equally credible evidence that was of an extremely positive nature. I do not think that this latter information came through to the general public to the same or with the same intensity. The statement was not made in criticism of anything that was presented here; it was simply in criticism of balance.

Senator NELSON. Of balance of what?

Dr. CONNELL. Of the overall balance of impact of the very positive aspects of some of the testimony as opposed to the more sensational, not so positive, aspects.

Senator NELSON. Are you talking about what was testified to here, or what was reported?

Dr. CONNELL. I am talking about what was testified to here, out of which came reporting. I am talking about both of these aspects.

Senator NELSON. What I am trying to clarify in my own mind is whether your criticism is that these distinguished people testified as to their view about the pill. Some of them have reservations, some of them presented scientific, accumulated scientific knowledge.

Do you think all the facts are not being presented, or that in reporting the facts in the press, some of this has been lost? That is what I am trying to get at.

Dr. CONNELL. I think that timewise and balancewise, we have seen more emphasis placed on the disturbing negative aspects of what medical evaluation has unearthed than on the positive aspects of the benefits, which have also been described here. It is a matter of balance.

Senator NELSON. Do you not think that may appear to be so, because the news for 10 years has been an almost unqualified endorsement in the lay press, and suddenly, for the first time, reports are being made by distinguished authorities expressing reservations, and therefore, it is not news to report that the pill is perfectly safe, as has been reported for several years, but it is news that distinguished scientists are expressing their reservations and concern about it? Is that not the case?

Dr. CONNELL. That may possibly appear to you to be the case, but I have heard these same distinguished scientists report precisely this same information for years. Therefore, I do not see wherein the newness necessarily arises. I have been hearing these same men and many others present similar data at meetings for many years. Therefore, to me, this does not represent anything new.

Senator NELSON. I think some of it may probably be 2 years old. It is sort of like chloramphenicol. For years, the American Medical Association warned against the misprescribing of chloramphenicol. When Dr. Goddard came in and testified that, "I am at wit's end on how to dissuade the medical profession from prescribing chloramphenicol for non-indicated cases," it became news. When Dr. Dame-shak appeared from Mount Sinai Hospital to testify that in his opinion, 90 percent of the patients were receiving chloramphenicol for non-indicated cases, it became news. I received all kinds of letters from doctors then, saying, you are driving a good drug off the market. You are disturbing my patients. The reason they were disturbed was that they were finding, from the best medical evidence, that 90 percent of the patients were getting chloramphenicol for non-indicated cases.

Now you have the situation where all the news has been positive and rosy about the pill, with little or no reporting on known side effects from the pills for years. But now even Dr. Hellman, chairman of the FDA committee is saying, "I have reservations." He cannot say it is perfectly safe. He says, "I am uneasy" about the pill.

I would think it ought to be news when the man who directs the report for the FDA says, I am uneasy about the pill; we cannot say

positively that it is safe. That was never reported before. When the FDA report came out, I scoured through everything I could find in the press. All they said was, the report says it is safe. It did not include the reservations in the report or the reservations that Dr. Hellman had himself, or reservations that Dr. Hertz had.

I think the problem is that this is the first time that the reservations about the pill by scientists are being aired in public, and the public has heard about them for the first time.

Dr. CONNELL. I think perhaps this is a matter of perspective. Obviously, you and I go to different kinds of meetings. I have heard much reporting of data on side effects for many years. How much of this gets into the media that the average individual sees and reads is perhaps our point of difference. I can only say that none of this information is new to those of us who are involved in patient care and research who have reported these findings who have been talked to and quoted by reporters, who have been involved with multiple presentations of this material at all types of meetings over a period of years. So maybe it is a matter of perspective from where we sit.

Senator NELSON. I am sure that those who are professionally engaged in the field such as yourself—

Dr. CONNELL. We have written about these things for a long time.

Senator NELSON (continuing). And have done studies of your own for a long time, so it is not news. I would guess that it is news to probably most of the medical profession, though, those who are not directly involved, that Dr. Philip A. Corfman, of the NIH, writes an article, in which his concluding sentence is: "Nevertheless, this use"—that is the pill—"should be monitored and restricted to women who cannot use other methods effectively."

I doubt whether 10 percent of the doctors in America know that that is Dr. Corfman's view. You no doubt do, if you have followed the literature.

Dr. CONNELL. I have read this statement.

Senator NELSON. But the public does not know that, and most of the doctors do not know this. I think the fact is that for the first time, this kind of information is being given to the public and, of course, it is upsetting and it is news because it is contrary to the general news for 10 years which has flatly asserted the pill is safe, that there are no problems.

Dr. CONNELL. This is not what we have been saying and writing.

Senator NELSON. So this is being widely spread. And suddenly, the user of that pill discovers there are some serious side effects.

I would guess it would be upsetting. My view, then, is that everybody who used the pill, if she knew or was advised in advance, maybe she would not take the pill, or if she did, she would not get concerned about the facts being brought out here.

Dr. CONNELL. I could only say in response to your quotation of Dr. Corfman's statement that this obviously represents his personal opinion, and does not necessarily represent the views of all physicians in active practice. Therefore, to present his opinion as a fait accompli and something new is, I think, a little bit out of context.

Senator NELSON. I was saying I am sure you knew about it, but I doubt whether the public or the medical profession knew about Dr.

Hellman's statement or about Dr. Corfman's. That is all I am saying. Those within the profession, those who are keeping up, know, but much of the medical profession and the public does not. That is why it is news. You are saying the news has been negative. That is the reason, because that is news. That it is safe has not been news, because that had been ailed in the news for 10 years.

That would be my guess as to why, when it is written about, that is the way it is written. I would much prefer that we put it in total balance. I would think that would be much better.

Dr. CONNELL. I could not agree with you more.

Senator NELSON. However, it is not.

Dr. CONNELL. I can only say that as an objective observer of the impact of the hearings to date, that I would not consider the balance at the moment, to be quite dead center. This is obviously only my opinion.

Senator NELSON. Sure.

Senator DOLE. I would like to add that, as you said, it depends on where we are seated. We see it one way, we listen to the testimony of experts. You are out in the field. I would suppose that many doctors have learned a lot about these hearings, and they have had a lot of phone calls based on what has been said in these hearings, and they have probably studied a little more about the pill than they had studied before. I think we are getting balance in the hearings, and I think your presence here will be very helpful in assuring this balance.

There has been a great amount of concern expressed across the country because of these hearings.

As you point out later in your statement, we are just now beginning to realize that there will probably be some unwanted pregnancies because of the publicity generated by these hearings.

Senator NELSON. I am very sorry; we shall have to interrupt you. That is a rollcall vote.

Maybe everybody could grab a little bit of lunch and return at 1:30 p.m.

Does that interfere with any plans you may have?

Dr. CONNELL. No, I think it is a marvelous idea.

(Whereupon, at 12:30 p.m., the hearing recessed until 1:30 p.m. February 24, 1970.)

AFTERNOON SESSION

Senator NELSON. May we have order, please.

Doctor, I apologize for interrupting your testimony.

STATEMENT OF DR. ELIZABETH B. CONNELL—Resumed

Dr. CONNELL. That was perfectly all right, Mr. Chairman.

Senator NELSON. Please go right ahead.

Dr. CONNELL. I think we were at the point of discussing the positive and the negative information as I saw it. I would like to go back to the statement that the relevance and the ultimate significance of both the positive and the negative data were not always

presented in such a way that it could be easily understood by the average individual. From a purely scientific point of view, much of the information displayed thus far, can be likened to the relationship between the drunken man and a light post—it has been used more for support more than for illumination. Even the most violent of critics under questioning conceded the limitations of his data, and stated that many of his conclusions were based on unsubstantiated speculation and would not bear the scrutiny of an objective statistical analysis.

Mr. GORDON. What page are you on?

Dr. CONNELL. I am summarizing. I am not reading my entire testimony.

We are already unfortunately beginning to reap the rewards of the publicity coming out of the January hearings. Most reporting, happily, has been both objective and accurate, but even so, it has created vast uneasiness and unhappiness. This was clearly foreseen and predicted by all physicians working closely with family planning at the grassroots level. I can speak most accurately about the results as I have seen them in New York City, but I know from many personal contacts that this experience is being mirrored throughout this country and abroad.

We are just now beginning to see the first of the pregnancies of women who panicked in January, stopped their pills and did not seek or use another means of birth control. These women will not be here to testify, but they now bear within their bodies mute testimony to the effectiveness of induced fear.

Quite parenthetically and most tragically, they also help to dispel the dire predictions made here of prolonged and widespread sterility following the use of oral contraception.

I have repeatedly heard the statement made that middle and upper class women might be upset by the adverse publicity, but that this would not be the case with her culturally deprived sister in the ghetto. Nothing could be further from the truth. Clinic personnel have told me that the mass media reaching low-income women in New York City were among the most active in reporting these hearings. Clinic staffs, as well as private physicians, have been inundated with telephone calls and visits by disturbed women seeking answers and reassurance.

It would be nice to think that out of this intense activity has come the needed and neglected patient consultation and instruction about which we have heard so much. Unfortunately, most of this was the purposeless activity of women who already have been properly instructed and cared for, had made their decisions and previously had been entirely satisfied with their contraceptive method. It is obviously too early to detect illegal abortions and deaths occurring as a result of these pregnancies, but it is axiomatic that they will occur in increasing numbers.

We might get some idea of the impact thus far by observing what has happened across the country in different localities. Let us look at the experience in planned parenthood clinics from January 14 to February 13 in such diverse areas as Detroit, Houston, and New York City. In Detroit, where approximately 10 requests for dia-

phragms have previously been made per month, 118 patients asked to discontinue the pills and be fitted with diaphragms.

Senator NELSON. May I interrupt there?

Dr. CONNELL. Surely.

Senator NELSON. The best statistics that we have had presented here are that the diaphragm, properly used, is about as good as the pill, is it not?

Dr. CONNELL. I think you will find, Senator Nelson, if you look at comparative data on use-effectiveness that we must talk about two different things here. I do not believe that you would find the use-effectiveness of the diaphragm in large studies to be as good as the pill. When you say "properly used" you are talking of total effectiveness for individual well-motivated intelligent women who use a diaphragm every time; this is one thing. But one must look at use-effectiveness, must look at the prevention of pregnancy for large groups of women over prolonged periods of time. When one does this one does not find the same order of efficiency and effectiveness.

Senator NELSON. Do you not have to, if you are going to start using these figures, include in your statistics the fact, and the testimony varies a little bit—that 40 to 50 percent of the women quit using the pill after a number of months or in other testimony that over half quit after two or three years? That is a much more important statistic than the 6 percent of the—that is, the one-third of the 18 percent in the survey made by Newsweek, who say they were going to quit because they have been concerned about the testimony.

In other words, Newsweek did a survey in which 18 percent of the women are now quitting the pill, 6 percent on account of what they have read in the papers about it. That is the smallest factor involved in that 18 percent. The 50 to 60 percent that quit after a year or two or three, according to one study, and the 30 to 40 percent that quit after a few months according to another study, are much more dramatic statistics than the 6 percent, are they not?

Dr. CONNELL. Here you are talking of use-effectiveness and you are also talking about the use of a method which are two different things. A patient who stops using a particular method cannot be used in the statistics for that method.

Senator NELSON. But the percentage of women who have quit using the pill for one reason or another has been dramatically higher by six or eight or 10 times than those who have quit because of reading something in the paper.

Dr. CONNELL. I think most of this data remains to be collected. We have some concept of the number who are switching, the number who have gone off pills. But we have no idea, there has not yet been time to measure the actual importance of these figures. Therefore, I think it would be dangerous to generalize today as to what the ultimate result of all this is going to be. I think it is a little premature.

Senator NELSON. All I am pointing out is—and I don't have it before me—that one study indicates that 50 to 60 percent of women, after a period of time, quit on their own.

Dr. CONNELL. I am familiar with this.

Senator NELSON. Another 30 to 40 percent quit, in another study, after 6, 7, or 8 months. So you have large numbers quitting, and all

you are talking about here is six percent who quit the pill on account of publicity out of the 18 percent that said they were quitting in the survey, and of that 6 percent, many are switching to the IUD and the diaphragm. So that again reduces substantially the percentage who are seriously exposed to becoming pregnant.

My view is that dramatic statements that I have been reading by some physicians around the country about how effective the pill is, simply ignore the statistics on how many quit voluntarily.

Dr. CONNELL. I think this may very well be true, but again, I think it is too early to draw any long range conclusions.

Senator NELSON. That is what I am saying. I think the doctors have been premature in drawing their conclusions.

Dr. CONNELL. I think that doctors are seeing their patients and are reporting that some have stopped taking pills and that some are pregnant. This is factual. The final outcome of all this, I agree with you, must remain speculative for the moment.

Also, we are looking at two different groups here, the women who stop a particular type of therapy because they have developed symptoms and the women who stop simply because they are afraid. I think these are two identifiable groups in both of which we are beginning to build numbers. Therefore, when you talk of 50 percent going off, as was testified here before, which group or groups are you talking about?

Again, I think one has to know a little bit more about what the numbers mean. Otherwise, it is statistical gamesmanship.

Senator NELSON. That is what I think has been going on. I have not been making many statistical observations, because I do not think anybody has any statistics yet.

Dr. CONNELL. I think they are coming. I think we will soon be able to do this.

Senator NELSON. Well, that may be. However, I have read dramatic statistics recited by doctors the day after the hearings, that this will mean 100,000 pregnant ladies.

What I do not see is statistical support. Certainly they would not use that kind of scientific evidence or unscientific evidence to make a diagnosis of a physical condition. They should not make such a diagnosis of a social situation.

All of these dramatic statements on the front pages all over the country are probably contributing in their own way to people quitting the pill.

Dr. CONNELL. What I am presenting here is not speculation if I may be permitted to go ahead. The numbers are factual. I do not intend to speculate.

Senator NELSON. You have your 118 patients that you mentioned quitting the pills and going to diaphragms.

Dr. CONNELL. That is a factual statement.

Senator NELSON. They are on a birth control device. How many of those are you now predicting are going to be pregnant against their will.

Dr. CONNELL. I would not predict this. The only way you could estimate this is to look at the use-effectiveness data for diaphragms for the particular patient populations involved.

Senator NELSON. So the number of people who have switched from the pill to the diaphragm, as advised by many doctors, does not indicate a single pregnant patient.

Dr. CONNELL. This may be true, but I think it is significant that in one month, you have 118 requests, whereas normally you have only 10. I think this is significant behavior. It indicates significant change in behavioral patterns, if you will.

Senator NELSON. That is what I mean.

Dr. CONNELL. This is all I am saying.

Senator NELSON. It does not indicate pregnant women?

Dr. CONNELL. Not yet, no.

Senator NELSON. All I am saying is that you state if they go off the pill, they must become pregnant. You are stating that they went off the pill and went to the IUD or diaphragm, and that is what many physicians recommend at present as a matter of practice.

Dr. CONNELL. I am not saying that all women stopping the pill will become pregnant just because they have changed to less effective methods of contraception. All I am pointing out is what we have observed statistically over a 2- to 4-week span of time, which I think is significant.

Senator NELSON. You say it is significant. We have had a number of doctors who testified that that is just what they would advise for their patients.

Dr. CONNELL. This is perfectly true, and they are certainly entitled to their medical opinion.

Senator NELSON. I thought the argument was made, the comment was made that this adverse publicity in the papers was causing a great catastrophe, and to prove it, you then cite the statistics of how many switched.

Dr. CONNELL. I am saying it has had an undeniable impact. The ultimate impact I would certainly not discuss. I do not think anybody is capable. I am simply pointing out that in certain centers across the country, there has been a change in patient behavior which I think is a perfectly fair statement of objective evidence.

Senator NELSON. I think so. We have a number of doctors who would be very pleased.

Dr. CONNELL. I presume that there might be some who would be delighted, but there are also many who feel quite the opposite.

Senator NELSON. I am sorry; we have another roll call.

It will be 10 minutes.

(A brief recess.)

Senator DOLE (presiding). Dr. Connell, you may proceed with your statement. The Chairman has gone to vote and will be back. In the meantime, do proceed.

Dr. CONNELL. We were discussing the change in patient behavior in a variety of cities, the first one being Detroit. Where before, a total of 60 IUD's have been inserted per month, 107 were inserted, 45 in patients who had switched from pills.

There have been 100 requests for sterilization, both male and female, which represents a marked increase over previous requests.

In Houston, 50 pill patients switched to IUD's and 10 to diaphragms. An additional 2 hours per nurse per day has been needed to cope with the extra activity.

In New York City, 25 percent of the patients who were taking oral contraceptives requested consultation when they returned to the clinic, and 18 percent were then given IUD's or diaphragms.

Acceptance of pills by new patients went from 70 percent the first week in January down to 47 percent in the first week in February.

All of these Planned Parenthood Centers reported that women were frightened, that the number of phone calls had doubled over the number previously coming in and is remaining at this level and that much additional time has to be spent conferencing and reassuring patients.

Objective data coming from the clinics in New York City also bear out the subjective impression of patient fears and subsequent behavior. In the OEO-funded clinics, approximately 80 percent of the new patients asked for the pill during the 3 to 4 months prior to January 15, 1970. Since that date, this has dropped to approximately 60 percent, and these clinics report that many patients have discontinued using pills for nonmedical reasons, unrelated to the development of symptoms.

In the Maternal and Infant Care projects in New York City, approximately 65 to 70 percent of their patients asked for pills in 1969. During the 4 weeks of January, percentages of their 1,200 new patients were 63, 62, 58, and 47, staying at this new low level in early February. A search for factors other than the adverse publicity did not reveal anything else that could account for this precipitous drop.

I am sure that such information will be most gratifying to opponents of the pill. However, I can only say that it strikes profound fear in the hearts of those of us who deal daily with women and population problems. Despite what has been stated here, I do not know of anyone with wide experience who feels that at this moment, there is any alternate method or combination of methods of contraception which can immediately and completely replace the oral contraceptive.

The statement is frequently and glibly made that IUD's and traditional methods can and should be used in place of the more dangerous pill. To anyone who has dealt with large groups of patients, such an assertion is not only untrue but is patently ridiculous on several scores, and therefore dangerous.

First of all, the fact that the IUD carries its own burden of side effects and deaths is frequently glossed over. Second and much more important is the fact that we have all seen that women will not universally accept and use these alternate and less efficient methods.

It is very easy to talk loosely about patient education and motivation. However, studies have been done in this area which point out that education alone will not provide the answer today, tomorrow, or anywhere in the immediate or foreseeable future, even with unlimited funds. In my opinion, and in the opinion of many other physicians, there is at this moment no panacea for the loss of the pill.

I would like to look at a few points raised here last month, as seen through the eyes of someone actively and vitally interested in contraceptive programs. In January 1964 I started and developed a

Family Planning clinic in Metropolitan Hospital, which is one of the larger municipal institutions in New York City. In addition, I am clinical consultant in family planning to the New York City Department of Health, project consultant to the family planning unit of the Human Resources Administration. I am a member of the Medical Advisory Board to Planned Parenthood of New York City, and have personal knowledge of most of the remaining large clinics in the New York City area.

Criticism has been leveled here at such clinics, saying that patients are not offered free choice of methods, that they are not told of possible side effects and warned to return immediately if certain untoward symptoms occur, and that follow-up care is inadequate.

I can say with the assurance of direct knowledge that such assertions are far from true. In point of fact, the care received by patients attending these facilities is not only good, but it frequently represents the only medical attention that these women get. Most of them have previously received only "crisis" care.

The family planning clinics in New York City, therefore, have great public health importance, because for the first time, patients now receive continuous medical supervision. To say that all patients, both service and private, receive superlative care in its broadest aspects would, of course, be foolish.

However, to allow the impression to prevail that most patients, particularly those in the lower socio-economic groups, receive deficient medical care in these clinics is equally foolhardy. Many clinic facilities are dingy and overcrowded, patients are forced to wait much too long to receive care, needed ancillary services are inadequate, but the contraceptive care per se is good.

Having suffered through the birth and development of a clinic, I feel very deeply the great handicaps under which we have had to work.

Family planning is a field which only recently has gained status and a minimum of support. Inadequate space, lack of personnel, the failure of city, State, and Federal governments to provide sufficient funds for this purpose has hampered all of us.

In my testimony is a small section of a paper which I presented in 1966 and which was published in the "American Journal of Public Health" in 1967. It expresses the frustration felt by many people in those years, points out the problems we faced and the solutions that we found for some of them.

Inevitably, I also became vitally interested in the evaluation of current methods of contraception and the development of improved techniques.

Senator DOLE. Dr. Connell, I think it might be well to clarify something, since the quotes will be part of the record. You do state that you had obtained grants and the clinic has been sustained in part by grants from pharmaceutical companies, which might be taken to indicate some bias in your testimony because of that relationship.

I wonder if you might expand on the nature of the grants and what, if any, effect this relationship with the pharmaceutical companies may have on your testimony.

Dr. CONNELL. I think one has to look at this fact in context. One of the reasons that I put this particular quotation in, quite obviously, was that I felt that this question was inevitable. I think it is quite safe to say that if you examine the history of most major clinics throughout this country, you will find that this type of financing has been necessary for the actual service and care of patients in these clinics.

We have never had sufficient funding. It has been the practice of medicine to accept funds from the private sector in order to run programs, in order to make developments possible, in order to evaluate new and better methods. Therefore, I, as practically every other practicing physician who has been before you, have been involved in contraceptive research, in return for which, of course, we receive funds.

This is how medical technology has been advanced in this country. Therefore, I am not unique.

I think it would be almost impossible to call any authority on the pill before this committee who is not in a similar situation, who has not done drug evaluation. This is simply the way medical practice in this country has been carried out. Therefore, I am representative, again, of a very large group of individuals.

This is how data are collected. This is how we learn.

I also do research on intrauterine devices. I also have trained students for the Department of Labor. I also have accepted funds from OEO. I also have accepted funds from HEW, from Planned Parenthood, from a variety of sources; frankly, anywhere I could get money to run my clinics. Therefore, I do not feel my personal obligation to be any greater to any drug company than to the Department of Health, to OEO than to Planned Parenthood, to HEW than to the U.S. Public Health Service.

Again, I think I represent probably the majority of people who have been here before you. All of us who do research, almost without exception, have been in a similar situation. I do not believe that any of us feels a greater obligation to any one funding source than to any other.

I have personally felt no bias. I have said some drugs are excellent, I have said some are very poor. This is part of the reporting of an objective research investigator.

Senator DOLE. It is well to have the fuller explanation in the record, because there are some who may believe that because of the relationship, you could not be objective or would not criticize.

Dr. CONNELL. I think we all do criticize. Again, if one looks at the medical literature, one will see that those of us who investigate drugs have been reporting that there are difficulties, there are problems. These preparations are not the panacea; they are not 100 percent perfect. We have said so.

Senator DOLE. You do not share the conviction of Dr. Ball, who said earlier this morning that there should be a 5-year moratorium on oral contraceptives?

Dr. CONNELL. No; I think this would be extremely unfortunate for many, many reasons.

Senator DOLE. Sorry to have interrupted you.

Dr. CONNELL. That is all right. I am glad to have this clarified, because I do not feel that my soul is owned by any drug company, any more than it is by any Government agency.

Like most of the practicing physicians who have appeared before you, I have conducted research programs because I recognized that our existing information was inadequate and our current methods imperfect. One of the areas in which I have worked for the past 4 years is the evaluation of eye findings in patients receiving oral contraceptives. I presented a paper on this material at the Annual Meeting of District II and III, American College of Obstetricians and Gynecologists, in New York City, on September 23, 1967, and it was published in "Obstetrics and Gynecology" in 1968. It points out the need for background information so that the discovery of abnormalities in a retrospective study does not lead to erroneous and damaging conclusions.

The accusation has been repeatedly made during these hearings that physicians engaged in research were either unaware of or deliberately disregarded the problems connected with oral contraceptives. Even worse, we have been charged with the actual suppression of data relating to these problems.

In a paper which was published last year in "Advances in Planned Parenthood," I described the changes in blood coagulation factors which we have observed in our patients. Hundreds of such papers have been published by me and by many other doctors over the last 5 to 10 years.

Thus it is hard to fathom how anybody who makes even the slightest attempt to keep abreast of current medical literature could say that doctors involved in drug evaluation have not been reporting the abnormalities that they see.

Senator NELSON (presiding). May I interrupt at this point?

Dr. CONNELL. Surely.

Senator NELSON. I just cannot recall the testimony—I am wondering what testimony specifically you are referring to when you say the accusation has been repeatedly made during these hearings that physicians engaged in research are either unaware of or deliberately concealing the problems connected with oral contraceptives. I do not remember that.

Can you tell me whose it was?

Dr. CONNELL. Dr. Williams', as I recall. I do not have his testimony with me, but it is my distinct impression that this was the sum and substance of it. As I recall, he discussed misstatements of facts by prominent physicians promoting the pill, suppression of adverse data from Puerto Rico, and failure to carry out proper research.

Senator NELSON. Then you say the accusation has been repeatedly made. I do not remember Dr. Williams' testimony.

Dr. CONNELL. Dr. Kassouf, also, I believe, mentioned this.

Senator NELSON. What did he say?

Dr. CONNELL. The implication, again, was that a great deal of information had been suppressed by a variety of people, including the clinical investigators. I believe that he used the Drill-Calhoun

paper on thromboembolic disease as an example. He also accused the AMA of suppressing information by refusing to publish papers on patients developing strokes and cervical cancer.

Senator NELSON. On the oral contraceptive?

Dr. CONNELL. Right.

Senator NELSON. I guess I shall have to look into the record.

Dr. CONNELL. This is my recollection.

Senator NELSON. Suppressed by whom?

Dr. CONNELL. The individuals doing the work, Committees reviewing the results, pharmaceutical companies, and editors of medical publications.

Senator NELSON. If you remember, would you give us the names of whoever it was?

Dr. CONNELL. Of course.

Senator NELSON. I would like to check it.

Dr. CONNELL. I would be happy to do this.¹

In the interests of time, and at the risk of beating a horse that perhaps should be dead, I would like to mention without further comment the problems of obtaining adequate and reliable data, the difficulties in evaluation of side effects, the relationship between dosage variations and results in both animals and humans, the total inadequacy of most studies to date—all of these and many other critical and vital topics have been brought to your attention.

I do not excuse our present lack of knowledge, but only point out that our areas of ignorance are known, are deplored, and are currently receiving all the attention that time and money at the moment will permit us to give.

Senator NELSON. I did not understand that sentence. You say you only point out that "our areas of ignorance are known, deplored, and currently receiving all the attention that time and money will permit us to give."

You are not saying, are you, that we do not need additional research?

Dr. CONNELL. What I am saying is that the funds we have available are insufficient to do the job properly. Within the confines of our present capability, we are doing the best we can, but we need a great deal of additional help in order to do the job more adequately. We acknowledge the inadequacy of many of our studies, the paucity of numbers. We have not done as much as we could have, because we have not had the support to do it.

Senator NELSON. The meaning that you intend to convey there is that with the limited money you have, all that can be done is being done. Is that what you are saying?

Dr. CONNELL. I think we are attempting to do, with limited funds, as much as possible. We all accept the fact that we could do a great deal better and we are not satisfied at all with what we have been able to accomplish to date.

Senator NELSON. And if there were substantially increased amounts of research funds in this field, it could be usefully used now?

¹ This information was not supplied by Dr. Connell.

Dr. CONNELL. I think this is quite correct. I think there are many programs that many of us would like very much to do but they would take additional funds. I think the problems have been made very clear, the enormity of the study, the enormity of the problem, and what one would have to do to get some answers to these questions. I think this has been testified to many times here.

We do not know all the answers we need to know, and we need support to find them.

Senator NELSON. I was just interested in ascertaining whether your statement meant that we have all the money that we need?

Dr. CONNELL. No. I meant that what we have is inadequate.

Before I leave this topic, I would like to emphasize three points, all made before by others.

First, with the single major exception of thromboembolic disease, there has been no proven relationship between any of the alterations reported here and the production of permanent damage.

Second, it has been repeatedly pointed out that most of these changes are either preventable or are detectable with good medical care, and usually disappear after cessation of treatment. Thus, even the accepted complications might be decreased with an acceleration of research and an augmentation of services.

Third, one of the stated aims of these hearings has been to determine the current level of patient training and information, and to find out whether those women who elect to use the pill do so with full knowledge of possible side effects. As both a clinician and a researcher, I see many problems in this area. There is absolutely no question in my mind that as substantiated data on adverse reactions become available, they should be communicated to patients.

However, to present the list of possible side effects as outlined in the present package insert to the average patient would serve no useful purpose, and would have many foreseeable and disastrous effects. We have been told here that almost all of these are still conjecture, not proven fact.

A patient cannot reasonably be expected to make a profound professional judgment—she is not a doctor. We have seen that even individuals with wide knowledge and experience are in disagreement. How can we ask or expect informed decisionmaking from these women based on such debatable information?

Senator NELSON. May I ask a question?

Dr. CONNELL. Yes.

Senator NELSON. On page 10 of your statement, you say criticism was leveled here at such clinics, saying that patients were not offered free choice of methods, that they were not told about possible side effects, were not warned to return immediately if certain untoward symptoms occurred, and that the followup care was inadequate.

I take it you are saying here that in your clinic, all these things are done? That is, that the patients are warned of possible side effects, warned to return immediately if certain untoward symptoms occur?

Dr. CONNELL. I think I speak for more than my clinic. As I mentioned here, I am a consultant to many of the major clinics in New York City. Therefore, I am involved in the training and supervision

of personnel. I supervise and approve the written material which is given to patients. Therefore, I think I can speak with a certain amount of concrete objectivity about what is actually told to patients, what is actually given to patients, what they are informed of, what they are told to watch for. I also know about the availability of personnel, to answer questions in person or by telephone, bilingual personnel in our situation because of our very large Puerto Rican population.

I think I can speak of my own knowledge of a large segment of New York City clinic populations. I believe that the vast preponderance of these women are informed in a way that most people would find quite satisfactory.

Senator NELSON. I was not referring to that. It seemed to me to be somewhat in conflict with what you are saying on page 14. You say on page 10 that the patients are offered a free choice of methods, that they are told of the possible side effects, that they are warned to return immediately if certain untoward symptoms occurred.

Then over here on page 14, you seem to be saying, to present a list of side effects, possible side effects, as outlined, and so forth, would not serve any purpose.

Tell me specifically, what you do tell them about side effects. What untoward symptoms could occur? What physiological upsets do you advise them of? Under what conditions should the patient call you?

Dr. CONNELL. Our personnel are trained to tell them that there is concrete evidence that in a small percentage of patients there is a causal relationship between the existing oral contraceptives and thromboembolic disease. I think the majority of physicians will agree that this is accepted fact.

I think that this fact has been clearly brought forth here. I think that above and beyond this, it has not been clarified here, or in any medical meeting which I have attended, that there is a scientifically proven and accepted cause and effect relationship in any other area.

There are certain symptoms, certain signs, which I think are warning signals. These have also been mentioned here.

This is the sort of thing I think you should tell a normal, healthy patient. You do not tell her that she has a very statistically small chance of getting diabetes or of getting a variety of other things. I think it is unfair to produce fears in patients when we do not know whether these factors are true or not.

If she has a swollen leg, if she develops a fever, if she has chest pains, if her varicosities get worse—these are the things we should and do tell the patient.

I certainly do not think every patient should take the pill. One of my immediate family called me at midnight last year and described symptoms she had developed while taking an oral contraceptive. I told her that she should immediately stop her pills. She is one of the small percentage of women, I feel, who should not take the pill.

Senator NELSON. Just to get this straight, you say on page 10 that you tell them of the possible side effects. You cite one, thromboembolism. Is that the only side effect you tell them about?

Dr. CONNELL. No. As I said, we tell them certain symptomatic

things to watch for—these would include swelling of the legs, tenderness of veins, headache—these are symptoms.

Senator NELSON. These are the things you are referring to when you say certain untoward side effects—certain untoward symptoms, is that right?

Dr. CONNELL. That is right.

Senator NELSON. What is the whole list—in other words, is there a uniform thing that everybody who advises the patient advises them exactly the same in your clinic?

Dr. CONNELL. I would rather doubt it. I do not think one can advise all patients in precisely the same way. I think one can give them all certain concrete information like that on thromboembolism, for instance.

Senator NELSON. Would you not give them all the same information if—

Dr. CONNELL. I would give them the same information. I might couch it in a little different language for different types of patients, but I would certainly give them all the same information.

Senator NELSON. On what basis would you distinguish one patient should be told if she has a swelling of the leg and others might not be told—

Dr. CONNELL. I am saying that they are all told.

Senator NELSON. What patients do you tell as on page 10, and are all patients told the same?

Dr. CONNELL. Yes, precisely.

Senator NELSON. I thought you said no.

Dr. CONNELL. I thought we were talking about the form in which the information was transmitted.

Senator NELSON. No. You are saying that you uniformly, in the clinic, tell each patient that if certain untoward symptoms occur, they are to call the doctor?

Dr. CONNELL. That is right, or come to the clinic.

Senator NELSON. Are these symptoms—how many of these symptoms are there that they are told about in the clinic?

Dr. CONNELL. Maybe half a dozen or so that I think are important.

I think the problem here is that if you look at the most recent letter to physicians which was discussed earlier this morning, there are a huge number of adverse reactions listed. My statement here is simply that the average individual could not be handed this list, realistically. I think they would neither understand it, nor do I think that we are justified in telling them to patients as proven, since these are admittedly still in the area of unproven scientific information. If they are scientifically proven, as in the case of thromboembolism, I think we can, we should, and we do transmit this information to patients.

Senator NELSON. When you tell a patient about these half dozen untoward symptoms which should cause them to call the clinic, to call a doctor, are these untoward symptoms listed for them in writing?

Dr. CONNELL. In many instances. Each variety clinic has its own technique of patient instruction.

Senator NELSON. In your clinic, are they?

Dr. CONNELL. In my clinic, they are all taught by a conference nurse. They are given an outline of methods with the advantages and disadvantages of each.

Senator NELSON. I mean, is the listing of the half dozen untoward symptoms which you say all patients in your clinic are advised about, is that given to them in writing?

Dr. CONNELL. In some clinics in New York, it is. In others, it is a verbal transmission at a clinic training session. Different clinics elect to do this in different ways but they are given in some form or other.

Senator NELSON. Suppose you have a patient who is on the pill for a year or two. If they do not have it in writing, how can you expect them to recall the untoward symptoms that were given to them in a clinic the first time they went?

Dr. CONNELL. I am not sure that giving it to them is necessarily going to mean that they will keep it and use it a year from now. I think we are talking in the area of continuing patient education, which happens to be a great interest of mine.

I think you do not give any patient anything and then abandon her. Within our programs, we have the capability of continued patient contact—reconferencing, reexamination, reevaluation. I think this is the essence of good medical practice. Therefore, I think as new things come along, they can be transmitted to patients.

This is part of continuing good medical care.

Senator NELSON. What is your opinion of Dr. Ley's statement, plus a number of others who have testified, that the user of the pill ought to receive in the package some simple statement of what the, as you put it, untoward symptoms are so they can look at it every month?

Dr. CONNELL. I think, in essence, this is what many of us have been doing when we convey information to patients both orally and written. Everything in my clinic, for instance, was translated into both Spanish and French so that we could most effectively communicate with patients.

Senator NELSON. I was getting to the question of whether or not a reminder of the possible untoward side effects should be in a package insert they would go to the user.

Dr. CONNELL. As I said, I think many of us already do essentially this.

Senator NELSON. I am sure you, in your clinic, do, but the fact is that the Gallup survey in Newsweek magazine found that many women were never told anything.

Dr. CONNELL. I cannot say anything about what Newsweek magazine found—I do not know how they determined this. I can only tell you that it goes on in clinics.

Senator NELSON. I understand that. I am asking you whether you think it would be useful to have a package insert in the package that they get.

Dr. CONNELL. I do. As I said, I have written such things for patient instruction.

Senator NELSON. I am just asking whether you consider what Dr. Ley is suggesting, and others, would be valuable.

Dr. CONNELL. I think so. As I say, I have given you a very concrete answer as to the fact that I think it is valuable in that I have already done it.

Senator NELSON. I am not talking about what is done in a good clinic or by a conscientious doctor. Obviously, two-thirds of the women, according to the survey, were not told anything. It might be well, therefore, to have in their hands a listing of the side effects.

I am not at all convinced that an ordinary person can carry around in his head the half dozen or eight or nine different precautions or cautions of side effects or indications for calling the doctor. It seems to me he ought to have it in his hand where he could see it.

Dr. CONNELL. I think that it is perfectly reasonable that a patient be told symptoms requiring medical consultation.

Senator NELSON. Do you agree, then, with the FDA Commissioner's statement in his letter of January 12 to 318,000 physicians, in which he says that: "In most cases, a full disclosure of potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risk associated with this method."

Dr. CONNELL. I think within the context that I mentioned in my testimony, which does not include a total listing of the items on the back page of the document from which you are reading, within the confines of what I said before, I think this is an excellent idea.

Senator NELSON. Thank you.

Go ahead.

Dr. CONNELL. Finally, I would like to make just a few comments on the part of the heretofore silent majority—women. The fact that I have chosen to pursue an active and exacting career while at the same time electing to produce six children, should be my most potent evidence for my overwhelming belief in the larger role to which women should aspire.

I know personally the excitement of feeling new life moving within my body; I have known the never-to-be-equalled thrill of seeing my own firstborn child; I know the private dreams and fears that all women have as they watch their children growing up. These joys and sorrows are the right of all women and should be denied to none.

However, I am equally aware of the happiness and fulfillment that comes with being part of the larger world, of making some contribution, no matter how small, to society as a whole, as well as to my immediate family.

With the advent of effective contraception, women, for the first time in history, have been able to plan their lives, space their children, and look to their futures with confidence. How vividly I can recall the countless women whom I have seen in the course of my career—active, creative, productive for the first time in their lives, cut down by an unwanted pregnancy, either because of lack of or failure of contraception.

This is always a tragic thing to see. Such a misfortune can perhaps be considered partially tolerable when it happens to a woman from the middle or upper class. When it befalls, as I have seen so often, the woman who has just begun to establish her identity as a

human being in her own eyes and the eyes of her family, only to be returned to the depths of the ghetto, to carry and bear her unwanted child—such a tragedy has far-reaching implications and ramifications that can escape only the most obtuse and unfeeling human mind.

If unplanned pregnancies increase, as we are beginning to suspect that they will because women have become frightened and turned to less effective methods of birth control, or worse, no method at all, it can only again widen the gap between groups of women.

For many years, adequate means of family planning have been the primary prerogative of the private patient who knew that such help was available and could afford to pay for it. During the past few years this care was increasingly being made available to the poor women as well.

Today, once again, we have created two groups, the haves and the have-nots. When a woman of means finds herself pregnant and wishes not to bear her child, a safe, clean abortion is within her reach. When one of my clinic patients finds herself in the same situation, she usually has one of three choices:

She may bear the unwanted child, she may attempt to abort herself, or she may have a cheap, dangerous, dirty, illegal abortion.

No matter what her decision, such a woman, her family, and society in general will be the ultimate losers. A similar disparate and unfair situation unfortunately obtains when sterilization procedures are examined. The private patient with three or four children who wishes to terminate her child-bearing finds it infinitely easier to do so than does her clinic counterpart with nine or 10. This double standard of medical practice is a gross miscarriage of justice.

Hopefully, legislative and legal measures now under consideration will free the hands and minds of doctors who abhor the situation in which they currently find themselves, disturbed, fearful, and helpless.

There has been much discussion here of the use of women for experimentation and their "internal pollution" with oral contraceptives. I would like to submit that the larger and far more critical and lethal experiment is underway—what happens to these women and society as a whole if we continue our present relentless march to inevitable doom via overpopulation and pollution?

What will happen if individuals and nations are deprived of their ability to control their population size, whether by law, ignorance, or fear? These are obviously rhetorical questions to which we all know the answers. The unplanned pregnancy, the unwanted baby, the battered child, delinquency, illegitimacy, crime, drug abuse, the endlessly repeated chain of events encircling our society at all levels is only too apparent.

Opponents of oral contraceptives always talk in terms of the treatment of "healthy women." Those of us who have to treat women who are pregnant with an unwanted baby do not feel that she can be considered to be healthy. The World Health Organization has declared that, "Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."

Looked at in these terms, we are currently facing a major epidemic. Evidence documenting the panic regarding the pill mounts daily, both here and abroad. If this panic continues, the problems resulting from these fears will be severe in the United States, but the problems abroad may be catastrophic.

Many developing countries where the poverty, maternal deaths from abortion, and all the consequences of the population explosion are most critical have been turning to the pill as part of the solution to their incredibly difficult situations. Our nation has been accused before of a double standard of medical care, of sending abroad, via our foreign aid programs, second class care.

For multiple reasons, oral contraceptives are widely and increasingly used in these countries. If the pill is discredited here, will we again be faced with the problem of appearing to supply something to women of other nations which is too dangerous to give to our own? The ultimate implications of the fear which is also growing abroad are terrifying to contemplate. If no answers are found, we may well be damning and ultimately damned by future generations.

Before closing, I would like to look at what can be done to channel all the energies that have been released into constructive pathways.

One of my favorite quotations from Aristotle goes as follows:

It is easy to fly into a passion—anybody can do that—but to be angry with the right person and to the right extent and at the right time and with the right object and in the right way—that is not easy.

We might do well to consider this ancient advice. There are a number of obvious ways out of our current dilemma. First of all, it lies within our scientific capability to answer many of the questions raised at these hearings, given sufficient funds and direction. Some programs designed to obtain valid answers are underway, others are awaiting support, and many remain to be written. The need for expanded research to find new contraceptive methods and the means to make them widely and rapidly available is too patently obvious to pursue further.

Much of this progress, of necessity, lies somewhere ahead of us. What can be done today? Remove all the archaic legislation on abortion and sterilization. This would free both women and their physicians and correct the current social and financial inequality of care.

Then, support the programs needed to implement the demands which will immediately and inevitably arise as a result of these reforms. Pass legislation dealing with population problems and their solutions. Provide funds for the training of people to work in these programs at the professional level, but, much more importantly, at the paraprofessional and community levels. It would be unrealistic to think that immediate solutions could be found to all the many and varied problems that we now face, even with unlimited funds. However, many paths are open to us today, and I feel that our next steps are clear.

(The complete prepared statement submitted by Dr. Connell follows:)

STATEMENT OF ELIZABETH B. CONNELL, M.D., ASSOCIATE PROFESSOR, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY; DIRECTOR OF RESEARCH AND DEVELOPMENT, INTERNATIONAL INSTITUTE FOR THE STUDY OF HUMAN REPRODUCTION, COLLEGE OF PHYSICIANS AND SURGEONS, COLUMBIA UNIVERSITY

Mr. Chairman, thank you for the invitation to appear before you today. I fully recognize the tremendous importance of the course and outcome of these hearings and believe that there are four areas in which I may be able to make some small contribution based upon my personal experience.

First and foremost, I am a physician. I have been a general practitioner in a small town and a specialist in Obstetrics and Gynecology in New York City. I have been privileged to care for some of the wealthiest people in our country; I have been even more greatly privileged to care for thousands of our most grossly deprived citizens. I have delivered women of their babies under ideal circumstances—in aseptic, brightly-lit hospital delivery rooms. On a bitter, cold night, I also delivered one woman of her child by moonlight on the front seat of an ancient pick-up truck, surrounded by her distraught husband and her seven fascinated children. Having cared for many patients, men, women, and children from all sorts and varieties of backgrounds, I hope, perhaps to bring to this situation something of a clinical flavor based on a long and varied experience.

Second, I started, developed, and ran a family planning clinic in Spanish Harlem in New York City.

This led to the third area which I presume may have prompted this appearance, that of a research investigator. I have worked both in the actual development of newer contraceptive techniques and the equally important peripheral programs related to patient motivation and behavior. Concurrent with the development of the clinic, I worked in the allied and critical area of training of community women to fulfill multiple needs in the health professions.

Finally, I would be naive and less than perceptive if I did not recognize that an additional fourth factor might be operative here—that I happen to have been born a female and have five sons and a daughter. Thus, I realize that I represent a group not previously heard by this Committee and I certainly cannot in any sense be considered to be opposed to the perpetuation of the species. I shrink from approaching my testimony in such a highly personal manner, but after carefully reviewing the situation, it seemed to me that only in this way might my combined areas of experience be of some value to you.

In looking at a subject with as many ramifications as the oral contraceptive, the problem of gaining a full and accurate perspective is indeed a most difficult and troublesome one. Those of us who have dealt with problems relating to individual patients, as well as major programs, are bound to see such a topic in a variety of aspects. On one hand, we can appreciate the obvious necessity for finding methods which are 100% effective and 100% safe—this is not entirely the province of the academic purist. The thought that any method which we currently employ falls short of this ideal is intensely disturbing to doctors. At the other end of the scale, we see the tragic results of unwanted pregnancies and the growing horrors of over-population and pollution. Those of us who live between these two extremes understandably find ourselves in a somewhat schizoid situation. The nicety of proper balance is not always easy to achieve. To date, these hearings have not made our lives any easier. I think much of the previous testimony has been rather like a bikini—what it has uncovered has been interesting, but what it has left concealed is vital.

One major misfortune to my mind has been the artificial and totally erroneous creation of two camps of doctors, the “pro-pill” and the “anti-pill”. Except for a few extremists among us, such an arbitrary division is not only totally unrealistic, but also most regrettable. I am quite sure that I speak for the overwhelming majority of physicians when I say that I do not belong to either group. Not to condemn the pill does not automatically make one a champion of oral contraceptives. Nature does not construct all things black or white, yellow or blue. She makes them in shades of grey and green. I believe that thinking, objective physicians are neither pro-nor anti-pill. We recognize the tremendous contribution made by these agents and we use them with the same judgement and with the same respect that we pay to any powerful drug. In this sense, we are “pro-pill”. We also recognize the element of risk inherent in all potent medications and so for particular patients we are “anti-pill”. However, to be forced daily by current pressures to declare ourselves as

belonging to the far left or the far right on this issue is not only increasingly annoying, but actually very destructive. Segregation into opposing camps is of value to no one, least of all the women we are all dedicated to serving.

I would like to look first at what has come out of the preceding days of testimony, as viewed by a self-styled moderate. First of all, except for one coy allusion to privy and unpublished information on coronary artery disease, nothing has been presented here that those of us working in this field have not read or heard many times over. When I examined the vintage of the testimony to date, I discovered that some is relatively new, much is several years old, and a few pearls of information were in print long before I started in medical school. It has been variously asserted that these hearings have thus far been slanted, one-sided, and unfair. Objective consideration suggests that, in one sense, this criticism is indeed valid. The bias which I feel has been noticeable on previous days is the bias of positive results. No scientist of experience would question the capability and integrity of almost all of the previous witnesses. Their work has been meticulous and their results are not in question. What is disturbing is the fact that such a great percentage of the time has been devoted to two areas, (1) experimental work carried out by competent men in excellent laboratories, but far removed from patient care and its implications, and (2) to side effects. In most instances, the latter occur in a tiny proportion of the population. What has been missing and what is needed to maintain an overall proper balance and perspective is a better look at the vast majority of women who can and are taking oral contraceptives safely and effectively.

As a physician who began practice before the advent of the pill, I am constantly aware of the immense difference it has made to the lives of women, their families, and to society as a whole. The look of horror on the face of a 12-year-old girl when you confirm her fears of pregnancy, the sound of a woman's voice cursing her newborn and unwanted child as she lies on the delivery table, the helpless feeling that comes over you as you watch women die following criminal abortion, the hideous responsibility of informing a husband and children that their wife and mother has just died in childbirth—all these situations are deeply engraved in our memories, never to be forgotten. With the advent of more effective means of contraception, the recurrence of these nightmares was becoming blessedly less frequent. The thought that we may once again be forced to face these disasters on an increasing scale because of the panic induced by these hearings strikes horror into the hearts of all of us who have lived through this era once before.

A great deal of positive information was presented at your hearings last month. Aside from the obvious personal, social, and economic advantages of planned pregnancy, we were told of lowered prenatal loss, fewer abnormal babies, and lessened maternal risks. Unfortunately, the general public was not always made aware of this type of information to the same degree that they became painfully aware of the ruminations and speculations and the diversity of professional opinion. They heard about triploidy found after stopping pills; they did not hear that there was no evidence that this was repeated in subsequent pregnancy. The spector of abnormal infants was raised; this was not countered by the knowledge that this situation has not occurred, or that there is no reliable data on mutations related to the newer oral contraceptives. They were not told that much of the criticism being leveled now, in 1970, at work done around 1960 was via the retrospectroscope, using information and techniques only recently available to scientists. Nor was it made clear that data obtained from human males and laboratory animals cannot, with total impunity, be transferred and considered applicable to women. On occasion, with a single testimony, curious dicotomies could be observed. Profound fears of the induction of malignancy were expressed. These were based on an assumption of 20 years of administration of the present oral contraceptives. In the same breath, we were told that the pill was a poor method of contraception because it was discontinued by more than half of all women in less than one year.

From a purely scientific point of view, much of the information displayed thus far can be likened to the relationship between a drunken man and a light post—more for support than illumination. Even the most violent of critics has been forced to concede the limitations of his data, and to state that many of his conclusions are based on unsubstantiated speculation and will not bear the scrutiny of an objective statistical analysis.



12.

Public Health" in August, 1967. The following quotation from this report, I believe, expresses the frustration felt by many people in those years.

"In spite of the fact that, by city policy, freedom has been granted to practice almost unrestricted contraception, the financial means and personnel to carry out this new policy have not been similarly freed. Although hospital space is provided for the clinic and some physicians services are covered, sufficient personnel to staff the clinic is not available through general city support to clinics. Nursing service is only minimally supplied and clerical services are entirely unavailable.

"It has been necessary, therefore, to find means to support the majority of the clinic personnel during the early stages of the growth and development. This has been done by obtaining multiple grants from pharmaceutical houses and social agencies. It would seem, however, that since this is an approved municipal hospital clinic, financial support should be available from the city. As general recognition of the necessity of contraceptive services to this population spreads, support should be granted on as firm a basis as to other medical areas."

Inevitably, like many other doctors who developed clinic programs, I also became vitally interested in the evaluation of current methods of contraception and the development of improved techniques. Like most of the practicing physicians who have appeared before you, I have conducted research programs, recognizing that our existing information is inadequate and our current methods imperfect. One area in which I have worked for the past four years is the evaluation of eye findings in patients receiving oral contraceptives. The following quotation from a paper which was presented at the Annual Meeting of District II and III, American College of Obstetricians and Gynecologists, New York City, September 23, 1967 and published in "Obstetrics and Gynecology" in April, 1968 points out the lack of necessary background information and the need for large and continued programs of evaluation.

"No extensive studies have ever been conducted with the purpose of determining the incidence of visual abnormalities in women of childbearing age, probably for at least 2 reasons: first, because women of this age seldom consult an ophthalmologist except for obvious visual difficulty . . . and second, because such evaluations would have served no particular purpose in the past. The current situation of a vast number of women in a restricted age group undergoing therapy with the same or similar drugs, and with the same objective—contraception—is unique. The raising of questions concerning possible side effects of the use of oral contraceptives makes it imperative that scientifically conducted investigations be carried out . . .

"The results of this study clearly indicate the large number of ophthalmologic abnormalities present in the control group. They also demonstrate the close correspondence of such ocular changes in the groups undergoing therapy . . . The vast majority of the data shown above does not indicate pathologic conditions in the sense that visual damage has occurred. However, the discovery of such abnormalities in a retrospective study could easily lead to erroneous conclusions . . . because of the . . . lack of information concerning the incidence of such conditions in the general population."

The accusation has been repeatedly made during these hearings that physicians engaged in research were either unaware of or deliberately disinterested in the problems connected with oral contraceptives. Even worse, we have been charged with the actual suppression of data relating to these problems. Again, with your indulgence, I would like to quote from a paper which I presented to the American Association of Planned Parenthood Physicians in San Antonio, April 16, 1968, and which was published the following year in "Advances in Planned Parenthood". It described changes in blood coagulation.

"Over 4,000 patients have been given oral contraceptives at the Family Planning Center during the past 4.5 years. To our knowledge no thromboembolic episode has yet occurred, a situation which correlates with the experience of many other investigators. This fact suggests that, if damage is produced by these agents, it must be very infrequent. In fact, the incidence may be so very low that it may not be possible to establish it even with the use of large prospective studies. Possible elements of bias are numerous and very difficult to determine and evaluate, whether the attempt be prospective or retrospective. It would appear that the final answer to this most perplexing problem will not be found until reliable rates of the various thromboembolic phenomena are deter-

mined in the general and specific populations, laboratory tests and results are standardized, common definitions of terms are agreed upon, records made uniform, comparable data-processing techniques are developed, and a large stable population found which can be subjected to meticulous multiphasic, long-range analysis."

In the interest of time, and at the risk of beating a horse that perhaps should be dead, I would like to mention without further comment a few areas which have been touched on by previous witnesses and in which we are all working. The problems of obtaining adequate and reliable data, the proper and objective evaluation of side effects, the relationship between dosage variations and results, in both animals and humans, the total inadequacy of most studies to date, the difficulty or impossibility of obtaining accurate control information and the need to establish not only use, but use-effectiveness data—all of these and many others have been brought to your attention. I do not excuse our present lack of knowledge, but only point out that our areas of ignorance are known, deplored, and currently receiving all the attention that time and money will permit us to give.

Before I leave this topic, I would like just to emphasize three points, all made before by others. First, with the single major exception of thromboembolic disease, there has been no proven relationship between any of the alterations reported here and the production of permanent damage. Secondly, it has been repeatedly pointed out that most of these changes are either preventable or are detectable with good medical care, and usually disappear after cessation of treatment. Thus, even the accepted complications might be decreased with an acceleration of research and an augmentation of services.

One of the stated aims of these hearings has been to determine the current level of patient training and information, and to find out whether those women who elect to use the pill do so with full knowledge of possible side effects. As both a clinician and a researcher, I see many problems in this area. There is no question that as substantial data on adverse reactions becomes available, it should be communicated to patients. However, to present the list of possible side effects as outlined in the present package insert to the average patient serves no useful purpose. First of all, we have been told here that almost all of these are still conjecture, not proven fact. Secondly, a patient cannot reasonably be expected to make a profound judgement—she is not a doctor. We have seen that even those with wide knowledge and experience are in disagreement—how can we ask or expect informed decisionmaking from these women?

Finally, I would like to make just a few comments as a member of the heretofore silent majority—women. The fact that I have chosen to pursue an active and exacting career while at the same time electing to produce six children, should be my most potent evidence for my overwhelming belief in the larger role to which women should aspire. I know personally the excitement of feeling new life moving within my body; I have known the never-to-be-equalled thrill of seeing my own firstborn child; I know the private dreams and fears that all women have as they watch their children growing up. These joys and sorrows are the right of all women and should be denied to none. I am equally aware of the happiness and fulfillment that comes with being part of the larger world, of making some contribution, no matter how small, to society as a whole, as well as to my immediate family. With the advent of effective contraception, women, for the first time in history, have been able to plan their lives, space their children, and look to their futures with confidence. How vividly I can recall the countless women whom I have seen in the course of my career—active, creative, productive for the first time in their lives, cut down by an unwanted pregnancy, either because of lack of or failure of contraception. This is always a tragic thing to see. Such a misfortune can perhaps be considered partially tolerable when it happens to a woman from the middle or upper class. When it befalls, as I have seen so often, the woman who has just begun to establish her identity as a human being in her own eyes and the eyes of her family, only to be returned to the depths of the ghetto, to carry and bear her unwanted child, such a tragedy has far-reaching implications and ramifications that can escape only the most obtuse and unfeeling human mind. If unplanned pregnancies increase, as we are beginning to suspect that they will because women have become frightened and turned to less effective methods of birth control, or worse, no method at all, it can only again widen the gap between groups of women. For many years, adequate means of family

planning have been the primary prerogative of the private patient who knew that such help was available and could afford to pay for it. During the past few years this care was increasingly being made available to the poor woman as well. Today, once again, we have created two groups, the haves and the have-nots. When a woman of means finds herself pregnant and wishes not to bear her child, a safe, clean abortion is within her reach. When one of my clinic patients finds herself in the same situation, she usually has one of three choices: she may bear the unwanted child; or she may attempt to abort herself; or she may have a cheap, dangerous, dirty, illegal abortion. No matter what her decision, such a woman, her family, and society in general will be the ultimate losers. A similar desperate and unfair situation unfortunately obtains when sterilization procedures are examined. The private patient with three or four children who wishes to terminate her childbearing finds it infinitely easier to do so than does her clinic counterpart with nine or ten. This double standard of medical practice is a gross miscarriage of justice. Hopefully, legislative and legal measures now under consideration will free the hands and minds of doctors who abhor a situation in which they currently find themselves, disturbed, fearful, and helpless.

There has been much discussion here of the use of women for experimentation and their "internal pollution" with oral contraceptives. I would like to submit that the larger and for more critical and lethal experiment is underway—what happens to these women and society as a whole if we continue our inevitable march to doom via overpopulation and pollution? What will happen if individuals and nations are deprived of their ability to control their population size, whether by law, ignorance, or fear? These are really rhetorical questions to which we all know the answers. The unplanned pregnancy, the unwanted baby, the battered child, delinquency, illegitimacy, crime, drug abuse the endlessly repeated chain of events encircling our society at all levels is only too apparent. In a recent paper presented by Dr. Charles F. Westoff of Princeton University's Office of Population Research, it was pointed out "the average annual number of unwanted births during those six years (1960-1965) was between 370,000 and 445,000 among the poor and near-poor, and between 410,000 and 540,000 among the non-poor."

Opponents of oral contraceptives always talk in terms of the treatment of "healthy women". Those of us who have to treat women who are pregnant with an unwanted baby do not feel that she can be considered to be free of disease. The World Health Organization has declared that, "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Looked at in these terms, we are currently facing a major epidemic. Anything that unnecessarily escalates this unhappy situation can only be deplored. It is already clear that this is beginning to occur both here and abroad. Evidence documenting the panic regarding the pill mounts daily. If this panic continues, the problems resulting from these fears will be severe in the U.S.A., but the problems abroad may be catastrophic. Many developing countries where the poverty, maternal deaths from abortion, and all the consequences of the population explosion are most critical have been turning to the pill as part of the solution to their incredibly difficult situation. Our nation has been accused before of a double standard of medical care, of sending abroad, via our foreign aid programs, second class care. We have been told that some of the IUD programs were viewed in this light—the IUD was less expensive and good enough for them, but American women were getting the pill. For multiple reasons, oral contraceptives are widely and increasingly used in these countries. If the pill is discredited here, will we again be faced with the problem of appearing to supply something to women of other nations which is too dangerous to give to our own? The ultimate implications of the fear which is also growing abroad are terrifying to contemplate. The pebble has been dropped in the pool, and all the concentric circles are going out. If no answers are found, we may well be damning and ultimately damned by future generations.

Assuming that the damage we see is not irrevocable, what can be done to channel all the energies that have been released into constructive pathways? One of my favorite quotations from Aristotle goes as follows:

"It is easy to fly into a passion—anybody can do that—but to be angry with the right person and to the right extent and at the right time and with the right object and in the right way—that is not easy."

We might do well to consider this ancient advice. There are a number of obvious ways out of our current dilemma. First of all, it lies within our scientific capability to answer many of the questions raised at these hearings, given sufficient funds and direction. Some programs designed to obtain valid answers are under way, others are awaiting support, and many remain to be written. The need for expanded research to find new contraceptive methods and the means to make them widely and rapidly available is too patently obvious to pursue further.

Much of this progress, of necessity, lies somewhere ahead of us. What can be done today? Remove all the archaic legislation on abortion and sterilization which would free both women and their physicians and correct the current social and financial inequality of care. Then, support the programs needed to implement the demands which will immediately and inevitably arise as a result of these reforms. Pass legislation dealing with population problems and their solutions. Provide funds for the training of people to work in these programs at the professional level, but, much more importantly, at the paraprofessional and community levels. It would be unrealistic to think that even with unlimited funds immediate solutions could be obtained to the many and varied problems we face, but the next steps are clear.

Senator NELSON. Thank you very much.

Let me say that one of the reasons stated for calling the hearings was specifically to get additional research funds into this field. One of the great tragedies is that the pill has been on the market for 10 years and neither the medical profession nor NIH, nor anybody else has outlined, in detail, the protocol of studies that ought to be made, and come to the Congress with requests for funds for it. I would think that very possibly, out of these hearings, that is what the results would be.

You refer a number of times in your presentation to the panic, and so forth, caused by these hearings. We still have a number of witnesses to go. Planned Parenthood and a number of other groups. Is it your opinion that the American public should not know the facts that have been developed in these hearings?

Dr. CONNELL. Absolutely not. They should be publicized, I agree, As I said before, the only thing that I disagree with here is the matter of balance.

Senator NELSON. Balance in what way?

Dr. CONNELL. Of the total impact, the total time devoted to particular topics. I think that most of what has been said here about the oral contraceptives is absolutely correct. But as I say in my testimony, I do not think anybody has looked concretely at the millions who are taking them happily and safely and what will happen to them if, for any reason, they could not continue to do so. This is what, as clinicians, we are beginning to see.

Senator NELSON. Of course, we have not completed the hearings.

Dr. CONNELL. I realize that. I said to date.

Senator NELSON. I suppose on the first day of the hearings, you could have made criticism that was much broader. I was pointing out that you cannot hear everybody on the same day.

We have Dr. Kenneth Ryan, chairman of the Department of Reproductive Biology of Case Western Reserve University appearing today; we have Dr. Paul Meier, of the University of Chicago; we have Dr. Alan Guttmacher, president of Planned Parenthood, who will be accompanied by Dr. Mary Lane, staff physician, Margaret Sanger Research Bureau, on our list for tomorrow. We have

Dr. Edward Lewison; we have Dr. Elsie Carrington, professor and chairman of obstetrics and gynecology at Womens' Medical College in Philadelphia.

We shall have Dr. Max Cutler on March 3; Dr. Anna Southam of the Department of Obstetrics and Gynecology at the College of Physicians and Surgeons at Columbia; we shall have General William Draper, Jr., and Mrs. Phyllis Piotrow, secretary and member of the board of the Population Crisis Committee—I would assume that the case that you are talking about will be made by these people.

Dr. CONNELL. I know most of these people and I respect their capabilities. I am sure that what they will tell you will help to give more precisely the balance that we need.

All I am pointing out is that in my testimony I am talking of the effects to date. Therefore, I can only talk of testimony to date. This is the only equivalency I have.

Senator NELSON. So you are talking as of today.

Dr. CONNELL. As of today, I think we have a lack of balance, and I think we can see the effects of this as we see patients at clinics.

Senator NELSON. Are you satisfied that when we hear from this list I have present today, including Dr. Edwards, Commissioner of the Food and Drug Administration, that the viewpoint you are concerned about will be presented.

Dr. CONNELL. I am sure it will be presented.

Senator NELSON. So your criticism is of the order in which the witnesses have been called?

Dr. CONNELL. No, my only criticism has been as an observer of the impact and an observer of what I believe to be imbalance to date. This is all I am saying. As a practicing clinician, along with many other practicing clinicians, I can only report that we are observing certain things. This is all I am reporting. I think these are valid observations.

Senator NELSON. I just want to be sure in my mind. You are satisfied, then, that after Dr. Guttmacher and General Draper and these various people are heard, the balance you are talking about will be—

Dr. CONNELL. This is a very hard question to answer. This has not transpired. I think you are asking me to make a judgment about what will happen over the next few weeks, which I find it very difficult, even impossible, to do.

Senator NELSON. We have tried to present a balanced viewpoint. We have publicly stated that anyone who is knowledgeable and has a suggestion to make, we shall be glad to put on as a witness.

I am just trying to get at the criticism. If we put in all the people I mentioned first, and then we came up with people who had some criticism later, then would you be saying that it was unbalanced if a lot of that appeared in the paper because it appeared at the end of the hearings and obscured what was testified to earlier?

Dr. CONNELL. Again, I am not quite sure I follow what you are saying.

Senator NELSON. I am trying to figure out precisely what you mean. You are saying that the hearings have not been balanced, and I am saying now that we are trying to present every viewpoint.

You are saying to date it has not been balanced. I am asking would you prefer that we had presented Dr. Guttmacher and all those people first, and then had those who had something critical to say last, so that the last impression around the United States would be only of these people who were critical of the pill, instead of the last impression being of those people who were in favor of the pill?

Dr. CONNELL. It is not my position to say.

Senator NELSON. Well, all right.

Senator DOLE. There has been a decline in the number of people taking the pill as a result of publicity; is that correct, Dr. Connell?

Dr. CONNELL. This fact is beyond the area of speculation. This is documented.

Senator DOLE. You have observed this trend yourself in your own clinic?

Dr. CONNELL. Considerably more than that. I have observed this through the eyes of statisticians who collect clinic data and through the eyes of patients.

Senator DOLE. Perhaps some of it was a wise movement on the part of the person stopping the pill?

Dr. CONNELL. I am not being judgmental. I am simply giving you numbers.

Senator DOLE. I am not certain what will happen after all witnesses testify and I do not know what they may say.

I think the point is that the hearings have had some impact, for good or bad, I do not think we can judge. Perhaps they should have been in executive session, because they are dealing with rather a highly technical and important subject matter. But if we are now experiencing some unwanted pregnancies and other things, they may not have provided the service we intended.

Dr. CONNELL. This, to an extent, is obviously my persuasion, based on what I see. My own observation of patients who are coming back pregnant—this is irrefutable. When a patient comes in and says, "I stopped my pills because I was scared," and she is pregnant, this, to me, is the most positive information one can get.

Increasingly, we can count these women in the various clinics in New York City, and people I know in other clinics in the country can begin to count. The numbers are beginning to be of such magnitude that you can titrate what is going on across the country.

I think these are statistics that, again, the ultimate impact—the number, what will happen, how these people will ultimately solve their problems, what will come out of this—I would not even hazard a guess on. This would be pure speculation.

The only thing I can report is that there are pregnancies; there are women already looking for abortions as a result of induced fear. This, I see; this, I know. I would hesitate to speculate beyond this point.

Senator JAVITS. Would the Senator yield for a question?

Senator DOLE. Yes.

Senator JAVITS. I would like to understand your conclusions, Doctor. I gather that you feel that, scientifically, there has been inadequate proof to reverse the proof upon which these pills were first allowed to be used. Is that not right?

Dr. CONNELL. Again, I think it is rather difficult. You are dealing with a preparation which was placed on the open market in 1960. I think I make the point in my full testimony that a great deal of the criticism of the 1960 data is actually based on 1970 knowledge. This is a very tenuous scientific approach, to look at any one era in time through the eyes of a different time.

It is sort of like being a knight at King Arthur's Court. I am not sure one can or should do this.

Senator JAVITS. But nonetheless, as I read your testimony, you say on page 8 that no factor other than adverse publicity could be found to account for this precipitous drop in use of the pill. That excludes, therefore, adverse scientific information sufficient to override the scientific information upon which this was made available for public use, does it not?

Dr. CONNELL. I believe so.

Senator JAVITS. That is the fact. And that is really a judgment, is it not?

Dr. CONNELL. I would say so.

Senator JAVITS. In other words, you are continuing to prescribe the pill, are you not?

Dr. CONNELL. Unless I have a definite contraindication. I do not feel the pill is the universal pill for all women. I think anyone with good medical judgment knows that there are some people who should not be on the pill.

Senator JAVITS. But certainly, you advise against it being taken off the market.

Dr. CONNELL. Most emphatically.

Senator JAVITS. What do you understand to be the purpose of these hearings?

Dr. CONNELL. I think the stated purpose was to explore the area of informed consent. I think this was the primary purpose. It was also my understanding, reading about the hearings at the end of last year, that they were to determine how much women knew on what basis they were accepting or rejecting the oral contraceptive. This is what I read; this is my understanding.

Senator JAVITS. Now, I noticed with interest the statement on page 9, where you say that the IUD carries its own burden of side effects and deaths. I have noticed that that is said and then dropped.

Second, but much more important, is the fact that we have all seen—this is in your statement—that women will not universally accept and use these alternate and less efficient methods.

Now, is there any scientific evidence that IUD has its own burden of side effects and deaths?

Dr. CONNELL. Oh, yes, surely. You can find this if you look at the data that Dr. Tietze, who has been quoted here many times has collected in his international IUD statistical cooperative through many years. This has been done to an extent that you can actually quantitate for any particular IUD the adverse effects of that device in terms of perforation, pregnancy, bleeding. This is well documented.

The other study that I think has also been mentioned here before is a study done by the American College of Obstetricians and Gynecologists, where there is actual data collection on the side effects of

the IUD's, and in the course of this, there were deaths reported. So I think this is on a reasonably good statistical basis.

These problems do exist. They are in print, and have been, again, for quite some time.

Senator JAVITS. Now, you have made your decision. Your decision is to continue to prescribe the pill.

Dr. CONNELL. Properly, for the correct patient, yes.

Senator JAVITS. Unless you have an affirmative belief that it would be deleterious in a given case.

Dr. CONNELL. And this exists. As I have said, there is no question that not everybody can take the pill.

Senator JAVITS. Have you learned more as a doctor as a result of these hearings about deleterious effects? In other words, have these hearings contributed to your education as a doctor?

Dr. CONNELL. No, because we are exploring a field in which I talk, I write, and I read extensively. No, I cannot honestly say that I have learned anything.

Senator JAVITS. Is there anything that you have learned new?

Dr. CONNELL. There has been no major new medical evidence that I am aware of that has been presented thus far.

Senator JAVITS. On this question of balance, about which you have testified, is it not a fact that no matter what the committee did, the sensational testimony would get the headline? In other words, the testimony, the fact that it is bad rather than good, would get the headline; is that not true?

Dr. CONNELL. Again, I am not being critical of the fact that there has been honest publication of the data that were presented here. I am simply talking, as a doctor, of the overall effect. I think this is above question.

Senator JAVITS. Well, I shall not ask you about your opinion as to how we could have done it better. But I gather from what you say at the bottom of page 12 that we might have done it better. What you say at the bottom of page 12 is:

Thirdly, one of the stated aims of these hearings has been to determine the current level of patient training and information, and to find out whether those women who elect to use the pill do so with full knowledge of possible side effects. As both a clinician and a researcher, I see many problems in this area. There is absolutely no question that as substantial data on adverse reactions becomes available, it should be communicated to patients. However, to present the list of possible side effects as outlined in the present package insert to the average patient would serve no useful purpose. First of all, we have been told here that almost all of these are still conjecture, not proven fact. Secondly, a patient cannot reasonably be expected to make a profound judgment—she is not a doctor. We have seen that even those with wide knowledge and experience are in disagreement—how can we ask or expect informed decision making from these women based on such dubious information?

Now, what else could we do to meet this problem? What else could we have done once we went into the subject, assuming we decided to do it, other than what we did? As Senator Dole says, do you think we should have had hearings in executive session—in other words a nonpublic hearing—and issue a report or something like that? What do you think we could have done to avoid what you consider the unfortunate effects?

Dr. CONNELL. I am not sure you could have avoided it under any

circumstances. I think this is the nature of human beings and the nature of the society in which we find ourselves.

Again, this is far outside my role. I really rather hesitate to answer this.

I think you could very well, perhaps, have presented, had people who would talk about such things as the relative number of deaths from criminal abortions, pregnancy hazards and maternal mortality statistics. We have heard a certain amount about these subjects, but they have been a small percentage of total time. It is not really so much what has been said and what has not been said, but the percentage of the time which has been allotted to the data on adverse effects of the particular preparation in a small group, rather than the predictable and known aspects of no contraception or somewhat less effective contraception in large groups.

I think this is the only bias.

Senator JAVITS. Dr. Connell, you have been very, very helpful, certainly, to my thinking. I have not, because of other problems, though I am the ranking member of this committee, been as close to these hearings as I should have. I shall take pains to check up on how they have been structured and do my utmost to use what influence I have in that regard. I have been very much helped and educated by your views on it.

Dr. CONNELL. Thank you.

Senator JAVITS. I have one last question to you as a doctor. Can you make any suggestions about FDA's allowing this medication to continue to be widely distributed, sold, and prescribed? Is there any change that you would recommend, or would you recommend the continuance of the present practice?

Dr. CONNELL. First of all, I think I would have absolutely no question that these should be allowed to be continued to be used. I think the alternative in terms of other methods or no methods at all, the medical alternatives are such that, in my own mind, there is no question that these should be allowed to stay on the market.

In terms of perhaps getting better information to patients, I think this is quite possible, provided it is done within the context of what the patient can understand and within the context of what we feel to be accepted reality in terms of good medical practice.

Senator JAVITS. Could we ask you to do a little job for us in view of your general attitude, which is a sympathetic one to the pills? Would you be good enough to put in writing any changes that you think should be made in the way in which this Government control over these compounds is now administered, if you think any changes should be made, or confirm that present practices are adequate?

This would mean that you would actually have to look into what is being done. But I do think it would be very valuable to have somebody with your point of view comment upon the present governmental operation in this field.

Dr. CONNELL. I would be delighted.¹

Senator JAVITS. I ask unanimous consent that whatever Dr. Connell presents be made a part of the record.

Senator NELSON. Certainly.

¹ This information was not supplied by Dr. Connell.

Dr. CONNELL. I can only say that it is our sincere hope and our prayer to come out of all this with some answers, with the support of the people on the committee and elsewhere, to do what we are competent to do if we are supported.

Senator JAVITS. I am told that it is a fact that this committee does not have legislative oversight over the Food and Drug Administration.

Dr. CONNELL. I am aware of this.

Senator JAVITS. But we do, as a Small Business Committee subcommittee, have the ability to recommend legislation to the Small Business Committee, which may then forward these recommendations to the appropriate legislative committee. It so happens I am also the ranking member of the appropriate legislative committee.

Dr. CONNELL. I am happy to know this.

Senator NELSON. We have had only one witness who has recommended that the pill not be used. Everybody we have had has been propill, some with reservations, some without. But only one has recommended that they be removed from the market. I expect that will be the next attack I shall get.

We have been attacked for being propill, for being antipill, so I feel comfortably balanced, in the middle.

Senator JAVITS. The Senator is too experienced a Senator to suffer from that.

Senator NELSON. I want to thank you very much for your capable contribution. I thank you for taking time from your busy schedule to come.

Would you wait just a moment? Senator Dole has some questions.

Dr. CONNELL. Certainly,

Senator DOLE. On page two, you made an interesting point. Your rationale might be of some interest to the committee. You say that the pill gives a woman opportunity to learn, to hold responsible jobs, and so on. Many indicate that this is their first opportunity to participate in these roles and to become, as you describe them, happy and productive members of society.

Do you care to elaborate on that statement? Do you find this to be true from your own experience?

Dr. CONNELL. Yes, this is a more recent area of interest of mine, and one which I think is increasingly important as we look at the problems of cities. We have been involved in the last few years in the actual training of these individuals.

There is a program in New York City, to which I am consultant, which takes women from the ghetto, and trains them as family planning counselors. These women are now actually working in most of the major hospitals in New York City in actual patient training and recruitment. They are highly effective people.

I have also been consultant to the Talent Corps, which is a Department of Labor-funded group, which for several years has been active in the training of these paraprofessional people, and the vast majority of these women do come from ghetto communities.

Many from welfare rolls. It has been one of the most exciting things, actually, that I have ever been involved in, to see these women come out of abject poverty. Many have never been creative

or constructive before. To train these people and see them enter the larger society—it is really a terribly exciting, as well as a very valuable thing to see.

I think this is very important. We need these people; they need our support. They need training. This, I think, is extremely important.

Senator DOLE. How many patients have you seen personally with reference to the pill? We have talked with numbers of other witnesses. Some have seen as many as 10, or at least based studies on that small number. Others have seen hundreds, some thousands. Do you keep any record of the number of patients you have had contact with?

Dr. CONNELL. I am in the thousands category.

Senator DOLE. And, of course, you have been practicing on up from the sort of prepill days through the postpill days.

Dr. CONNELL. I hope not.

Senator DOLE. Maybe not post, but at least during the introduction and beginning of the pill. Do you see any changes now, any differences that you might comment on between women now who take the pill and women before the pill was available?

Dr. CONNELL. I think socially there is just no comparison. The feeling of confidence that women have, the lack of fear of pregnancy, the improved relationships with their husbands, with their children, all these things have made a tremendous improvement in their entire outlook on life.

They also have the assurance of knowing that they can sign up for training and they can assume that they are going to be able to finish it and help to support their families. They can only do this because they have effective contraception.

In this sense, I think we have made a major contribution to the enlarging role of women, in which I very obviously believe. I think this is very important.

Senator DOLE. At the same time you have indicated that not every patient should be a user of the pill.

Dr. CONNELL. I have patients to whom I say, you should never take the pill. You have a contraindication to the pill and it would be dangerous for you to take the pill in its present form.

Senator DOLE. Plus some that may start the pill, and you take them off the pill?

Dr. CONNELL. Of course. This is the essence of good medical practice; to select properly, to follow properly, and to live up to one's knowledge to the best of one's ability. I think that is what a good doctor is.

Senator DOLE. We all share the same concern.

I certainly appreciate your testimony. You are the first of your sex to testify before the committee. There were others here earlier this year who were available for testimony, but you are the first scheduled witness. You have been very helpful.

I would hope if there has been reduction in the use of the pill because of publicity, that the apprehension which has been generated would be balanced as to whether the pill is good or bad. Such is the determination that must be made.

I think it is better if it is made on the basis of a doctor-patient relationship rather than on a Senator-patient relationship. I do not know if you can blame all these babies that are born on the members of the committee or not.

Dr. CONNELL. Perhaps all of us have to accept a portion of the blame for the unfortunate events which are producing these babies.

Senator DOLE. I do appreciate your testimony.

As Senator Javits and Senator Nelson have pointed out, you have been most helpful.

Dr. CONNELL. Thank you.

Senator DOLE (presiding). The next witness is Dr. Kenneth Ryan, chairman, Department of Reproductive Biology, Case Western Reserve University, Cleveland, Ohio.

Dr. Ryan, you can either read your statement in its entirety or summarize. It will all be made a part of the record. Proceed in any way you wish.

I apologize for the lateness of the hour, but we have had some interruptions on the floor.

STATEMENT OF DR. KENNETH J. RYAN, CHAIRMAN, DEPARTMENT OF REPRODUCTIVE BIOLOGY, CASE WESTERN RESERVE UNIVERSITY, CLEVELAND, OHIO

Dr. RYAN. Thank you very much, Senator Dole. If I may, I would like to read my presentation. It is quite concise and it says exactly what I want to express.

Senator DOLE. Mr. Gordon may have questions during the reading of your statement or I may have questions.

Dr. RYAN. Thank you.

I would like to preface this by saying by way of basis or qualification for testifying before the committee that I have had 20 years of experience in research as a steroid chemist. We have known about these hormones for only 40 years. In addition to that, I do participate in the practice of medicine. I am neither an unrestrained advocate nor an unqualified critic of oral contraceptive medication. It seems to me we have just heard that in the previous testimony. As with all medical therapy, the advantages of curing or preventing the disease should outweigh the risks of the drug used. It is no better to cure an ailment and then lose the patient from a toxic medicine than to have a patient die without treatment or the wrong form of therapy. With the pill, the object of therapy is pregnancy prevention. Fortunately, the risks to life and limb from both disease and drug are low. Pregnancy is supposedly a physiological or normal process but carries a 0.04-percent mortality rate. An unwanted pregnancy is a recognized "disease" state with additional challenges to life, health of the mother, to her psyche and society. The pill has acknowledged hazards and its effectiveness in preventing pregnancy must be balanced against safer, less reliable means of family planning and pregnancy itself. The relative risks are calculable for groups of people but unfortunately not for the individual patient trying to make up her mind which course to follow.

The patient can make decisions only with adequate information

from her physician, drug package inserts, and other reading materials. Unfortunately, I would agree with Dr. Connell that public pronouncements on the pill, either pro or con, are known more for their rhetoric than for their objectivity, often leaving both physician and patient misinformed or confused.

Acting as chairman of a department of obstetrics and gynecology, I can testify to the fact that many physicians are as confused as their patients in this respect.

Since these hearings will aid in the dissemination of information, I appreciate the opportunity to present a perspective on the pharmacological properties of the medications. That is what I would like to talk about now, what we know about some of these oral agents, what we can predict about the side effects, and so on.

Most oral contraceptives, whether of the sequential or combined type, contain a synthetic estrogen used in sequence or in combination with a synthetic progestin. I will describe each in turn.

Synthetic estrogens have been available since 1937 when Dodds first described diethylstilbesterol which is a synthetic as potent as the natural estrogen, estradiol, but unlike the native hormone is active by mouth. Since then, two other synthetic orally active estrogens have been produced—ethinyl estradiol and mestranol. I bring these up because these are the two compounds which are used in most of the contraceptives. They are of almost equivalent potency to one another but some 10 to 25 times as active as diethylstilbesterol. The latter two compounds are the ones most frequently used in contraceptive medication.

All of these active estrogens, whether it be estradiol or mestranol, have a comparable spectrum of biological properties and like the native hormone have actions on the reproductive tract as well as broad metabolic effects. The observation written in the FDA report and publicized that contraceptive pills containing these estrogens have extensive metabolic effects on many tissues of the body is neither novel nor surprising to any student of estrogen physiology. This is a normal consequence of estrogen action, and no particularly unique activity, of any of the synthetic estrogens has yet been described.

In any case, synthetic estrogens have been in extensive clinical use for 30 years. Very high doses have been used in men with prostatic cancer, for instance. There has never been a documented case of induction of cancer in the human by these agents and no serious sequelae have been reported save for their current implication in the embolism and phlebitis associated with pill usage and this is reported with a high dosage. If you recall, the British experience and the recent American experience, that thromboembolism seems to be less frequent in the patients taking the smaller dose, the preparation having the smaller dose estrogen.

I notice that you have the book on the metabolic effects of these contraceptives in the human and I know it says in there that you cannot equate one drug to another, nor can you equate it to the native hormone. But I know of no information that indicates that the biological properties of the estrogens used in the contraceptive pill are any different than stilbesterol for which we have at least 30

years of clinical experience or, for that matter, different than the natural hormone, estradiol, which circulates in the blood. In other words, we have no data that they are more dangerous than the native hormones at comparable levels of potency. They may be proven to be more hazardous, but there just isn't any evidence for this as yet. Even natural estrogens are toxic to laboratory animals when given in excessive dosage. Then the important thing is the relative amount that is given to the patient and how it is given.

Information on the amount of hormone produced in the normal cycle indicates levels of 50 to 200 micrograms of estradiol per day. The oral contraceptive medications contain a dose on a potency basis some four to five times the peak levels of the cycle, clearly providing amounts outside the physiological range. I think the current recommendations to lower the estrogen dosage and indications that complications are fewer with less estrogen would be in keeping with sound pharmacological principles. It is obvious that we need more studies with the lower level medication in terms of their efficacy in preventing pregnancy as well as in the production of side effects. But I would clearly make a plea for studying the possibility of using drugs with lower estrogen in them.

Now, so much, then, for the estrogen. I could summarize it by saying we have had 30 years of experience and there is not much that has come out with the newer preparations that we have not seen already, that has not been known and has not been written about at one time or another. It might be related to dose potency, but there is no other information of unique character of the estrogens used in the pill.

When you come to the progestational agent used in these oral medications, they are different from the estrogens. There are more marked qualitative and quantitative variations in biological effects and we don't have the same number of years of clinical usage. Rather than 30 years of experience, it is closer to 15 years with these agents. Experience with some of these progestins is longer than with others and the dosage has varied some tenfold since the first pills were introduced. It is not fair to talk about the side effects produced with the higher dose medication today, because the higher dose medication is usually not used. It is, therefore, not possible to bring to bear the same clinical experience as with the estrogens, and there is even less certainty about equating biological properties within this class of compounds. Clearly more information is required for current dose levels and types of hormone. With a given side effect, we still may not know whether it is the estrogen or progestin component or both which are responsible. For instance, we have some thoughts on this, but we do not have enough information as yet—again a plea for more research in this area.

Now, the synthetic estrogens have been used with the progestin because the two together can usually prevent pregnancy more effectively and provide a more natural artificial cycle at a lower dosage level than either alone. That is why they are used together, either in the combined pill or sequentially, one followed by the other.

Now, the combination of estrogen with progestin, unfortunately, produces effects which are different than the sum of their individual

properties and experience with the estrogen alone or the progestin alone cannot be equated to the combined medication. The best model for the biological effects of the pill is still pregnancy. Again in your reference books, you will see that many physicians and scientists rightly object to an oversimplistic comparison of the pill's effect to the pregnant state, however, there are still useful analogies to be made with respect to the metabolic alterations and health risks involved. It is just as wrong to say we cannot compare them as it is to say the comparison is complete. Just about all of the side effects and metabolic alterations produced by the pill were first observed years ago as complications of pregnancy, including thromboembolism, blood clotting disorders, hypertension, liver disorders, alterations in fat and carbohydrate metabolism, pigmentation, hair loss, and post-pregnancy infertility, just to name a few problems shared by pregnant women and pill-takers. I am not trying to equate the two conditions, but the similarities are striking.

Mr. GORDON. Dr. Ryan, may I interrupt you?

Dr. RYAN. Yes.

Mr. GORDON. Do you know any studies to show what the lowest effective amount of estrogen would be?

Dr. RYAN. For what purpose?

Mr. GORDON. For oral contraception?

Dr. RYAN. There have been some studies conducted to test—

Mr. GORDON. Who is the sponsor?

Dr. RYAN. There have been studies to test the minimal dose of mestranol, which will inhibit gonadotropic release. These have not been the characteristic dose response curves that people would like to see. The reason that the higher estrogen has been used is that they can with more certainty prevent the release of the gonadotrophin with the higher dose—0.02 mg., for instance, of mestranol will not consistently stop gonadotropic release, where as 0.05 in many cases does, and 0.08 certainly does.

Mr. GORDON. We have 0.05-mg. pills, do we not?

Dr. RYAN. In a combination pill.

Mr. GORDON. You have considered it effective?

Dr. RYAN. Yes.

Mr. GORDON. We also have higher numbers, too, don't we?

Dr. RYAN. Yes.

Mr. GORDON. If we have 0.05 in the market and it is effective, why do we need the higher dose, the higher amounts?

Dr. RYAN. This becomes, again, very complicated. There are two problems. One is the effectiveness and the other is the ease and control in breakthrough bleeding and other of the less serious side effects, what you might call nuisance side effects in the management of the woman's cycle. It has been that kind of balance that the pharmaceutical industry has become involved in this trying to come out with a pill that is acceptable to woman, which will provide her with the most natural artificial cycle and still prevent pregnancy.

The other relates to the red tape, the problems they have in trying to go through the red tape in getting a pill on the market. They did facilitate the medication with the new doses on the market much faster than would ordinarily be the case.

Getting back to the pregnancy question, it has often been the changes that we have seen in pregnancy that provides leads to metabolic alteration that were subsequently demonstrated for oral contraceptives. This doesn't make the complications more acceptable, just less frightening since one is mimicking changes seen in nature. As a matter of fact, I can think of no complication, described for the pill, that recently received so much publicity, actually no alteration, metabolic side effect of the pill, which has not already been reported in pregnancy at a higher incidence, including alterations in the cervix that mimic carcinoma-in-situ.

Of the many side effects of the pill, the risk of thromboembolism appears to be significantly increased and dangerous. We still have to remember that these are retrospective studies, not prospective studies. These are still going on. The combination of thromboembolic phenomena is shared with pregnancy but fortunately occurs at a lower level of incidence with the oral contraceptives. It will be important to try to determine whether lowering the estrogen component of the pill will reduce or remove this hazard.

The risk of inducing cervical or breast cancer with the pill cannot be predicted at this time. However, I think it has been the publicity about this which has frightened many patients, not only those taking the pill for contraceptive purposes, but women who are on estrogens, for instance, for replacement purposes in post-menopausal period. There are no convincing data for or against this possibility and only careful study will provide a definitive answer.

Aside from suspicions of the relationship of animal models to man, these were mentioned in the FDA report and quoted by, I believe, Dr. Davis in this committee, there is no evidence for steroid induction of breast cancer in humans or primates. Long-term clinical experience with estrogen thus far provides no obvious cause-and-effect relationship, but this is no substitute for careful epidemiological studies. There just is not any information on the subject one way or the other.

The reports indicating increased carcinoma-in-situ of the cervix in pill-users cannot be evaluated as yet since the patients did not routinely have cancer screening prior to being put on the contraceptives. Earlier short-term careful prospective studies did not demonstrate in-situ carcinoma as a consequence of pill use and only carefully controlled additional investigation will resolve these conflicting reports.

The pregnant state with which pill use has most often been compared does not in itself predispose to the cancers in question, and while experiences with estrogens in the past and knowledge of the effects of pregnancy cannot be equated with the current contraceptive medications, this does provide in my opinion a tempering balance to the cancer fears which can ultimately be resolved only by more study.

Finally, the occasional infertility that follows stoppage of the pill can fortunately be effectively treated in many cases with ovulation inducers, but it still presents a problem.

I would like to conclude these observations by saying that the on-going public drama of the pill should tell us more than anything

else that we need more research into the biological effects of these agents and certainly more research to develop alternate methods of fertility control.

In the meantime, the patient and her physician are left in a quandary and still must make the right decisions with insufficient information. For the patient who desires family planning and cannot or will not use other methods, the pill still offers a healthy 15-to-1 odds advantage over pregnancy mortality risks which are already quite low. At the present time, there is actually little more which can be said.

Senator DOLE. Dr. Ryan, thank you very much. First of all, in the statements you make based on personal observation, based on your own practice, and again, knowing that numbers are not solely meaningful, how many patients have you had over the years?

Dr. RYAN. Well, I have a limited personal private practice, but I am director of one of the largest hospitals in the State of Ohio that has a large indigent patient population and a large private practice population, so vicariously, I would say my patient experience is quite large. I also participate as much as I can in the planned parenthood groups within the City of Cleveland, so again the experience is quite large, though not all of it is personal in the rendering of care to individual patients.

Senator DOLE. Then in your own experience, direct and indirect, you pointed out at least some areas of possible danger. I assume that there are persons you would not recommend use of the pill to and probably others, as Dr. Connell has stated, that once they have taken the pill, they can be taken off the pill because of something that may develop.

We had testimony earlier this morning of 16 different major symptoms from taking the pill. You mentioned that perhaps one area where we needed more information was knowledge provided to the patient. You are not just suggesting that you give the patient a laundry list with each pill prescription of all the things that might possibly happen?

Dr. Connell indicated earlier that maybe if they were advised in writing or maybe orally, but not given every possibility that might happen.

Do you share generally this view?

Dr. RYAN. We are treading on very, very narrow ground when we determine how much information to give our patients. I think they should be informed as much as possible, because they in fact are the ones that are taking the risk.

Senator DOLE. Does that mean to say in a printed circular, "this may cause thromboembolism," would not be meaningful to most patients? You may as well recite a nursery rhyme as far as the message he receives?

Dr. RYAN. This is right. I think the patient should receive not only written information which she can read, she should receive interpretation of this by her physician, and she should receive, as Dr. Connell already mentioned, careful follow-up, because you do not give medication to a patient and let her turn to her own devices and ask her a year later what you said or gave to her in a written

presentation. I think from the questions we ask of our patient, they know what we are after, when we ask have you had headaches, have you noted these symptoms or those—the patient very quickly learns the areas of consideration to us. I think it is important to inform the patients. I do not want to be privy to information that the drug was potentially harmful and not disclose as much of this information to the patient as possible in a meaningful way without frightening the patient, and not with minutiae. But we don't very often tell the patient when we give an injection of penicillin that they may drop dead from an anaphylactic reaction. Nor should we. We as physicians know this occurs, we know as physicians that the patient should be asked if he is sensitive to the drug.

I think an apparent analogy could be made to the pill. We know those signs, symptoms, complications of the pill which are apt to be most serious and for which the patient is taking the greatest risk. The patient should be informed about these.

Senator DOLE. As I understand, in some of the clinics and some of the planned parenthood groups, the information is disseminated on an informal basis, in a group-like atmosphere, of perhaps 30, 40, 50 or more women, where the pill is discussed. It is not all done on a person-to-person basis, is it?

Dr. RYAN. It is done in two ways ordinarily. It is done very often in group indoctrination and then on a one-to-one relationship thereafter, or in combination with the group—sometimes with film, sometimes with strip films and so on—to introduce the patient to just exactly what's going on in relationship to their bodies, to the types of medication which are available, to the types of family planning which are available.

Senator DOLE. Do you have any questions?

Mr. GORDON. Am I correct that you prescribe the pill for those patients who, one, desire it for family planning, and, two, who cannot or will not use other methods?

Dr. RYAN. Yes.

Mr. GORDON. Am I correct in assuming that if the patient is willing or is able to use other methods, you do not as a general rule prescribe the pill?

Dr. RYAN. I hate to make generalities. I think that the only other method which I would customarily discuss with the patient on a parity with the pill, based on a patient's motivation, would be the diaphragm.

Mr. GORDON. But if the motivation is there?

Dr. RYAN. If the motivation is there, I think it is a reasonable approach, and certainly safer. I know of no complications from that form of family planning. I don't think anyone would quarrel with that.

Senator DOLE. Have you noticed any change in the pill habits of your patients because of the wisdom emanating from this committee?

Dr. RYAN. Again, just from personal experience, when I go down to the lunch room in the hospital now, physicians stop over and say, what do you think we ought do? What's your latest feeling on the pill. I have had several patients call up and ask about the cancer

question, some of them not taking these medications for contraceptive purposes, but for others. I have had several patients who decided not to use the pill in the light of the publicity associated with these disclosures.

Senator DOLE. I am not saying we should not have held the hearings but am trying to determine what your own experience has been to the reaction?

Dr. RYAN. I might say this is not too different from the kinds of experiences we have had over the last 4 or 5 years every time a new article comes out in any of the lay press. As I said in my introduction, public pronouncements always seem to come out with more rhetoric than objectivity. It is extremely difficult to get the balance in for a patient. In general, it is not the most ideal way for the patient to be informed about her decisions in health matters concerning herself. I think it can give her information which she can then use in discussing it with her physician or clinic.

Senator DOLE. At least she is alerted to some of the potential problems or speculative problems.

Did you have a question?

Mr. GORDON. Yes.

As I understand it, you do not think there is anything wrong with people asking questions about it, do you?

Dr. RYAN. Absolutely not.

Mr. GORDON. Does it not take the physician off the hook, in a way, when people start asking questions?

Dr. RYAN. Practicing physicians very seldom, in a sense, get off the hook. We cannot, you know, delegate some of the responsibilities we assume in patient care. I think well-informed patients are a pleasure to deal with.

Mr. GORDON. And also you mention the fact that when you go down to the lunchroom, doctors ask themselves, well, what do you think, what shall we do, and so forth? Don't you think that is good?

Dr. RYAN. I think it is, yes. I was not making judgments on the propriety of whether or not people should ask questions or whether or not they should be informed. There is no question in my mind that most of the public pronouncements on the pill have involved rhetoric and scare because they come out with, the pill causes cancer or something, as the snap headline. Then, if you are industrious enough to read the whole article, you will get down to the bottom and see that there were animal models or something of this nature that were involved. This has been going on in relationship to the pill, as I say, almost from the time it has been on the market, and the rhetoric for and against it has been of equal quality in terms of informing people.

Senator DOLE. A lot of it may depend on who is asking the questions. If you were sitting up here and another doctor were the witness, you could probably ask very meaningful questions. Maybe Mr. Gordon has not had that problem. Maybe he is an expert in this area.

Mr. GORDON. Thank you.

Senator DOLE. The basic weakness probably is that we lack the expertise and we may, therefore, unintentionally present an improper picture.

Dr. RYAN. I was sitting through the prior discussion and I think that on balance, the committee hearings will have the opportunity to hear from people of all interests, experiences, and persuasions. And I think this is all to the good and I appreciate the opportunity to express my own in this respect.

I think out of this we would hope would come an awareness that there are problems and patients should be so informed, that we need more information and that we hope that the support for that type of research will come from the Federal Government, because it is involved, with long-range type of observations of patients.

Senator DOLE. Have you observed any shortcomings with reference to the pharmaceutical companies themselves? Are there areas where you feel they can improve communication of information?

Dr. RYAN. Really, I have very little comment about this. I think that the interchange between the regulatory agency—that is, the FDA and the pharmaceutical agency—the interchange between them I believe provides the physician with the kinds of information he needs.

Senator DOLE. That is all.

Thank you very much, Doctor.

Dr. Meier. Dr. Meier is professor of statistics at the University of Chicago.

You may handle your statement any way you wish. You may summarize or read the entire text. It will all be made a part of the record. Proceed in any fashion you wish.

**STATEMENT OF PAUL MEIER, PH. D., PROFESSOR OF STATISTICS,
DEPARTMENT OF STATISTICS, UNIVERSITY OF CHICAGO,
CHICAGO, ILL.**

Dr. MEIER. I understand that. Senator, thank you.

A decade ago, the first oral contraceptives were made available and shown to be highly effective and widely acceptable. Side effects were noted from the start, but oral contraceptives have become increasingly accepted nonetheless. Many of these side effects are transient and disappear after a time, and many occur in some users and not in others. Other possible side effects are potentially very serious and occur seldom enough that an individual physician cannot hope to make judgments about them on the basis of his own experience. It is this latter class of side effects with which I shall be concerned.

There are two aspects of public policy with respect to such effects which I believe require clear identification.

There is, first, the right of an informed individual to elect to take a reasonable risk in order to achieve some goal which he believes desirable. I make several trips a year from Chicago to Washington. Purely for convenience I travel by air and not by rail. I am one of the few who have examined the available information on risk in the two modes of travel and I judge that I am accepting a non-negligible risk in choosing the convenience of air travel, but I do it quite deliberately. On the other hand, I no longer smoke cigarettes, although I was once a regular smoker. The benefits were in that case

outweighed for me by a number of serious disadvantages. I am a strong believer in the freedom of the informed individual to decide for himself how to balance benefits and risks which primarily concern him, and I include here the right of the patient, consulting with her physician, to elect to accept some risk in return for the benefits of oral contraceptives. To me, the role of government in this area is clear—it is to be sure that both physicians and patients are as well-informed about the state of knowledge on the benefits and risks of oral contraceptives as it is reasonably possible to make them.

A second aspect of public policy is of comparable importance. It is to protect the public from clearly unreasonable risks, both by seeing that the risks are adequately studied and understood and, in some cases, by eliminating them from the environment. In some respects the level of concern by government should be much greater than that of even a prudent individual. For example, an increase in the level of ionizing radiation over the United States due, perhaps, to building nuclear power stations, would increase the risk that I might get leukemia. If the increase were small, I might reasonably ignore it, as an individual. The government, however, must weigh the combined risk to all of us against the benefits which additional nuclear power plants might provide.

In either case it must be emphasized that reasonable judgments are only likely to arise out of a weighing of risks and benefits. It is common to hear that "even one avoidable death is too many," or that the "only acceptable level of pesticide residue on food products must be zero." Neither as governments nor as individuals do we in fact behave this way, and the refusal to weigh risks against benefits often results in the blind acceptance of risks which analysis would show to be unreasonably high. I believe, for example, that the almost disastrous errors made in the program of safety-testing for the Salk vaccine in the mid-1950's resulted from an unwillingness to accept the notion that there might be a measurable risk and to seek to evaluate its magnitude. A typical example of a known risk which we accept in return for benefit is the requirement of smallpox vaccination for schoolchildren. A small but definite number of children die as a result of being vaccinated. We accept such costs as necessary to achieve a greater benefit.

How one weighs the benefits and risks is strongly conditioned by his background and general outlook. Since 1957 I have been a professor of statistics at the University of Chicago. One of the areas of applied statistics in which I have been most interested is the design and evaluation of clinical trials for new therapies. I have served on numerous review committees for the National Institutes of Health. I am currently a member of the Heart Special Project Committee of the National Heart Institute, and I served also on the National Heart Institute's Diet-Heart Feasibility Study Review Committee. For the past 15 years I have done occasional consulting for pharmaceutical firms, although never for a company which was a manufacturer of oral contraceptives.

My interest in the problems of population growth and conception control is of long standing, but my direct involvement is recent. I participated in the preliminary analysis of data gathered at the

University of Chicago which, it was hoped, might shed some light on the question of the risk of cervical cancer which might be associated with the use of oral contraceptives. It was the judgment of those involved that this particular set of data is unsuitable for that purpose, and further work is now being carried out. In the course of this effort, I had occasion to review papers dealing with other studies, particularly those dealing with thromboembolic phenomena. As a result, also, I was asked to participate in a conference on side-effects sponsored by Planned Parenthood of Los Angeles and other groups. Last November I was asked by a medical director in one of the firms which manufactures an oral contraceptive to review the Sartwell report—the American study of possible association between thromboembolic phenomena and use of oral contraceptives—and to attend two meetings held between company representatives and staff of the Food and Drug Administration. (A letter to Dr. Ortiz of the FDA, summarizing my remarks at these meetings, is attached.)¹

I agree with those who see population pressure as both a short-range contributor to many problems, such as poverty and environmental pollution, and a long-range potential disaster. Of course, in the long run population size will be controlled by Malthusian forces, such as war and famine, but I believe that no humane individual could wish us to be left to the mercy of those forces. I believe that motivation to limit family size is of first importance, but I feel that the continuing improvement of a still unsatisfactory technology for achieving conception control is also essential. I expect that American society, along with many others, will insist on effective means of conception control and, since I regard abortion as at best a necessary evil, I place a high value on the search for other means of limiting population growth. This does not mean that I favor continued distribution of the pill, no matter what effects it may have. If the level of risk associated with it should prove unacceptable, existing alternatives will have to substitute until better methods are found.

The current evidence is this. There are a number of side effects which are less than life-threatening and which, because they occur with fairly high frequency, are more easily studied and on which there are many reports. I have not reviewed these studies and I have no further comments to make on this class of side effects.

More difficult problems are associated with potential side effects which are relatively rare, but of utmost seriousness. Substantial attention has been given to two such diseases—thromboembolic disease, and cervical cancer. The evaluation of the effect of a drug on the incidence of a relatively rare disease is a very difficult problem. Thromboembolic disease and cervical cancer are not unknown among young women, quite apart from use of the pill, so that case reports, while suggestive, cannot provide convincing evidence of a causal relationship. The direct or prospective approach, although demanding, is far and away the most satisfactory method of study. If we can periodically examine a large group of women taking the pill, say five to 10 thousand, and an equivalent group using some other method of contraception, over a period of years, any difference in

¹ See p. 6555.

disease or death rates large enough to be of concern to us should become manifest. Ideally, subjects should be offered different contraceptive methods in accordance with a randomized allocation scheme. In some circumstances the random allocation procedure may be impractical and one must try to achieve relative comparability of groups in other ways. There are likely to be other difficulties as well—losses from observation, refusal to continue with periodic examinations, and the like—but none of these difficulties is insuperable and none, in my opinion, justifies the very nearly complete absence of such studies in this field.

In fact, one of the earliest studies initiated on oral contraceptives was a controlled prospective study. After initial exploration, starting in 1960, established the very nearly complete effectiveness of the pill, Dr. Gregory Pincus and others initiated such a study in Puerto Rico in 1962. Although sound in design, the study was beset with a number of administrative difficulties and, after the death of Dr. Pincus, it has come to be regarded in some quarters as a lost cause. The study is nonetheless still on-going and it represents the only long-term prospective controlled study of the pill in existence. Early reports from this study were highly favorable to the pill, but these reports also have been subjected to unfavorable criticism and the study is not at present accepted as a substantial contribution to our knowledge on the problem of safety.

Regarding thromboembolic disease. Early case reports led to the suspicion that the use of oral contraceptives might be leading to an increase of thromboembolic disease, and the pill has correspondingly been considered as contra-indicated in cases of circulatory disorder. However, until quite recently no important studies of this problem were carried out in this country. Last year two British studies were reported (Inman and Vessey; Vessey and Doll) and, at the request of the FDA advisory committee, a similar study was carried out in this country under the supervision of Professor Philip Sartwell of the Johns Hopkins University. In addition, vital statistics related to thromboembolic disease were reviewed.

The British studies have been hailed as models of clinical study design and appear to have been taken in most quarters as incontrovertible evidence of a pill-induced increase of thromboembolic disease. The Sartwell report, similar in design and at least equal in thoroughness and care in execution, indicates an increased risk of hospitalizable, nonfatal thromboembolic disease. Let me interpolate that it was an interview study post-hospitalization, and therefore, of necessity was concerned only with nonfatal diseases. This conclusion is widely accepted and perhaps prudence requires us at least to take it as a working hypothesis, and to evaluate the seriousness of the implied increased risk. (The risk of excess mortality due to thromboembolic disease is estimated from other studies to amount to approximately three deaths per 100,000 per year.) However, for the reasons indicated in my letter to Dr. Ortiz—see attached—I find this type of evidence to be far from convincing. Suspicions about oral contraceptives and thromboembolism have long been current and could readily have led to somewhat different hospitalization rates for women suffering similar disorders according to whether or not

they were known to be on the pill. Differences in choice of contraceptive methods by women of different demographic characteristics also contribute to the difficulty of drawing firm conclusions from such evidence.

The uncertainties of interpretation are given emphasis when we consider the disparity between the conclusions of the Sartwell report and those of a recent prospective British study reported by Ellen Grant. The Sartwell report, in addition to implicating oral contraceptives generally, concludes that sequential preparations are more hazardous in this regard than are the combination products. The Grant study, on the other hand, suggests that combination products with high estrogen content show a greater hazard than other preparations. She found relatively less hazard with the usual sequential formulations.

Mr. GORDON. Excuse me, Doctor. You talk about the Grant study and the Sartwell report? Are they mutually exclusive?

Dr. MEIER. Well, I do not intend any preference for one or the other in the language. The Sartwell report is a part of the FDA Advisory Committee report and it is commonly referred to by those involved in it as the Sartwell report. It is a study and in general terms, a highly meritorious study, every bit as good quality as the Grant study, as far as I know. The Grant study is one carried out in Britain, the Sartwell one carried out in the United States.

Mr. GORDON. Do they conflict?

Dr. MEIER. They do conflict, yes, quite flatly.

The testimony of vital statistics is also ambiguous. This was first noted by Drill and Calhoun, whose report has been criticized on various grounds. However, the far more intensive analysis of vital statistics rates in the Sartwell report seems also to lead to an ambiguous conclusion. The rates of mortality from thromboembolic conditions have increased over recent years, but this has occurred in most age groups and in men as well as women. A somewhat greater increase is found in women aged 25-34, although the difference is not statistically significant. The interpretation given in the Sartwell report is as follows:

In our opinion, these findings are consistent with the hypothesis that oral contraceptives have produced a small increase in the mortality from thromboembolism, but they do not add any great support to it.

I do not disagree with this conclusion, but I would add that if we consider it at all likely that the diagnosis of thromboembolic death in young women may have been influenced to some extent by a heightened index of suspicion in the case of pill users, one might also argue that the vital statistics results are consistent with the hypothesis that oral contraceptives have not produced an increase in mortality from thromboembolic disease.

I turn now to information on cervical cancer. The possibility that long term administration of hormones might give rise to one or another form of cancer has been a concern from the start. The possibility of an effect which might be long delayed makes it one of the most potentially difficult problems to study and, correspondingly, one for which continuing studies should have been initiated

promptly. Early reports from the Puerto Rican study were highly favorable, but again the evaluation of long-term results from this study is in question.

There exist almost no other clinical studies which purport to deal in a serious way with the cancer risk. The study in Chicago in which I participated was initiated as a supplement to a cytology screening program. No appreciable demographic information was recorded and there was considerable uncertainty about the validity of some of the data. No attempt has been made to randomize or otherwise control the choice of contraceptive methods and, as indicated earlier, it was judged that no useful results could be obtained from the material at hand. A study initiated in New York City is liable to some of the same difficulties and it has not so far contributed information on incidence among patients under continuing observation. Finally, a prospective study has been initiated at Kaiser-Permanente, but this has just begun to get underway. At the present time, then, we appear to have very little useful evidence on the question of possible carcinogenic effects.

The main point I have been trying to make is that, in the area of low incidence-high fatality diseases which might be related to use of the pill, we are deplorably ignorant. Why should that be so?

It is easy to lay the blame on the manufacturers, and they certainly deserve their share. It is in my view a major responsibility for the manufacturer and distributor of any product to investigate and to inform the public about the consequences of its use. At the same time, I take it for granted that manufacturers in general—whatever their line of effort, and whatever their rhetoric—are primarily concerned with making money, and that they will undertake to fulfill such responsibilities only to the extent that custom, pressure, or regulation require.

Of far greater concern to me is the failure of our governmental agencies to exercise their responsibilities in seeing to it that appropriate studies were carried out. It seems to me that the reasons are complex, but I think it is worth our while to consider some of them and to consider how the defect may be repaired. I spoke on this point at a conference a year ago, and my next remarks are a paraphrase of what I said then.

I think what has happened is that we have been overcome by a lack of appropriate organizational structure. It is only recently that we have begun to take responsibility for monitoring such effects as these, and we are not very experienced in this role. After all, which agency really had the responsibility? The Food and Drug Administration, even in those periods when it has enjoyed some fraction of the administrative and political support that I think it merits, does not ordinarily take on-going responsibility for long-range studies of a drug or food additive, once it has been judged that the product is reasonably safe. Certainly it has never had the staff or the budgetary support to justify such ventures. The National Institutes of Health, while budgetarily better equipped, has not seen this kind of activity as coming within its scope.

One might have expected the NIH research grant mechanism to fill the gap. It has not, and I think there are obvious reasons why it

has not. Frankly, the required research, although important, is not especially appealing to scientists. It is not fundamental and it is not exciting. It is difficult, it is expensive, and it is fraught with the risk of attack from all sides. Who would willingly prepare himself for such a study, make an application to be weighed competitively with others on scientific merit, and risk the loss of support halfway through the study when a review committee with different views or priorities comes to consider renewal of support, when he stands to gain so little in scientific recognition or otherwise?

Evidently, for whatever reasons, there is no sound body of scientific studies concerning these possible effects available today, a situation which I regard as scandalous. If we proceed in the future as we have in the past, we will continue to stumble from one tentative and inadequately supported conclusion to another, always relying on data which come to hand, and which were not designed for the purpose. The planning of better studies is difficult, and the recruitment of investigators willing to commit their efforts to these purposes may be more difficult still. I believe both are possible and essential to the public welfare.

The situation has become a little better recently, but not much. One or two studies executed in the manner which appears most suitable to those directing them will not provide us with the broad-based kind of information that we need. Appropriate studies can be generated only if a capable advisory group, proceeding in the knowledge that its recommendations will be acted upon, can outline in some detail the work that is needed and advise on the resources available and on appropriate sources for funding and management. I speak primarily of prospective studies with concurrent and probably randomized controls. I know it has been taken as a truism that such randomization is impossible with well informed volunteers. The same was said during the planning of a field trial for the Salk polio vaccine, but it proved to be very feasible once the determination to undertake such studies was firm.

Recommendations: Are there steps we can take to remedy the admittedly deplorable situation? I believe there are, and I have some views on what we should do now.

1. In view of the pressing problems of overpopulation which we face, we badly need to maximize the number of options for conception control which are open to us. With respect to the potentially most serious hazards of the pill we are basically ignorant but, at least with respect to thromboembolism and cancer, the pill has not been shown to be associated with unacceptable risks. I believe it would be tragic if, on the present evidence, it were to be removed from the market.

2. Both as a matter of principle and as a matter of sound public health policy, the fullest possible information about what is and what is not known should be given the widest possible distribution. This includes technical information for the physician and information in understandable language for the patient. Of course, it is all too easy for such information to be given in a way which either minimizes or exaggerates its significance. Here an unavoidable element of judgment comes in, but the key should be an intention to inform rather than to persuade.

3. Although I understand that the 1962 Puerto Rican study has been given up as a lost cause by its foundation supporters, I am not at all convinced that the case is hopeless. In view of the uniqueness in design and duration of this study, a federally supported review of the history and present circumstances should be undertaken with a view to possible renewed effort on it.

4. A committee including experts from Government, the academic community, and industry should be convened to consider the design of suitable short-term and long-term studies and to recommend ways in which they might be funded and carried out. It may be that the National Academy of Sciences could contribute to the process of naming a suitable committee. A commitment is needed both from the Congress and from the administration to full support for such a committee's recommendations. Without such assurances, the proposed committee would be simply one more in a long list of advisory groups which have operated in the knowledge that their advice in support of further studies was most unlikely to be acted upon.

5. A final recommendation of broader scope concerns the role of the Food and Drug Administration. It must develop the capacity to deal effectively with problems of the type before us. As it is organized at present, this is an unrealistic expectation. This agency, which has so critical a role in the public interest, needs a great expansion of Federal support, both in terms of budget and in commitment to its role.

That completes my statement.

(Attachments to Dr. Meier's prepared statement follow:)

THE UNIVERSITY OF CHICAGO,
DEPARTMENT OF STATISTICS,
Chicago, Ill., November 18, 1969.

Dr. EDWIN ORTIZ,
Director, Division of Marketed Drugs, Bureau of Medicine, Food and Drug Administration, HEW, Washington, D.C.

DEAR DR. ORTIZ: I write in response to your invitation at the time of our meeting on November 4. As you recall, I discussed with you and your colleagues some of the limitations which, I feel, are inherent in the interpretation of the findings in retrospective studies—in particular as these apply to the Sartwell report on the possible relationship between the use of oral contraceptives and the occurrence of thrombo-embolic phenomena.

As you know, my professional work brings me into close contact with a number of public health problems, such as the evaluation of the Diet-Heart Feasibility Study Report, and, more particularly, the study of undesirable effects following from the use of oral contraceptives in the studies undertaken by Professor George Wied of the University of Chicago. I read the British studies which provided the early evidence of the possibility of a relationship between oral contraceptives use and thrombo-embolic phenomena with great interest and with concern that the suggestive evidence provided there be followed up with more convincing studies—particularly large scale prospective studies.

I came to see you at the request of Dr. William Govier of Mead Johnson. I knew Dr. Govier when he was employed at Warner-Lambert pharmaceutical Co. where I was (and am) a statistical consultant. Late in the previous week Dr. Govier called to ask if I would be willing to read the Sartwell report and send him my comments. On Friday he asked if I would be willing to be present at the Tuesday meeting. The report had been in my hands only since Saturday. I should add that although Dr. Govier and his colleagues evidently feel that my view is helpful to their case, I have no connection other than the one I have described with Mead Johnson and I have no special interest in their

position in this controversy. I have no view on what should or should not be included in the package insert for their product. I do, of course, have a view of what conclusions can reasonably be drawn from the evidence provided by the Sartwell report.

Summary of my position

I should say first that I think that the study reported by Sartwell and his colleagues appears to have been done with great care and thoroughness and that it appears to be representative of the best work of this kind. The reporting is especially careful and meticulous, both in respect of the description of methods and in detailed reporting of the results. The study, standing alone, or taken together with the British studies, raises serious questions about the possibility of a casual relationship between the use of oral contraceptives and thrombo-embolic phenomena.

At the same time, this study is subject to the same kinds of limitations which afflict the British studies, and these limitations, which are mostly unavoidable, are of a kind which are not mitigated by replication of more studies of a similar kind. On account of the meticulous reporting in the present study it is possible to document some of these limitations from the evidence provided in the report itself.

I hold that none of these reports, nor all of them taken together, can be considered to provide conclusive evidence on the possibility of a casual relationship between the use of oral contraceptives and thrombo-embolic phenomena. Even less do they provide a satisfactory basis for discriminating degrees of risk due to different products.

Retrospective studies

Before I deal with the evidence of the report itself, let me mention by way of hypothetical examples the kinds of difficulties which arise in retrospective studies. Because the population at risk is dealt with only indirectly, it is entirely possible for important subgroups of afflicted individuals to escape observation altogether, or for incidental associations between use of a drug and exceptional incidence of the affliction in some particular stratum of the population to emerge as an apparent increased risk due to the drug. It is ordinarily far easier to recognize such situations in prospective studies and to correct for their effects. It is frequently difficult even to recognize them in retrospective studies, and often impossible to correct for such effects, even if they can be recognized.

As an example of a case in which an important segment may be entirely unavailable for observation in a retrospective study, consider an affliction which in an appreciable fraction of cases results in sudden death. A study which depends on post hospitalization interview must necessarily miss this segment entirely. If the effect of the drug is to modify such cases in a helpful way, so that they survive to be diagnosed and treated, the result of a retrospective study would be a finding of increased risk due to the drug—the exact opposite of the situation that would in fact obtain.

A second example is the following. Suppose we are dealing with an illness which tends to afflict those who engage in sedentary occupations and that the drug is expensive and used for minor conditions. It might happen, then, that professional individuals would tend to have a higher frequency of drug use, and a higher incidence of the disease. In a retrospective study where occupation was not one of the matching variables, the result would be to show an increased risk associated with the drug. There is, in fact, no great problem when the relevant characteristic is recognized and used as a matching variable in setting up the study. The problem is serious when, as is usually the case, there are many possible relevant variables, and matching is possible only for a few of those recognized—not to mention those of which we are unaware.

Aspects of the Sartwell study—data acquisition

As is clearly set forth in table 1, p. 66, over 2600 records of patients with thrombo-embolic phenomena were abstracted, but over 85 per cent of these were eliminated because of possibly predisposing conditions. The report makes the valid point that the concern is with the population of subjects for whom prescription of oral contraceptives would be expected. Despite the claim, however, that few women actually using oral contraceptives would be subject to

these conditions, no evidence on the point is provided. In fact, one could and, I think, should have undertaken to interview a sample of ostensibly normal women to form some estimate of the extent to which this very high level of selection might eliminate some proportion of oral contraceptive users in the population. A priori it seems likely that an appreciable fraction of ostensibly normal women might fail to pass such a test. The result of such heavy selection could be serious. An inadvertent bias which might have only a minor effect were the selection less rigorous could have a profound effect when such a high rate of rejection is employed.

Further unavoidable selection—reducing the case-control pairs from 261 to 175—resulted from failure in some instances to obtain interviews from the case or either control. Again, it is entirely possible that availability for interview may be correlated with characteristics which are related to use of oral contraceptives, or to liability to thrombo-embolic phenomena. (The potential effect of such relationships could be studied from the data on the abstracts for all the abstracted cases and controls. I understand that this data can be and will be made available. I should welcome the opportunity to review it.)

A final note on selection, and the possible bias which may be entailed: The report notes that among prospective controls those matching the demographic characteristics of the case in the record room index, it was sometimes necessary to review over 100 cases to obtain a suitable match. (see p. 50). Any inadvertent bias, say having a tendency to exclude oral contraceptive controls because of incidentally related characteristics, could be overwhelmingly magnified in the presence of such extreme selection as was exercised here.

Unfortunately, the commendable effort to exclude all cases from non-relevant strata of the population tends to open the door to other biases of comparable magnitude. There is no ideal middle ground, and this problem is one of the inherent difficulties faced by retrospective studies.

Evidence of possible bias

From the careful reporting in the study itself it is possible to see evidence of relevant population strata which are not equally represented in the two groups.

Table 5 (p. 70) shows the distribution of cases and controls on a number of factors which were not used as matching variables.

There is some evidence that Catholics are less represented among the cases than among the controls, substantial evidence that the less well educated are likewise less represented among the cases, and marked evidence that patients connected with medical settings are better represented among the cases. If, in fact, non-Catholics, better educated, and medically connected people tend more often to be oral contraceptive users, the disproportions in these variables between cases and controls could represent a serious bias.

A dramatic example of the difficulties which beset studies of this type is provided by the situation of the student nurses (p. 60). It is concluded that such individuals are more subject to hospitalization for thrombo-embolic phenomena than are others, and it is suggested that there may even be an elevated true rate of thrombo-embolic phenomena among hospital employees who must stay on their feet for considerable periods. One need only add the possibility that hospital employees may have readier access to oral contraceptives than do most control patients, and the possibility for spurious association between oral contraceptives and thrombo-embolic phenomena is evident. (In fact, the number of admitted oral contraceptive users in this group was only two, and they do not contribute substantially to the evidence. The point is that there may be other more significant relationships of a similar kind. In part these may be elucidated by study of the individual case-control data).

Comments on specific conclusions in the report

Although most favorably impressed with the evident care and thoroughness in the conduct and reporting of this study, I disagree with a number of the assertions and conclusions drawn.

p. 45—The report says that the retrospective approach was appropriate and criticises the prospective approach as "difficult, costly, and slow." In view of the impossibility of obtaining convincing results from more retrospective studies, this affirmation seems to me misguided.

Both in the fact that this method is suggested for study of possible effects on cancer incidence and in the fact that the committee makes no recommenda-

tion for further study of the problem of thrombo-embolic phenomena, I find vastly more cause for concern than is represented by the use of this method in arriving at the present position. I emphasize that the method does not approach the reliability of a well conducted prospective study and is not a suitable basis on which to draw firm conclusions in a case such as the present one.

p. 49—The choice of two controls for each case is described here—the purpose being to have a second chance if the first control were unavailable for interview. It is a truism in sample survey practice that such substitution can often lead to highly disturbing selection biases. The rate of unavailability was non-negligible (it appears to be in the neighborhood of 20 per cent), but this potential contribution to bias is not discussed in the report.

p. 53—A dozen lines are devoted to the affirmation of a difference in risk between sequentials and combinations. Prof. John Fertig has calculated an over-all chi-square for the 12 different products and gets a chi-square of about 15 (11 d.f.) which does not approach significance. The decision to group the sequentials together (15:0) but to leave Enovid E (14:1) with the other group requires explanation, and none is given. Without additional input to justify it, there is no evident ground from the data itself to justify this separation into the two groups presented. A description of the results, based on the data, would certainly take note of the situation of Enovid E. (Significance levels, based on selected comparisons do not have the unequivocal interpretation of those related to a single predetermined question.)

p. 60—It is suggested that the possible bias due to oral contraceptive users being more likely to be hospitalized for equally severe thrombo-embolic phenomena than non oral contraceptive users is satisfactorily tested for by comparing the situation for severe and mild cases. This is certainly one comparison worth making, but it is by no means justifies a firm judgment on this point.

p. 61—The issue of religion is dealt with in a short paragraph which I believe misses the major point. The point discussed is the possible effect of the correlation between pairs in religious background. No special point need be made about religion in this regard. If the matching is at all effective, many variables which were not ascertained will be similarly associated. The important point—for which this one might be mistaken—is that discrepancy in religion between cases and controls—for which there is some evidence—could introduce an apparent risk where there might be none. This very serious problem is not discussed.

p. 62—It is claimed here that “most of the women in the population who use oral contraceptives have none of the predisposing conditions.” Evidence on this point could have been obtained by additional interviews, but no evidence is given. Rather mild predisposing factors led to exclusion, and the point is an important one.

p. 72—The data in table 7 are used to justify the conclusion that discontinuance of oral contraceptives leads to prompt elimination of risk (p 51). I have no judgment of the relative likelihood of alternatives, but it should be pointed out that table 7 is equally open to the interpretation that the physicians predisposition to hospitalize is higher for current oral contraceptive users than for others, but that this predisposition does not exist for those no longer using oral contraceptives.

Appendix 2B

The conclusion stated is that the vital statistics “are consistent” with an increase in thrombo-embolic phenomena among women due to use of oral contraceptives. They are at least equally consistent with the opposite.

Summary

In sum, I feel most strongly that the problem of risks associated with use of oral contraceptives are too important to be assessed solely by means of retrospective studies. As I suggested in the meeting on November 6 with Dr. Ley, I believe that prospective studies are feasible and should be initiated without delay. I should welcome the opportunity to contribute to the planning of such studies.

Sincerely yours,

PAUL MEIER,
Professor of Statistics.

Senator DOLE. Dr. Meier, could you summarize the letter to Dr. Ortiz which is attached to your testimony.

Dr. MEIER. Yes, I will be glad to try to do that.

The critical issue is the limitations of inferences that one can draw from a retrospective study. The burden of this letter is to try to bring into sharp relief the reasons for some of the limitations.

Perhaps the most significant comment in the Sartwell report that led me to feel it was important to meet with the FDA people was the suggestion which I hope I can find that the retrospective study is really an ideal method for carrying out investigations of this kind. I do not find that statement. If you do, I would appreciate it.

In any event, the kind of limitation that arises comes from the two sources in my direct statement, primarily from those two sources. One is that you have no opportunity to see anything about the population which did not wind up in the hospital, which did not wind up with the relative designation on the death certificate if you are doing a mortality study. Information was not gathered on these subjects with a view to evaluating the pill. It may be true as in the hospital studies that you are interviewing the patients and thus gathering information directly related, but that information is gathered after the event of thromboembolism and in the presence of a large body of information that pills may be implicated.

In consequence, as I indicated in the direct testimony, it may very well be the case that a doctor having a patient whose symptoms might suggest thromboembolic disease might be more likely to press ahead and make that diagnosis if he knew the patient were on the pill than he might otherwise be. If he is not dealing with that patient in the context of a study in which he has a regular protocol to follow in evaluating the patient, this could introduce a very serious bias.

The other major limitation which comes in in considering retrospective studies is that there may well be associations which were not allowed for in the plan for the studies, and one such of small magnitude shows clearly in the Sartwell report. There were a number of student nurses who had thromboembolic disease and they had a very high rate of pill use. Well, it is not in the least surprising that student nurses, (a) might be more liable to thromboembolic disease, being on their feet more than most of us are; it is not in the least surprising that they should be on the pill, because they are in the place that the pill might be more accessible. If we have any reliability at all for a causal mechanism for showing the relationship, it might be difficult to disentangle these. It is much more likely one will be able to see anything that is going on in any sort of prospective study. As I have indicated, the only kind of satisfactory study is one in which you have concurrent control. It is the point closest to my heart that despite repeated assurances from one expert to another that it is not possible to carry out such studies in the United States, I strongly believe that it is possible to carry out such studies and that it is very important that we should do so.

Senator DOLE. On page 15 of your statement, you state the pill has not been shown to be associated with unacceptable risks as far as thromboembolism and cancer is concerned. That is contrary, of course, at least in part, to some of the testimony we have had from

some of the experts who have appeared before our committee. But again, yours is based on a statistical study of some magnitude. Can you elaborate on this one point? This is the one area where we have found some general agreement among witnesses.

Dr. MEIER. Yes, I am sorry to disturb the general unanimity of all parties, but I must stick to my conviction that on these retrospective studies, although important, and as I say, prudence may require us to assume that they mean what they appear to mean, still for the reasons I detailed in the letter and alluded to earlier are not considered by me to be convincing evidence that the relationship exists. In this statement, I have said that the pill has not been shown to be associated with unacceptable risks, and that incorporates what I have just said, that it has not in my mind been proved that the pill causes thromboembolic disease. It also embodies some assessment of judgment that I read on the part of many people that if, as has been estimated, there are three thromboembolic deaths per hundred thousand women on the pill for a year, this rate, although regrettable, is low compared to many other risks and comparable or lower than some risks, which we take for comparable reasons of convenience, even if that risk is real, it is not necessarily an unacceptable risk.

Mr. GORDON. How about the morbidity rate of one in 2,000? Would you consider that—

Dr. MEIER. That certainly would have to be weighed, and here, although I have been ready to state opinions on almost everything, I must admit that I am not ready to state an opinion on that, whether that is or is not an unacceptable risk.

Mr. GORDON. Well, whether it is acceptable or unacceptable would depend on the patient, would it not? Is not the patient entitled to know that one in 2,000 women develop blood clots serious enough to be hospitalized?

Dr. MEIER. Emphatically, as I tried to indicate in my testimony, I feel very strongly that the patient has a right to know and I would like to see further steps taken to insure that that right is accommodated.

Senator DOLE. Thank you very much. The bell indicates that we have to go. We appreciate very much your testimony.

The hearing is recessed until 9:30 tomorrow morning in this room.

(Whereupon, at 4:15 p.m., the committee adjourned until 9:30 a.m., Wednesday, February 25, 1970.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition In the Pharmaceutical Industry)

WEDNESDAY, FEBRUARY 25, 1970

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

The subcommittee met, pursuant to notice, at 9:45 a.m., in Room 4221, New Senate Office Building, Hon. Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson, Javits, and Dole.

Also present. Benjamin Gordon, staff economist; Elaine C. Dye, clerical assistant; James P. Duffy III, minority counsel; and Dennison Young, Jr., associate minority counsel.

Senator NELSON. The hearings will come to order, please. Our first witness this morning is Dr. Alan Guttmacher, president, Planned Parenthood/World Population; emeritus professor, Mount Sinai School of Medicine in New York City; lecturer on Maternal Health at Harvard School of Public Health, Boston; formerly clinical professor in Obstetrics and Gynecology at the College of Physicians and Surgeons, Columbia University.

Dr. Guttmacher, we are very pleased that you took the time to come here this morning and give us your views. Your statement will be printed in full in the record. You may extemporize from it or present it in any way you please.

If at any time you desire to add to the statement extemporaneously, feel free to do so.

I assume you have no objections to questions being asked as we go along?

STATEMENT OF DR. ALAN F. GUTTMACHER, PRESIDENT, PLANNED PARENTHOOD/WORLD POPULATION, NEW YORK, N.Y.

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

Senator NELSON. Very well.

Dr. GUTTMACHER. Thank you very much, Mr. Chairman. I appreciate very much the opportunity to appear before you in these hearings on the birth control pill. I probably have one of the largest birth control practices in the world, since my organization in 1969 served approximately 350,000 women in 525 centers, in 130 cities of this country. I assure you that this is a responsibility which neither

I nor my organization, particularly the National Medical Committee and its capable medical staff, takes lightly.

I assume that the primary consideration for these hearings is the health of the American female. I interpret your more specific goals to be twofold—to have potential users of the pill forewarned of its risks; and to make the medical profession more cognizant of their responsibility in its prescription.

Senator NELSON. May I interrupt for just a moment to add that one of the other stated reasons is to attempt to get knowledge and understanding of the whole issue so that we may get from Congress larger appropriations for further needed research in the field of birth control devices and family planning.

Dr. GUTTMACHER. I applaud that, sir.

Unfortunately, I assume that you share my apprehension that there have been undesirable side effects from these hearings, and as you know full well, they have created a sense of great alarm. Certainly, nothing fundamentally has changed in respect to hazards from the pill since these hearings began, and well-informed physicians found nothing revealed by the hearings which was not previously recorded in a published literature or presented at scientific meetings.

The Second Report on the Oral Contraceptives, issued by the Obstetrical and Gynecological Advisory Committee of the Food and Drug Administration was published just 6 months ago. It was based on 189 references to the current literature and covered the same data covered in the January hearings of this body.

In many instances these data were written by many of the witnesses who appeared before you.

Now, I need not extol the competence of the Food and Drug Administration Advisory Committee, because I think you know full well that it was picked from the most representative and competent people in this whole area. It is made up of very respected physicians, other scientists, and statisticians, and no doubt you know, but I would like to emphasize once more, their final statement in their recent report, which says when these potential hazards and the value of the drugs are balanced, the committee finds the ratio of benefit to risk sufficiently high to justify the designation safe within the intent of the legislation.

In mid-January, the American College of Obstetricians and Gynecologists made the statement that it "considers that the oral contraceptives are accepted therapeutic methods," and they deplored the inaccurate and sensational reports concerning the drugs.

At the January 28th meeting of my own very distinguished medical committee, which forms the National Medical Committee of the Planned Parenthood Federation, our physicians went over the data and they came up with the report that the committee continues to recommend the prescription of oral contraceptives.

Of course, the reason I quote these authorities is not to whitewash the pill, but I have a compelling interest to place this matter in proper perspective, in the hope, which I am sure you will agree with, of stemming unwarranted and dangerous alarm.

The pill, in my opinion and that of my colleagues, is an important prophylaxis, perhaps the most important, against one of the gravest

sociomedical illnesses extant. That, of course, is unwanted pregnancy.

I would like to tally the results of unwanted pregnancy, a condition which is tragically common in our country. First, experts estimate that between 200,000 and 1,000,000 illegal abortions are performed each year in this country, with a death rate estimated to be 100 per 100,000 illegal operations when performed by nonmedical persons.

I would like to add at this point that there is a large, general municipal hospital in the Harlem area of New York City, the Harlem Hospital. The Chief of Obstetrics and Gynecology, Dr. Donald Swartz, kindly furnished me data at my request.

Like most city hospitals, the aftermath of illegal abortion has been one of their worst scourges. Dr. Swartz opened an intrauterine contraceptive clinic late in 1963 and until January 1, 1965, employed only the IUD in a relatively few patients.

In 1964, Harlem in the ghetto, had 3,857 deliveries and 1,291 abortion complications cases with five abortion deaths.

With the introduction of the pill in 1965, the birth control clinic rapidly expanded and in 1969 there were 2,226 deliveries, 1,631 (42 percent) fewer than 5 years before; there were 507 abortions, 784 (61 percent) less than in 1964 and zero abortion deaths, five less than in 1964.

The Harlem Hospital prescribes five methods of contraception from which each patient may choose. Sixty-seven and six-tenths percent preferred the pill, that is, until these hearings made headlines.

I am afraid to estimate the Harlem Hospital figures for 1970, but it is fair to assume that the proportion of birth control pill users will decline acutely, abortion admissions will rise, abortion deaths will go up, and in 1971, I am sure that they will exceed the 2,226 deliveries which they had in 1969.

Senator NELSON. May I interrupt, Doctor?

Dr. GUTTMACHER. Yes, sir.

Senator NELSON. You do not have a single statistic to support that. This is, as you stated, just your assumption?

Dr. GUTTMACHER. Mr. Senator, we have noticed at Kings County; Metropolitan Hospital; Harlem Hospital, that when they have established an active, vital birth control clinic, the abortions in all of these institutions have gone down significantly, and in all of these clinics, the primary method of birth control which patients choose is the birth control pill.

Now, it seems to me that it is not accidental that abortions have gone down among their clients. There is nothing that happened in the social picture which would change this. The thing that has changed it is a very active birth control clinic which saturates the peripheral community around these great hospitals.

Now, if patients depend primarily on the pill—certainly 67.6 is lower than I thought; in most of our institutions, 75 percent take the pill. To me it is pretty obvious that the pill has made a deep impact in these areas, in ghetto areas, on the horrid and undesired illegal abortions which take up so many beds and cost so many lives.

Senator NELSON. I would not quarrel with that. All I am saying is that all that you have said is based upon, as you put it, "I

assume" in 1970 there will be more abortions, more unwanted births. It is an assumption without a single statistic to report as of this date, is that not correct?

Dr. GUTTMACHER. Well, I think it is too early to make a factual statement. I think I can create a hypothesis, but I do not think I can prove the hypothesis until the year has run out.

Senator NELSON. One of the interesting things in Dr. Connell's testimony yesterday was that in one certain period, whatever it was, a week or two weeks, 118 of their patients quit the pill but went to the diaphragm. Statistics are being thrown around as though, if people quit the pill, they did not go to some other birth control device, whether it be IUD or the diaphragm.¹

Dr. GUTTMACHER. I certainly would not argue the fact that some are going to. I would certainly argue the fact that all are going to. This is an assumption, again. You may not say that I can declare it as a fact. And also, we have had such rich experience with the diaphragm with the class of patients that people our great hospitals, we now know how relatively unsatisfactory this has been. We have had long tradition of the use of the diaphragm and I think, in certain elements of the population, it is a very effective method of contraception. But I would not say we have had uniformly good results with the diaphragm in our clinic populations. I think I get to that a little later in my testimony, sir.

Senator NELSON. I just point out that I think it is rather interesting that Dr. Hellman, who headed the Department of Obstetrics and Gynecology in his own clinic, stated that more people were using the IUD than were using the pill.

Dr. GUTTMACHER. Of course, that depends a great deal upon the interest of the chief of service and the research he is carrying out. He is carrying out research with the Majzlin spring device, which is one of the new IUDs. It has been my experience that the man in charge of the clinic largely dictates the contraceptive used within that clinic.

Now, as you know, they have an excellent clinic at Kings County. I know it very well, I know the people working there. But they are particularly anxious to see the merits and demerits of this particular IUD device.

Senator NELSON. Is this a lower-income group?

Dr. GUTTMACHER. Yes.

Senator NELSON. Does it not indicate, in any event, that those who say they cannot persuade people to use the diaphragm or the IUD are refuted by the statistics of Dr. Hellman's own clinic?

Dr. GUTTMACHER. Certainly the IUD is used by patients of the lower-income group and quite widely, in certain types of patients.

May I go on, sir?

Senator NELSON. Go ahead.

Dr. GUTTMACHER. I was attempting to tally the, to me, tragic sociomedical results that occur as the aftermath of unwanted pregnancy. I think I made my point.

At least one out of six U.S. brides is pregnant when married; half of the brides are pregnant when the couple are teenagers.

¹ See statement of Senator Nelson, p. 6638.

No less than 300,000 illegitimate children will be born in the United States during 1970, based on the experience of the past decade.

A recent study shows that at least 750,000 children born each year were unwanted at the time of their conception. We refer to the study of Westoff and Bumpass of the Princeton group.

Now, with all this evidence of social pathology associated with unwanted conception, I believe it is inaccurate to belittle the importance of the contraceptive pill by stating it is a potent drug given to healthy women. What is omitted from such a statement is the fact that the pill is the most effective means yet known to prevent a very serious affliction, unwanted pregnancy. It is a serious affliction for the parents, but far more for the children.

Now, I should like to attempt to separate fact from conjecture concerning the safety of the pill. Most of this data has been presented to this committee. I am strongly of the belief that the pill does cause thromboembolism. I am strongly of the belief that the British data confirmed by American studies prove to us that there are approximately three deaths per one hundred thousand pill users per year. I think that this data, to me, is completely convincing.

I need not go into greater detail about the incidence of the effect of age on this and so forth, because this has all been given before this committee.

On the other hand we have, of course, the risk of pregnancy which, in 100,000 women who are pregnant outweighs the risk of danger from the pill many fold.

Now, it is obvious that not all women who discontinue the oral contraceptive are going to get pregnant, but since it is by all means the safest method of contraception and, from our experience, the most acceptable, I have a feeling that pregnancy is going to rise rather precipitously. Again I think the Senator would take issue with my assumption, but nevertheless I hold to that assumption.

Senator NELSON. May I interrupt you?

Dr. GUTTMACHER. Surely.

Senator NELSON. In April, 1969, Dr. Hellman, whom you know, of course, and who directed the FDA study on obstetrics and gynecology, wrote an article in Redbook magazine, in which he said—

We can say that the risk in taking the pill is less than the risk in having a baby. I suppose this is a legitimate statement. But the risk in having a baby is not the same for all individuals. A healthy young girl runs a very negligible risk, but someone who has serious heart disease or is older, or who has hypertension, runs a real risk in having a baby. To say that the risk of taking the pill is less than the risk of having a baby doesn't make sense.

What do you think of Dr. Hellman's statement?

Dr. GUTTMACHER. Well, I like Dr. Hellman, but I don't agree with his statement. I think you run a risk in trying to judge mortality in ordinary pregnancy. Obviously the risk goes up with increasing parity, with increasing age; we know the figures moderately well.

We know that the risk is considerably more among the economically-deprived segments of the population. We have a higher mortality among lower-income groups, among Puerto Ricans, among blacks—we know those facts. I unfortunately have seen death occur to an

obviously very healthy woman and so has Hellman. I think that that statement does not present my point of view very accurately.

I think that pregnancy, in good hands—that means excellent facilities, in a well-nourished woman who has had excellent prenatal care—carries with it a relatively minimal risk. But I think that anyone would state that if you took a thousand women—you would have to take them in terms of 100,000 women—who were so fortunate as to have this type of care, this type of nutrition, I think you would find you have a higher maternal mortality of more than 3 per 100,000. It may not be the 20 that we find in our American white population; it may not be the 30 which we find in our American black population. But it certainly would be a mortality higher than 3, and I think Hellman would be the first to admit this, because he knows the facts as well as I do; but whether it is eight or 12, I cannot argue that point. But I am certainly not willing to accept that mortality, even among our most preferential pregnancies would be less than 3 per hundred thousand, sir.

Now, in addition to the danger from thromboembolism which has been described to this committee on several occasions by several witnesses, I think that there are other dangers for the pill. I think that there are other serious adverse side reactions, or bad effects, which may occur in an occasional patient.

The more common have been certainly detailed to you, such as high blood pressure, headache, depression, interference with vision, and so on.

Fortunately these serious side effects are reversible, and most disappear if contraceptive pills are discontinued. I certainly recognize that there are very profound metabolic changes in some patients on the pill. I also know that there has been nothing in the literature and nothing before this committee that these changes are or will be harmful.

Senator NELSON. Is it not also true that it has not been demonstrated that they will not be harmful?

Dr. GUTTMACHER. I suppose that is true. I suppose you are asking whether these changes, if they exist long enough, will cause permanent deterioration of body systems. This is a possibility. I am certainly not going to whitewash the pill by saying we know all the answers. We do not; just as you say in your statement that we need more research, I would underscore that 20 times. I agree with you completely and utterly. There is no problem about that.

Senator NELSON. On the question of the metabolic changes—I have here a book.

Dr. GUTTMACHER. That is Dr. Salhanick's volume. I can see it here. It is an excellent book.

Senator NELSON. I also have a pamphlet that discusses a particular oral contraceptive. The cover says, "So Close to Nature."

Dr. GUTTMACHER. "So Close to Nature," sir?

Senator NELSON. Yes, that is the title of the pamphlet.

Dr. GUTTMACHER. I do not think Salhanick wrote that.

Senator NELSON. Oh, no; it is the pamphlet of one of the drug companies, explaining the use of the drug to doctors.

Dr. GUTTMACHER. I see. I was concerned—

Senator NELSON. So there it is, a slick little piece, and it says:

So close to your natural feminine pattern.

Your doctor has prescribed this newest kind of fertility-control tablet for you. Unlike others available for the same purpose, this preparation follows the principles and system of nature itself. Its actions closely resemble those of your natural menstrual pattern, and it works without upsetting the delicate balance of your normal body function.

Would you agree with that statement?

Dr. GUTTMACHER. No, sir; I do not.

Senator NELSON. This is the literature that is being given to the users, the only piece that is being handed out to them, since there is no package insert. Would you think that this ought to be stopped?

Dr. GUTTMACHER. Well, of course, I have not read the whole thing, sir, but from what you have read, I do not agree. It is obviously not stating facts. These are different drugs than the normal-occurring estrogens and the normal progesterone. I do not think one can say that the way you read it. I would disagree with it.

Senator NELSON. The sentence at the end, "and it works without upsetting the delicate balance of your normal body function," do you agree with that?

Dr. GUTTMACHER. I would say it may work without upsetting; yes. There are some women who obviously do not have the chemical changes and some women have no side effects. But I think certainly the way it is written is inaccurate.

Senator NELSON. Well, this is one of the reasons for the hearings, the fact that all the data included in the FDA-sponsored study has not been widely disseminated. Although it has been published, it does not go to the user. Instead, the information in this pamphlet is what goes to the user.

This is the sort of thing being widely run in women's magazines, with an exception or two. Now, do you think that the patient who gets this, or even the doctor, is aware of the Salhanick report on "Metabolic Effects," etc.; this is the one from the workshop sponsored by NIH. Do you think the women of America are aware of what is said there?

In fact, do you think that most of the doctors—I would like the answer to both of those questions—I mean doctors who are not professionals in this field, such as you are, the gynecologic phase of it—do you think doctors are aware of what this report says? I shall read to you from it. This is the preface of the volume on page 9:

Until recently the metabolic effects of the sex steroids have been inadequately investigated or ignored. These accumulated data and others suggest that no tissue or organ system is free from a biological, functional and/or morphological effect of contraceptive steroids. Many of these changes appear to be reversible after short periods of treatment, but it is impossible to form judgments on the reversibility of some of the changes resulting from prolonged administration. This question becomes more important daily for the many patients who have already had long-term contraceptive steroid treatment.

Further down on the same page:

Nevertheless, the consistency of such reports on such findings reject the possibility that they are of no consequence and require that certain questions be answered.

Does the user of the pill in America know this?

Dr. GUTTMACHER. No, sir; she would not get much if she read that, either. That is the difficulty. I have been in active practice for 25 years as a private practitioner, and in addition, a full-time chief of service for 10 years. I have had contact with thousands of patients in my long medical life. Unfortunately the physician has to make the decisions for patients. You may discuss this with the patient at considerable length, and usually, when the discussion is over and you are talking about a particular therapy or operation, the patient will look at you and say, "What shall I do?"

Now, I do not think that you are going to be able to educate the American woman as to what she should or should not do with regard to the pill. I think you can educate the American doctor. He is educatable. I think that the average doctor certainly has not read this volume of Salhanick, and I think that much of the information which is in there might be new to the American physician.

I think on the other hand the American physician is a conscientious man. I do not think that he willfully threatens the life of his patient. I think he probably is so overwhelmed by his medical practice and the normal activities of making a living that he tries to get his medical information in capsule form and he is very likely to take the particular throwaway literature which comes across the desk, not seldom, from the pharmaceutical firms.

Senator NELSON. Not seldom?

Dr. GUTTMACHER. Not seldom, from the pharmaceutical firms.

Now, I certainly feel that the more we can instruct the American physician about the intricacies of the birth control pill, the wiser the effort. My feeling is that when you attempt to instruct American womanhood in this, which is a pure medical matter which I am afraid she has not the background to understand, you are creating in her simply a panic reaction without much intellectual background. And this is what I think has been unfortunate.

I do not accuse these hearings of any diabolical purpose, but I must say that the reaction of the American public, parading this across the news media, particularly with the news media picking out those portions which are inflammatory, have done a great deal of harm.

I think educating the American physician is absolutely commendable and important and necessary, and I think perhaps the American physician has been remiss in not trying to educate himself about the intricacies of the pill.

I feel that in our own clinics, Planned Parenthood, as I say in my testimony—but it appears at this point we ought to depart from it—I think in our own clinics we have been extremely vigilant, certainly in instructing our clinicians in the United States on what is considered to be a good practice in regard to examinations, Papanicolaou smear, breast examinations, and so forth, with the pill. As you see in my testimony, we had a directive on January 26, 1966, which is more than 4 years ago, in which we stressed this to the physicians working in our clinics.

We have tried to keep our physicians working in our clinics—there are thousands of them—intimately apprised of all of the charges made against the pill. All of the evidence—certainly any doctor working in Planned Parenthood knew about thromboembolism and the results of Vessey and Doll and that group. They knew it certainly within a week after publication. Now, whether one can do a similar job to the larger medical profession, I have some uncertainty. But I think that the committee has served a useful purpose in making the doctor more careful in regard to this and making him keep up to date with what is going on in the literature.

On the other hand, I have the reaction that unfortunately the layman has tried to share this, and the layman is a terribly confused person.

Senator NELSON. The literature which are distributed by the manufacturers of the pill read quite similarly, deemphasizing any serious side effects, substantially deemphasizing them in a way which I think would be considered inaccurate. Do your clinics give out any of these?

Dr. GUTTMACHER. As far as I know, no, sir. We have our own publications in which we describe the pill, and we do go into some of the difficulties.

Senator NELSON. Now, since this literature comes out to doctors' offices, and this is what the doctor is reading, I assume that if he thought it were inaccurate, he would not give it to his patients.

So we have a situation in which thousands of doctors are handing out the promotional literature of the drug companies, which you agree is not accurate. Does that not necessitate somehow or other ventilating this problem, so that the doctors themselves will become aware, so that the public and the woman who uses the pill will know that the statement I read from the pamphlet, as Dr. Guttmacher says, is an unsupportable statement?

Dr. GUTTMACHER. I think it is unfortunate that in educating the doctors, you have to confuse the public. This apparently is a byproduct which seems necessary by this technique. Whether the doctor could be educated in a way which would not expose the public to this panic and this fear reaction and distrust, I think is open to debate.

Now, I am not a politician and I know nothing about running Senate hearings, but I think there is a tremendous amount of undigested pabulum which comes out in the daily press. I think the press is trying to be fair, but witnesses have been adverse in the main.

There has been a tremendous amount that becomes terribly undigestible to the average layman. This is my problem, and I am sure it is your problem. I do not think you are trying to panic the American female. Certainly, she has taken the pill for several years with tremendous satisfaction in most instances, and I think still will, until we get a better contraceptive method, and I hope that we will get a better contraceptive method through immense increase in research efforts. I think until we do, I still think the pill has a tremendous and very important indication, and I would hate to see

American women in good health give up the pill simply because they do not understand what is going on here.

Senator NELSON. I might say in reference to your comment about panic—I do not know whether that is the right word or not—some doctors were quoted in the paper 2 weeks after the hearings started that they were now seeing the first pregnancies from the hearings.

Dr. GUTTMACHER. That is a rapid pregnancy.

Senator NELSON. You have to be pretty panicky to get pregnant in 2 weeks, I think.

In fact, yesterday, Dr. Connell testified, and I think it was instantly called to her attention—we heard testimony from Dr. Connell, a very distinguished gynecologist, who runs a clinic in New York—

Dr. GUTTMACHER. Dr. Connell? I helped train her, so I think she is great.

Senator NELSON. Now, we received her testimony on the 17th of February. The hearings opened on the 14th of January. Her statement had to come through the mail and she also had to prepare it in advance. So, in less than a month, she was able to say, "Several pregnancies ascribed to stopping the pills because of fear have been seen."

So you have a situation in which doctors were supposed to have reported pregnancies before 30 days go by. Does that not give you a little pause about panic statements of the doctors themselves?

Dr. GUTTMACHER. This is a misinterpretation, I think, Mr. Senator. What has happened, of course, is that there have been a tremendous number of scare articles in the lay literature, quite sometime before these hearings were scheduled. We found that in some of our clinics, patients were not using the pill. The Margaret Sanger Research Bureau, which is one of the great institutions of the United States, noticed in 1969 a 9-percent drop in pill-users, and they have thousands of patients.

This was, of course, a reflection of a lot of the scare literature which got into the Ladies Home Journal and other volumes. So I do not think Dr. Connell or anyone else is insinuating that your hearings have impregnated women. I think the thing which has impregnated women is the scare literature which anticipated your hearings by several months.

I think this is the difference, sir.

Senator NELSON. That is the first explanation I have heard. I suppose we shall get some credit for people having dropped the pill 3 years ago.

Senator DOLE. Mr. Chairman, some of my own doctor friends have indicated that we might better be doing something else for the world. As a member of this committee, of course, it has been very interesting. Our own promotion of these hearings started in December, so we have had, really, more than 30 days.

There has been a great amount of publicity everywhere in America, including my own State, Kansas, concerning the hearings and

the comments of some of the witnesses. I would suppose everyone who has appeared has been properly motivated.

But on the other hand, when the headline reads, "Pill May Cause Cancer," it certainly is disquieting to the woman who may be taking the pill. Perhaps testimony such as yours, that I and others who have had practical experience with great numbers of people, can lay to rest some of the panic that has been caused and created—not, of course, purposely by the committee, but as a direct outgrowth of committee hearings.

I am not certain how many babies are going to result from the hearings, but you have indicated that there is some evidence there has been a reduction in the taking of pills.

It is fair to assume that some of this has resulted directly from the hearings and the reports of the hearings, but hopefully, with your testimony and the testimony next week, we can have a balanced record to present the American people.

Dr. GUTTMACHER. Of course, I think that is very important, Senator Dole, to have a balanced record. I think that the hearings have done some good, and I also think, of course, they have done a great harm. I think the great harm is done because the American woman does not know how to evaluate all this.

The pill has some strong advantages in certain situations. In premarital sexual situations, the pill is an extraordinary medicament. If we want to live with the facts of life in America, there is an extraordinary change in our sex ways, our sex mores. We know that we have to give protection to unmarried adolescents, because a pregnancy unwanted is a tragedy in an older woman, but it is twice the tragedy in a child.

This kind of thing, I think, is going to be very, very dangerous.

It is interesting that Dr. Hugh Davis, who castigated the pill so severely in your hearings here, in a very interesting project which Planned Parenthood is conducting in the city of Baltimore, which Dr. Davis is responsible for, in very young teenage children giving birth control to them, some before they have had their initial sex experience, of the 40 patients whom he has served, he gave 26 the pill and 14 the IUD.

So even Davis, who seems to have great distrust for the pill, recognizes that in certain indications it is a terribly important technique.

I think in early marriage, while couples——

Senator NELSON. May I say something on that subject? This is referring to Dr. Davis. Dr. Davis' testimony was that he would prescribe the pill not to exceed 2 or 3 years for the specific purpose of spacing pregnancy. He would hope that they might be persuaded to use another device. So he did not testify here that he would abolish the pill. He was for limiting the extended use of it.

Dr. GUTTMACHER. I recognize this, but I should imagine these young children would have to have extended use of the pill at the age at which they start. So despite the fact that he would like to

carry this out, whether he is going to be able to in this group, I cannot say.

Senator DOLE. Doctor, we all recognize that you indicate it is difficult to inform the patient by setting forth a list of the possible risks involved. Is the pill in this respect different from any other medication?

Is there anything different about the pill and hundreds of other medications? Is there anything about oral contraceptives where the problem of communication is any greater?

Dr. GUTTMACHER. I suppose not. Certainly, when it comes to aspirin, we know that we have gastric hemorrhages for aspirin. We have fatal cases of aspirin, even in people who are not taking a vast amount. But I feel that the pill probably is a pretty special kind of medicament.

Of course, other drugs have reactions. Certainly, we know of death from penicillin, one of the most widely used drugs, or virtually any drug you can name. Whether the rate from penicillin is higher than from the pill, I cannot answer; I do not know that.

On the other hand, as Senator Nelson has pointed out, this is a drug given to women who are in a state of good health. My reaction to those remarks is that this is a powerful combination of drugs given to women to prevent a most serious illness, and that is unwanted pregnancy. From my point of view, it is justified.

Now, you asked me whether special things should be done in, I suppose, packaging and labeling. I have the feeling that most patients do not read what is put into their pill packages or medicines, and if they do, they have some difficulty understanding it.

Again, my thesis goes back to the fact that your target should be the education of the American physician and that he has to take the responsibility of whether or not to prescribe the pill for Mrs. A or Miss B. This has to be his judgment. I would like to give him, equip him with all the knowledge possible so that he can make his judgment correctly and authoritatively.

I am all for educating the American medical profession. I have rather dim enthusiasm for attempting to educate the recipients of therapy. I think that the dispenser of the therapy is the person who must be educated and not the recipient.

Senator DOLE. We have an obligation to communicate the dangers to the dispenser, as you say. He should be aware, and then somewhere along the line, there should be a judgment based on the doctor-patient relationship made whether to use the pill, or whether, after having started the pill, to drop the use of the pill.

It might be well to have a copy of the information that is made available in your clinics for the record, to see how you approach the problem, what you may give the patient.

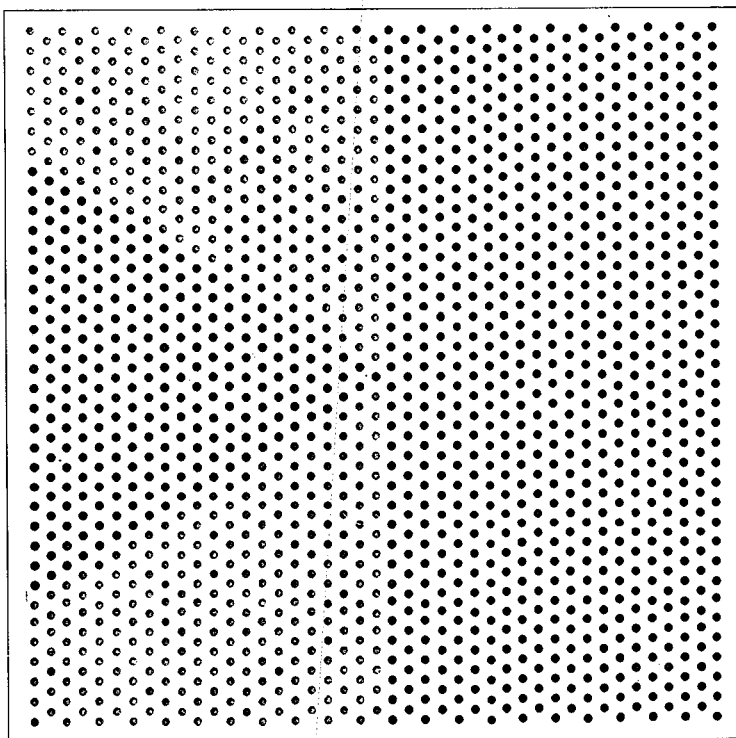
Dr. GUTTMACHER. Yes, I am sure we can furnish that.

(The material above-referred to, follows:)

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For Professional Use

**Methods of
Contraception
in the
United States**



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Methods of Contraception in the United States

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Methods of Contraception in the United States

Contraception is accepted by the medical profession as one of the standard techniques of preventive medicine. (See policy statements p. 12)

The methods presently used in the United States include: hormonal steroid contraception (of which oral contraceptives are the only products currently approved by the Food and Drug Administration); the intrauterine devices; the diaphragm and cervical cap; the chemical contraceptives (foams, creams, jellies, foaming tablets, suppositories); the condom; coitus interruptus, and the rhythm or safe period technique. Contraception is differentiated here from surgical sterilization and from induced abortion.

Criteria for Choice of Methods

Safety

The device or product must have undergone adequate laboratory and clinical testing to have been proved safe for short and long-term use.

Acceptability

Acceptance by the patient is most important. A method of high theoretical effectiveness may fail because the patient dislikes it and uses it inconsistently or not at all. Therefore, the physician must assess whether or not the patient is likely to employ a given method conscientiously, and should insist on adequate follow-up interviews so that he may learn whether the method is satisfactory for the couple. For example, if the diaphragm is to be prescribed, the physician must consider carefully such factors as the ability of the woman to use it correctly, possible hidden fears about its "loss" within her body, proper choice between spermicidal jelly or cream, depending on the patient's esthetic needs and preference, her attitude regarding the amount of self-manipulation necessary, the probable regularity of her use of the method, and the attitude of her husband. Such factors as level of education, degree of available privacy and sanitary facilities, and basic attitudes about fertility and sexual practices undoubtedly play decisive roles in the successful use of all methods. Sensitivity to the psychological make-up of the patient and her husband as a biological unit will thus be crucial in the physician's selection of methods offered for their choice.

Effectiveness

Comparative figures for effectiveness of contraceptive methods are difficult to obtain. Some effort has been made by several investigators to differentiate "patient failures" from "method failures." This is difficult, for the cause of failure is often impossible to establish: semen may reach the female

genitalia by post-ejaculatory spill from a condom as the flaccid penis leaves the vagina; a diaphragm that is either too small or too large may allow deposition of semen at the os; or a woman may unintentionally omit an oral pill on several critical days of the cycle. It is likewise impossible to establish or even to estimate the errors of omission that occur when couples decide not to bother with a contraceptive "just this once" and yet do not admit or even realize their responsibility for the "failure."

In helping a couple to choose a method, it is most important that the method is one the couple prefers, understands and therefore uses. The following basic principles must be borne in mind: Methods of birth control vary markedly in effectiveness, but the best method for any couple is the most effective method that the particular couple will use consistently.

Acceptability is therefore as critical as theoretical effectiveness in the practice of successful birth control.

Best results are obtained when couples are made to feel free in their choice of methods, and free to change or to use more than one method.

Methods Requiring Pelvic Examination and Prescription

1. Oral contraceptives.
2. Intrauterine devices.
3. Diaphragm with contraceptive jelly or cream.
4. Cervical cap.

Oral Contraceptives

(See attached product list and p. 14 for related readings.) Oral contraceptives consisting of a synthetic progestin combined with a small amount of an estrogen have been extensively tested over the past ten years. The attached product list indicates oral contraceptives which have received approval of the U.S. Food and Drug Administration for use as contraceptive agents. Dosage schedules vary with different products. The physician is advised to read the product brochures carefully as to administration, and advise his patient as to the specific regimen prescribed. With all oral contraceptives however, not a single day should be omitted, for with interrupted administration the effectiveness has been shown to drop significantly. If a daily dose is omitted it should be taken as soon as it is remembered and the next tablet taken at the regular time—even if this means taking two in one day. If a tablet is omitted on more than one day the patient should be advised to continue taking the tablets and to use another contraceptive for the remainder of the cycle.

If breakthrough bleeding occurs the medication should be continued for the remainder of the cycle. There is no convincing evidence that in-

creasing the daily dose is of value in controlling the bleeding. If a menstrual period is missed completely the patient must resume the medication seven days after taking the last tablet. When the oral contraceptive is discontinued it is important to advise the patient that her first menstrual period may be delayed as long as two or three weeks after the expected date. The patient should remain accessible to medical supervision for control of any side effects.

Further reductions and modifications in dosage schedule are being introduced. One variation is sequential therapy—administration of an estrogen alone for 15 or 16 days followed by the progestin-estrogen combination for the remaining five days of the 20 or 21 day schedule. Another regimen which consists of taking a pill every day, is now also available. Under this regimen a "combined" pill is taken for 21 days and a placebo for the remaining seven days.

Not yet approved by the FDA for other than research in this country (but already marketed in several countries abroad) are two new methods, the so-called "minipill," consisting of a minute dose of a progestin only, and taken every day of the month and the once-a-month, and once-every-three-month injectable. The once-a-month injections consist of the same estrogen-progestin combination as are contained in the combined pill, injected intramuscularly so that the ingredients are only slowly released into the system. The once-every-three-month injectables, like the minipill, consist of a progestin only. Neither of the progestin-only contraceptives appears to consistently suppress ovulation in most cases. Their contraceptive effect is thought to depend primarily on the production of a hostile cervical mucus and effects on the endometrium.

Mechanism of Action

The mechanism of action of the currently approved oral contraceptives is primarily that of ovulation suppression. Other mechanisms which may contribute to the effectiveness of this method include an acceleration of endometrial development, alteration of tubal factors, and the production of a hostile cervical mucus. According to the World Health Organization, "...it seems likely that different types of compound, or even the same compound at different dose levels, may act in different ways, and that the individual compounds and their combinations may exhibit multiple mechanisms of action. There is also evidence to suggest that the mode of action of contraceptive steroids in the first one or two cycles of use differs from that in later cycles... Inhibition of ovulation is not essential to the antifertility effect of steroids. For example, the continuous administration of low doses

4 of progestogens does not consistently inhibit ovu-

lation, although it offers a very high degree of protection against conception. The way in which fertility is inhibited in the presence of ovulation is incompletely understood..."

Effectiveness

Taken according to instruction the combination oral contraceptives now available are virtually 100 per cent effective. The report of the Advisory Committee on Obstetrics and Gynecology of the FDA, August 1, 1966, states: "The efficacy of the combined agent is exceptionally high. The more recently introduced sequential regimens are also highly effective in controlling fertility although to a slightly lesser degree. Present evidence indicates that the frequency of pregnancies occurring with the patients on sequential medication remain unchanged over the two and one half year period, thus supporting the contention that tolerance to or escape from the medication probably does not occur."

Acceptability

Clinical studies have demonstrated that patient tolerance of this method of contraception varies somewhat with the different products and dosages, and is also dependent upon other factors such as culture, motivation, income, and level of education. In general, the pills have been found acceptable to between 70 per cent and 90 per cent of patients. Secondary benefits of the oral method have also been reported. The menstrual cycle is regulated in practically all women and is accompanied by a decrease in the amount of menstrual flow and an improvement, in many cases, of pre-existing dysmenorrhea.

According to the 1965 National Fertility Study, conducted by Professor Charles F. Westoff of Princeton and Professor Norman B. Ryder of the University of Wisconsin, the overall dropout rate from the pill among all U.S. women for all reasons is about three to four per cent a month over the first three months, and one to two per cent in subsequent months. About 80 per cent continue with the pill for at least one year; and, the study found, some two-thirds of women who had started with the pill in 1960 were still using it five years later. Rates of discontinuance appear to be higher among women of lower educational attainment. Most who discontinue drop out because of side effects such as nausea or intermenstrual bleeding. A Population Council report indicates that about 13 million women are using oral contraception as of July, 1967, 6.5 million of them in the U.S. (representing nearly one-fourth of married women of childbearing age). The report found drop-out rates for the pill considerably higher in developing countries studied than in the U.S. In half the countries studied more than half of those women initially ac-

cepting the pills discontinued by the end of the sixth cycle and the mean of continuance after one year is 68 per cent. Acceptance rates vary enormously from country to country; in Ceylon, a study found 76 per cent continuing after a year, and in Bombay over 71 per cent. These were roughly the same continuation rates reported from developed countries.

Side Effects

The most common side effects include nausea, break-through bleeding, weight gain, headache, bloating and breast tenderness. These side effects generally disappear by the fourth cycle and appear to be significantly reduced with the lower doses of the compounds currently available. Fertility is promptly restored following cessation of the medication. No causal relationship between the current oral contraceptives and any type of malignancy has been reported. However, the World Health Organization declares it is accepted practice to withhold oral contraceptives containing estrogen from pre-menopausal women with diagnosed breast cancer.

Because in occasional cases pre-existing fibromyomata have been observed to enlarge during administration of these drugs, the medical Committee of Planned Parenthood Federation of America has recommended that pelvic examination be done before the initiation of treatment and again six months later.

The question of a possible causal relationship between the use of oral contraceptives and the occurrence of thrombo-embolic phenomena has been raised. Three recent responsible British studies have shown a slight increase in thrombo-embolic accidents and fatalities among users of oral contraceptives. In one of these British studies it was found that the risk of incurring thrombo-embolic disease was increased nine times for pill users from five per 100,000 to 47 per 100,000. Another study found that the risk of mortality from pulmonary embolism or cerebral thrombosis among women 20-34 increased from 2 per million to 15 per million. Among the age group of 35-45, however, the risk is increased from 5 per million to 39 per million. The World Health Organization, taking note of these studies, points out that the risk among pill users of incurring thrombo-embolic disease, or dying from it, "appears to be small in comparison to the overall risk incurred by planned and unplanned pregnancy." Nevertheless, the World Health Organization cautions that a history of thrombo-embolic disease should be considered "a contraindication to the use of steroid contraceptives," and the Food and Drug Administration recently required that all Pill manufacturers revise their labeling so as to inform U.S. physicians of the British findings, and advise them to

discontinue the use of the pill should thrombo-embolitis, cerebro-vascular disorders, pulmonary embolism or retinal thrombosis occur or be suspected.

Masculinization of the female fetus causing partial fusion of the labia and/or hypertrophy of the clitoris has been observed in cases where progestins were given in large doses during pregnancy for the purpose of preventing threatened abortion. No fetal masculinization has been reported resulting from the contraceptive use of these compounds.

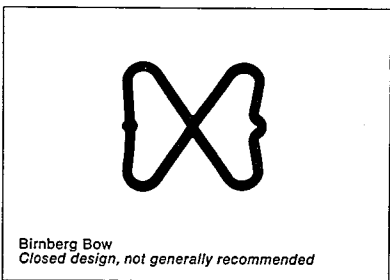
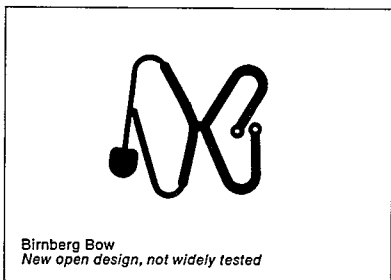
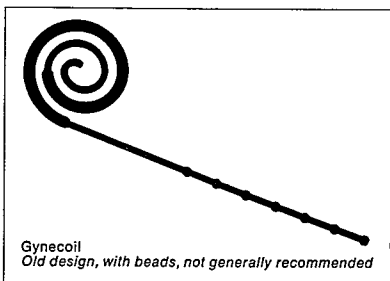
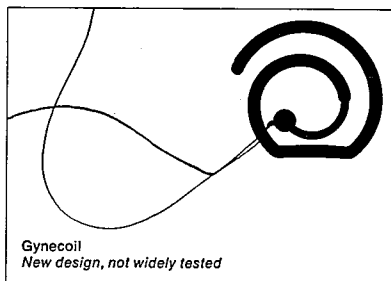
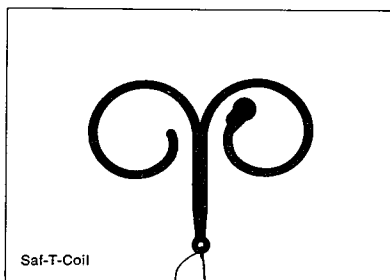
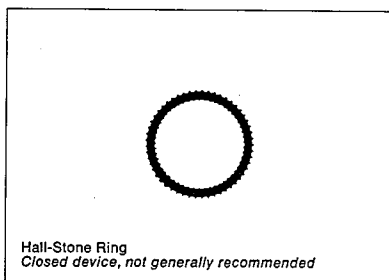
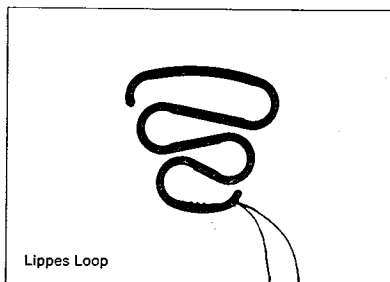
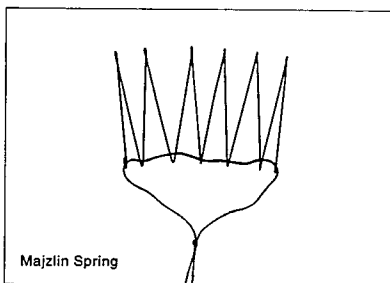
Intrauterine Devices

(See attached product list and p. 15 for related readings.) The recent development (1959) of new intrauterine devices has reawakened medical interest in this method of conception control.

The early intrauterine devices, such as the Gräfenberg ring, fell into disrepute because of the fear of complications. The development of new and relatively inert materials such as plastic and stainless steel along with the urgent need for a simple, inexpensive, effective method to prevent conception, independent of coitus and not requiring sustained motivation, was responsible for the revival of interest. Intrauterine devices have received the most careful and extensive clinical evaluation of any contraceptive method to date. Statistics from the National Committee on Maternal Health are currently available for over 27,600 women with a record of use in excess of 477,000 woman-months. On the basis of these results the Medical Committee of Planned Parenthood Federation has found the present "open" devices are both safe and highly effective.

Insertion

Insertion of the plastic and some stainless steel devices into the uterine cavity is accomplished by loading the device into a slender plastic tube which is then introduced through the cervix. A plunger is inserted into the tube and the device is pushed into the uterine cavity. The tube is withdrawn, leaving the device in the uterus, where it rapidly resumes its preinsertion shape. The stainless steel ring is inserted by being stretched over a forked instrument. With most patients cervical dilation is not required for insertion of either the plastic or stainless steel devices. Insertion during the last one or two days of a menstrual period is preferred because introduction is easier at this time, an existing pregnancy is not threatened, and post-insertion spotting, which occurs in a significant percentage of patients, is less likely to alarm the patient. Another favorite time for insertion is at the post partum examination. It was previously believed that intrauterine contraception was more suitable for the parous than the nulliparous women.



New evidence suggests that unless the woman experiences pain or syncope in the first day after insertion, and must have it removed, devices can be used with equal success in the nulliparous.

All patients should receive a complete pelvic examination, including visual inspection of the cervix, and a Papanicolaou smear prior to insertion of an intrauterine device. Where pelvic disease is suspected or diagnosed, patients should be referred for definitive diagnosis and treatment. Early examination following the first or second menstrual flow after insertion offers the best chance of detecting an expulsion not noticed by the patient before pregnancy has occurred. Good medical practice requires that all women be seen annually for a complete pelvic examination and Pap smear.

Side Effects

Chief among the minor side effects of intrauterine devices are irregular bleeding and uterine cramps or pelvic pain. They occur commonly during the first two or three months after insertion and tend to disappear with continued use.

More serious is the occurrence or recurrence of pelvic inflammatory disease (PID). The incidence of PID in women using IUDs has been reported to be about 2.5 per cent during the first year, falling to about 1.5 per cent during the second. The rates are highest during the first month after insertion. An advisory committee of the Food and Drug Administration believes that even this low rate of infection can be reduced by use of sterile pre-packaged devices with disposable inserters. The use of pre-packaged, sterile devices is recommended. If these are not used, it is recommended that a 1:2500 solution of aqueous iodine be used. (2 cc tincture of iodine, USP. In 100 cc water, soak for 5-10 minutes; if Betadine is used, 1.5 cc in 100 cc water.) There are also indications that antiseptic cleansing of the vagina and cervix reduces infection. Acute or subacute pelvic inflammatory disease, however, is considered a contraindication, as are large fibroids, especially those causing distortion of the uterine cavity.

Perforation of the uterus following insertion is extremely uncommon and often unnoticed by the physician. Its incidence, from 1 to 4 per 10,000 insertions, is probably the result of trauma caused by the introducer during insertion. The FDA believes that the incidence of perforation can be reduced by careful sounding of the uterus before insertion to ascertain the depth and direction of the uterine cavity, and by routine use of a tenaculum to maintain the uterus relatively straight. With the closed devices there have been reports of intestinal obstruction following perforation. Perforation of the uterus with intestinal obstruction has not been reported, however, with open devices. In

general, therefore, the closed devices can no longer be recommended. If perforation is known to have occurred with a closed device, the device should be surgically removed without delay. If perforation occurs with an open device, removal will depend on the judgement of the attending physician, after consultation with the patient.

In no instance has the IUD been shown to produce a neoplasm in either the cervix or the endometrium of women, and available reports indicate no effect of the device on the course of preexisting dysplasia.

If pregnancy occurs with the intrauterine device in situ, and proceeds to full term, the device is found to be outside the membranes or occasionally beneath the placenta. The limited numbers of infants so far available for study do not have a greater than expected incidence of prematurity or malformations.

On the few occasions when pregnancy does occur with the device in place, ectopic gestation occurs about once in 20 pregnancies. Although this ratio is 10 times the normal rate, it is attributed to the relatively greater reduction in the number of intrauterine pregnancies. In other words, IUDs prevent intrauterine pregnancies more effectively than they prevent ectopic pregnancies.

Mechanism of Action

The exact mechanism of action of the intrauterine devices in humans is yet to be determined. IUDs have an anti-fertility effect in every animal that has been tested, but the mechanism is different in different species. It is thought that the action takes place sometime between ovulation and implantation. The suggestion that the device acts in humans by increasing tubal motility has not been proven, according to the FDA, but needs further study and confirmation.

Effectiveness

In terms of use effectiveness in clinic patients the IUDs have proved far more reliable than the traditional methods of contraception and slightly less reliable than the oral compounds. Theoretically, however, the IUDs are less reliable than oral contraceptives given according to the combined or the sequential regimen, and are probably not more effective than the diaphragm or condom, if the conventional forms of contraception are used correctly by highly motivated patients. Unlike other forms of contraception, however, the IUDs use effectiveness approaches theoretical effectiveness, since the method requires neither daily nor periodic medication nor any manipulation before, during or after intercourse. The FDA points out that the careful woman can, however, increase her chances of protection by inspecting her menstrual pads or tampons to see whether the device has

been expelled; or, if the device has a transcervical appendage, by examining herself periodically.

In the United States the most successful IUDs are associated with a pregnancy rate of from 1.5 to 3.0 per 100 women during the first year of use. These rates tend to decline during the successive years and in general the rates vary inversely with the size of the device and with the age of the patient.

Acceptability

Among clinic patients in the United States the FDA finds that rates of continuation have been much higher for the IUDs than for traditional contraceptive methods. Experience of family planning programs in developing countries has been similar. Fragmentary evidence suggests that in the lowest socioeconomic group with the most minimal education, rates of continuation are higher with IUDs than with the oral compounds. But adequate information comparing rates of continuation of IUDs with oral compounds for non-clinic patients is unavailable.

About 80 per cent of women will continue to use IUDs for the first year after insertion; 70 per cent for the second year and, from limited data available, about 50 per cent of women are still using the IUD at the end of the fifth year. The incidence of involuntary expulsion varies widely among different types of IUDs. The great majority of expulsions occurs in the first year of use; about one half of the total within four months after insertion. More devices seem to be expelled with the menstrual flow than at any other time. If an IUD is re-inserted after an expulsion the chance of re-expulsion is two or three times as high as the chance of expulsion after the first insertion of the same type of IUD. Nevertheless, about one half of all women who experience a first expulsion eventually retain the device after one or more re-insertions. Expulsion rates for all types of IUDs tend to decline steeply with increasing age of the woman and less steeply with parity. Expulsion rates are very high following insertion during the first few days after childbirth. They are lower following insertion five to 12 weeks after childbirth and the lowest following insertion at three months or later. For all IUDs, voluntary removal at either the doctor's or the wearer's initiative, is the most important cause of discontinuation and may exceed the combined effect of pregnancies and expulsions at a ratio of 2 to 1 or more. The most common reasons for removal are bleeding and pelvic pain and account for about 60 per cent of all removals, excluding those for planned pregnancies. Like the expulsion rate, the removal rate is highest in the first month after insertion.

Some 6-8 million of these devices are now in use, perhaps one million in the U.S. As results are

confirmed, it is likely that contraception with the intrauterine device will assume even more importance in the future.

Diaphragm with Contraceptive Jelly or Cream

(See attached product list and p. 16 for related readings.) The medical profession has found the diaphragm and jelly/cream method very effective among intelligent and highly motivated patients. However, in many population groups a disturbing proportion of users of the diaphragm is known to abandon this method rapidly. The appropriate size and type of diaphragm (supplied commercially in various types from 60 to 105 mm. in diameter) must be selected by trial fitting during pelvic examination. The diaphragm when properly in place lodges in the posterior vaginal fornix, completely covers the cervix, and fits snugly behind the pubic symphysis. The largest size which can be worn comfortably and is unnoticed by husband and wife should be prescribed. Various types are available, some of which are more effectively held in place in the presence of a cystocele or mild prolapse. The size and type of diaphragm needed may change following delivery, pelvic surgery, weight gain or loss, and particularly after the honeymoon period. Once the appropriate size has been determined, it is essential that the patient be instructed carefully in the method of insertion and be given an opportunity to demonstrate her proficiency during this instruction period.

Effectiveness

The diaphragm, used in combination with jelly or cream, offers a high level of protection, although occasional method failures may result from improper placement or displacement during coitus. A rate of 2-3 pregnancies per 100 women per year would seem to be a generous estimate for "perfect users." If motivation is poor, much higher pregnancy rates should be expected.

Patient Instructions

Approximately one teaspoonful (5 ml.) of a contraceptive cream or jelly (see attached product list) should be placed on either side of the diaphragm; some is spread around the rim, and the diaphragm inserted with the cream or jelly side uppermost. The diaphragm may be inserted up to six hours prior to intercourse and may be left in place for as long as twenty-four hours. It must remain in place at least six hours following the last ejaculation. Douching should not be permitted during this interval. If intercourse is repeated, the diaphragm should not be removed, but additional cream or jelly should be inserted vaginally prior to each coitus. The patient may go to the toilet at any time. The diaphragm is easily removed by hooking the

finger behind the symphysis, grasping the diaphragm and withdrawing it. At removal, douching is unnecessary. The diaphragm should be washed in warm, soapy water, dried, powdered with corn starch, and kept in a closed container. Periodic checking of the condition of the diaphragm by holding it to a light is recommended. With care the diaphragm may be used for several years without replacement.

Cervical Cap

(See attached product list and p. 16 for related readings.) The cervical cap is a method widely and successfully used in Great Britain and Central Europe, but less well known in the United States. It may be used in a manner similar to the diaphragm; those made of plastic may be left in place for several days or even for the entire intermenstrual period, in which case renewal of the chemical contraceptive is unnecessary and douching is undesirable. Studies have shown that the cervical cap has a use-effectiveness rate in the same range as that of the diaphragm and that this effectiveness in all probability relates more directly to the mechanical barrier of the cap itself than to the spermicidal action of the product used with it.

Some physicians think the effectiveness of the cervical cap may be lowered by the possibility of displacement, but this rarely occurs when patients are carefully and properly chosen for this method. In any event, the woman should be instructed to feel for the position of the cap before intercourse.

It is essential with the cervical cap, as with the diaphragm, that the patient be thoroughly trained in the technique of insertion and removal.

Methods Not Requiring Pelvic Examination or Prescription

1. Condom.
2. Chemical contraceptives.
 - a. vaginal foams, jellies, creams alone.
 - b. vaginal foaming tablets.
 - c. sponge and foam.
 - d. vaginal suppositories.
3. Coitus Interruptus.
4. Rhythm.
5. Postcoital douche.

Large-scale distribution of simple contraceptive methods may be made possible only with elimination of the pelvic examination. The Medical Committee of Planned Parenthood Federation of America nevertheless recommends that a yearly pelvic examination, including a Papanicolaou smear, be done on every adult female whenever feasible.

Condom

(See attached product list and p. 16 for related reading.) The condom, rolled over the erect penis, is ordinarily highly effective without the use of additional chemical contraceptives.

Certain couples, however, demand a more absolute sense of security. For such couples it is recommended that, in addition to the consistent use of the condom by the man, the woman should, prior to intercourse, place an applicator filled with jelly, cream or foam (see attached product list) in the vagina. A contraceptive cream, jelly or foam is not only useful for vaginal lubrication where such is necessary, but in case of breakage or slipping of the condom, it eliminates the necessity for a douche.

Chemical Contraceptives

(See attached product list and p. 16 for related reading.)

Laboratory Testing

The Fertility Research Laboratory of the Margaret Sanger Research Bureau in New York, official testing center of the Planned Parenthood Federation of America, conducts a spermicidal testing program on all vaginal chemical contraceptive products manufactured in the U.S.A.

For the laboratory assessment of the efficacy of chemical topical contraceptives, the Evaluation Subcommittee of the International Planned Parenthood Federation has evolved a test for spermicidal action in vitro. Known dilutions of the contraceptive product are mixed with human semen of excellent quality, and the time required for immobilization of the sperm is measured.

It is universally agreed that an in vitro test of spermicidal effectiveness is no substitute for clinical experience, but many factors have militated against adequate clinical testing of vaginal contraceptive products. These include the mobility of the American population, and the reluctance of physicians to place their patients at possible risk of pregnancy.

Vaginal Foams, Jellies, Creams Alone

These are introduced into the vagina by means of a plastic applicator. After being filled from the container, the applicator is inserted to the depth of the vagina and its contents expelled. The vaginal foam is associated with minimal complaints of messiness and has a high acceptance. Insertion may be performed within an hour prior to coitus. If a longer period elapses or coitus is repeated, an additional applicatorful should be introduced. Douching is forbidden until six hours following the last coitus, although the patient may go to the toilet at any time in the interval.

Vaginal Foaming Tablets

Vaginal foaming tablets are presently used extensively outside of the United States and occasionally in this country. Because of their simplicity and low cost they are suitable for mass distribution. A rather common complaint is persistent burning following insertion due to the foaming action. Their use is simple: a tablet is slightly moistened with water or saliva and inserted deep into the vagina not less than five minutes nor more than one hour before coitus. If more than one hour has elapsed before coitus, a second tablet should be used; another tablet should be used before each subsequent coitus. Douching is prohibited until six hours after coitus. The patient may go to the toilet at any time. Although the foaming action is initiated upon moistening and insertion, the tablet is not completely dissolved until ejaculation, when the foam generated releases the spermicidal ingredients. To protect from atmospheric moisture, vials of foam tablets must be kept tightly stoppered. After prolonged storage a tablet should be tested by dipping in water. Foaming action can be seen and heard if the tablet is fresh.

Sponge and Foam

This method is one of the simplest and least expensive and, because of its simplicity, is highly acceptable to certain population groups. A synthetic or natural sponge of convenient size (i.e., 2 inches square by $\frac{3}{8}$ inch thick) is moistened and partially squeezed out, then a spermicidal foam liquid or foam powder is worked into it until a foam is formed. The sponge is then pushed high into the vagina to be left in place until six hours after intercourse. Douching should not be permitted until the sponge has been withdrawn.

Vaginal Suppositories

These are widely available and probably rank with the vaginal foaming tablets in effectiveness, although studies of this method are not numerous. Suppositories are removed from the foil wrapping and inserted into the vagina without moistening a few minutes before intercourse, and otherwise used in the same manner as vaginal foaming tablets. Their stability may be affected in hot climates, but if packed individually in stiff, shaped foil they may be re-solidified by cooling if liquefied before use. Patients should be warned that suppositories advertised and sold "for feminine hygiene" may not be effective for contraception.

Effectiveness of Chemical Contraceptives

The effectiveness of chemical contraceptives used alone is believed to be lower than that of the diaphragm used with a chemical, or the condom. Nevertheless, significant reductions in pregnancy rates may be obtained by the use of these simple

methods. Among the various forms of chemical contraceptives the vaginal foams appear to be most effective, followed by the jellies and creams. Foaming tablets and suppositories are less effective. No statement can be made on the sponge-and-foam method.

Coitus Interruptus

(See p. 16 for related reading.) This is an ancient technique. It has particular advantages: it requires no devices or chemicals, and is thus available under all circumstances and at no cost. The couple proceeds with coitus in any manner acceptable to both partners until the moment of ejaculation, when the male withdraws so that emission takes place completely away from the vagina or the external genitalia. Most couples using this method are able to develop their own technique so that the woman as well as the man derives full satisfaction. Some couples are unable to use coitus interruptus at all; others find it entirely satisfactory and preferable. Studies showing adverse effects among users are lacking.

Effectiveness

While coitus interruptus has been responsible for many failures of family planning, it is also the principal method by which the historical decline of the birthrate in Western Europe was achieved from the late 18th Century onward. Statistical studies suggest a level of effectiveness similar to that associated with mechanical and chemical methods. But should ejaculation begin before withdrawal, the possibility of pregnancy is as great or greater than if no birth control method was used, since the early part of the ejaculate contains the greatest concentration of active spermatazoa. Physicians will rarely have occasion to recommend coitus interruptus, but if the method has been practiced successfully for a number of years, with full sexual satisfaction for husband and wife, it would be unwise to insist on a change. For occasional use when other methods are not available it has its unquestioned place.

Rhythm

(See p. 16 for related reading.) Rhythm, also called "temporary abstinence" or "periodic continence," is the only method besides total continence presently accepted by the Roman Catholic Church and some other Churches as licit for the regulation of conception. According to Ogino, the first potentially fertile day is determined by subtracting 18 from the number of days in the shortest menstrual cycle observed during a period of one year, and the last fertile day by subtracting 11 days from the longest menstrual cycle. If, for example, a woman has observed cycles ranging from 26 to 29 days, her potentially fertile period (period of abstinence)

will extend from the 8th day (26 minus 18) through the 18th day (29 minus 11).

Because very few women have absolutely regular menstrual cycles and most women do not remember their irregularities, the computation of the fertile and infertile days of each cycle should be made from a written record of menstrual cycles preferably extending over at least a year. If the rhythm method is prescribed on the basis of a menstrual record kept for a period shorter than one year, the fertile period should be calculated according to the complete details provided in The Safe Period booklet (see page 17). It is not advisable to estimate the fertile period on the basis of the patient's statements concerning her menstrual cycles without a written record, especially if she claims "perfectly regular" cycles.

BBT Method

The use of a basal body temperature (BBT) chart may be useful to the woman who is sufficiently motivated to learn how to take a truly basal temperature (immediately on awakening before any activity whatsoever), and to interpret the chart correctly. A drop in temperature followed by a rise (usually around 0.7°F.) indicates that ovulation has occurred. It is not known whether ovulation takes place just before or at the time of this rise in temperature. The higher level is then maintained for the remainder of the cycle, and sexual relations may safely be resumed on the evening of the third day of sustained higher temperature. One must make sure, however, that the woman understands what her basal body temperature is. Any slight indisposition makes it unreliable to depend upon this method since even a mild upper respiratory illness can cause a slight rise that might be misinterpreted as the post-ovulatory rise.

The temperature record can be used to indicate only the end of sexual abstinence; it cannot be used to determine when the period of abstinence should begin. To calculate when abstinence should start, the woman should refer to her shortest cycle figure minus 18. On that day, when abstinence begins, she should begin also to take her temperature on awakening and carefully record it each day until relations are resumed on the third day of higher temperature.

For those couples who want minimal risk of pregnancy, or for women whose menses are too short or too irregular, total abstinence may be advisable from the beginning of menses until the third day of higher temperature.

The presently available methods of determining the time of ovulation by means of chemical tapes have not proven reliable. While not generally accepted, chloride determination of the cervical mucus has been advocated by some workers for women whose BBT curve is abnormal.

Effectiveness

Correctly taught, correctly understood, and correctly practiced, the effectiveness of the rhythm method may be comparable to that of mechanical and chemical contraceptives, especially if women with grossly irregular menstrual cycles are excluded. However, such successful use implies periods of abstinence longer than most couples find acceptable. Self-taught "rhythm," haphazardly practiced, is one of the most ineffective methods of family planning. According to the World Health Organization, pregnancy rates range from 0.8-1.4 per 100 women-years for women using basal body temperature alone; 3.2-8.0 per 100 women-years for women using basal body temperature plus calendar, and 14-40 per 100 women-years for women using the calendar method only. According to the World Health Organization, biological variation, failure to understand the method, and unwillingness to abstain from coitus all contribute to failures. The lowest pregnancy rates, of course, are obtainable only by intelligent, highly motivated women.

Postcoital Douche

(See p. 16 for related reading.) The postcoital douche is considered to be a poor method of contraception because sperm enter the cervical canal within seconds after ejaculation. Statistical studies have confirmed this low level of effectiveness. The only value of the douche is in an emergency, such as following the breaking or slipping of a condom.

Policy Statements of Medical and Health Organizations

World Health Organization

Health Aspects of Population Dynamics, 1968

The Twenty-first World Health Assembly, having considered the report of the Director-General on health aspects of population dynamics;

Noting with satisfaction the development of activities in reference services, research, and training, and the provision of advisory services to Member States, on request, on the health aspects of human reproduction, of family planning, and of population dynamics...Emphasizing the concept that this programme requires the consideration of economic, social, cultural, psychological, and health factors in their proper perspective...

Recognizing that family planning is viewed by many Member States as an important component of basic health services, particularly of maternal and child health and in the promotion of family health and plays a role in social and economic development;

Reiterating the opinion that every family should have the opportunity of obtaining information and advice on problems connected with family planning including fertility and sterility;

Agreeing that our understanding of numerous problems related to the health aspects of human reproduction, family planning and population is still limited...Requests the Director-General

(a) to continue to develop the programme in this field...including also the encouragement of research on psychological factors related to health aspects of reproduction;

(b) to continue to assist Member States upon their request in the development of their programmes with special reference to:

the integration of family planning within basic health services without prejudice to the preventive and curative activities which normally are the responsibility of those services; appropriate training programmes for health professionals at all levels;

(c) to analyse further the health manpower requirements for such services and the supervision and training needs of such manpower in actual field situations under specific local conditions...

American Medical Association

Policy on Human Reproduction, Including Population Control, 1964

...The Board recommends adoption of the following four-point statement of policy:

1. An intelligent recognition of the problems that relate to human reproduction, including the need for population control, is more than a matter of responsible parenthood; it is a matter of responsible medical practice.
2. The medical profession should accept a major responsibility in matters related to human reproduction as they affect the total population and the individual family.
3. In discharging this responsibility physicians must be prepared to provide counsel and guidance when the needs of their patients require it or refer the patients to appropriate persons.
4. The A.M.A. shall take the responsibility for disseminating information to physicians on all phases of human reproduction, including sexual behavior, by whatever means are appropriate.

Policy on Dissemination of Birth Control Information at Tax-Supported Institutions

...There should be no restraints on the physician concerning the dissemination of birth control information, and, as with other forms of quality medical care, such information should be equally available to both private and clinic patients. It is recognized, however, that in some areas restraints do exist for both physicians as purveyors and patients as recipients of such information...

It is recommended that the prescription of child-spacing measures should be made available to all patients who require them, consistent with their creed and mores, whether they obtain their medical care through physicians or tax or community-supported health services...

American Academy of Pediatrics

Policy Statement on Family Planning, 1965

The American Academy of Pediatrics recognizes that an intelligent program of total health care of children should include considerations of family

planning. Pediatricians should become informed about the social, health and demographic problems associated with prolific child bearing. They should work with parents and with teachers in educational activities designed to give young people a proper sense of responsibility about sexual matters, marriage and parenthood. When the needs of their patients require it, pediatricians should be prepared to discuss conception control in a manner consistent with the creed and mores of the individuals concerned, or to refer their patients to appropriate persons for such advice. The American Academy of Pediatrics further believes that federal, state and local governments should include family planning as a part of their health programs.

American Public Health Association

Policy Statement on Population, 1964

...In the United States, an increasing number of official health and welfare agencies have instituted programs of family planning to reduce the incidence of unwanted pregnancies, illegal abortions and maternal and perinatal mortality and morbidity. Governing bodies, from the Congress of the United States to town councils, have voted to make family planning information and services available, but millions of Americans are still denied such help as a part of the health or welfare services provided them for tax funds.

Although both tax and private funds are supporting research on reproduction related to birth and population control and remarkable advances in contraceptive technology are emerging, the National Academy of Sciences has clearly indicated how great are the unmet needs in research and training.

Governments of developing nations are officially recognizing rapid population growth as a serious deterrent to improved well-being of their people. Increasingly, they are adopting national policies and initiating national programs of family planning. To implement these programs, many seek technical assistance which remains difficult to obtain from governmental sources.

These events call for added leadership by the public health profession in understanding acting upon public health implications of rapid population growth. The American Public Health Association, therefore, believes it important to reaffirm its 1959 policy statement, dedicates itself to intensified study and action on population problems and urges that:

1. Federal, state, and local governments in the United States include family planning as an integ-

ral part of their health programs, make sufficient funds and personnel available for this purpose, and insure such freedom of choice of methods that persons of all faiths have equal opportunities to exercise their choice without offense to their consciences.

2. Federal and state governments, foundations, universities, and other research institutions give higher priority to the need for more research and training on all aspects of population problems.

3. The United States expand its technical assistance in population programs to those nations requesting it and urge efforts by the World Health Organization and other appropriate international agencies to do likewise.

American Nurses' Association

Statement on Family Planning, 1966

...The American Nurses' Association, the professional organization of nurses concerned with the health and welfare of individuals and families, feels that it is the responsibility of all registered nurses:

1. To recognize the right of individuals and families to select and use such methods for family planning as are consistent with their own creed and mores
2. To recognize the right of individuals and families to receive information about family planning if they wish
3. To be responsive to the need for family planning
4. To be knowledgeable about state laws regarding family planning and the resources available
5. To assist in informing individuals and families of the existence of approved family planning resources
6. To assist in directing individuals and families to sources of such aid.

Because nurses have a real and enduring interest in the well-being of people, the American Nurses' Association endorses efforts to promote understanding of family planning methods and supports positive and realistic programs designed to cope with the implications of unchecked population growth.

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Chemical Contraceptives

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Vaginal Foaming Tablets

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Sponge and Foam

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Vaginal Suppositories

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Coitus Interruptus

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Rhythm

72. Ogino, K. "The Ovulation and Conception Periods in Woman: Their Application for Conception Control," *Fifth International Conference on Planned Parenthood*, 141-144, 1955. London: International Planned Parenthood Federation.

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Postcoital Douche

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Literature for Patient Use*

	Single	100
Modern Methods of Birth Control	15 cents	6.00
Questions & Answers About the Birth Control Pill	15 cents	4.50
Questions & Answers About Intrauterine Devices	15 cents	4.50
The Complete Book of Birth Control, A. F. Guttmacher, M.D.	50 cents	35.00
The Safe Period	15 cents	7.50
To be a Mother... To be a Father	15 cents	7.50
Basal Temperature Chart (instructional)	15 cents	2.50
Basal Temperature Chart (blank)	15 cents	2.50

*Obtainable from Planned Parenthood-World Population, 515 Madison Avenue, New York, N.Y. 10022. Physicians and other professionals may obtain single copies of these publications free of charge except for *The Complete Book of Birth Control*.

List of Contraceptive Products
Prepared by the Medical Department of Planned Parenthood-World Population

Products Requiring Prescription:

1 Oral Contraceptives

(Approved by the U.S. Food and Drug Administration)

Product	Available Dosage	Composition Progestin	Estrogen
Enovid	10 mg.	9.85 mg. Norethynodrel	0.15 mg. Mestranol
Enovid	5 mg.	5 mg. Norethynodrel	0.075 mg. Mestranol
Enovid-E	2.5 mg.	2.5 mg. Norethynodrel	0.1 mg. Mestranol
Ovulen	1 mg.	1.0 mg. Ethynodiol Diacetate	0.1 mg. Mestranol
G. D. Searle & Co. P.O. Box 5110, Chicago, Ill. 60680			
Norinyl	2 mg.	2 mg. Norethindrone	0.1 mg. Mestranol
Norinyl	1 mg.	1 mg. Norethindrone	0.05 mg. Mestranol
Noriday	21 tablets 7 inert tablets	1 mg. Norethindrone	0.05 mg. Mestranol
Norquen	14 tablets 6 tablets	2 mg. Norethindrone	0.08 mg. Mestranol 0.08 mg. Mestranol
Syntex Laboratories, Inc. 701 Welch Road, Palo Alto, Calif.			
Norlestrin	2.5 mg.	2.5 mg. Norethindrone Acetate	0.05 mg. Ethinyl Estradiol
Norlestrin	1 mg.	1 mg. Norethindrone Acetate	0.05 mg. Ethinyl Estradiol
Parke-Davis & Co. Detroit, Michigan 48232			
Ovral	0.5 mg.	0.5 mg. Norgestrel	0.05 mg. Ethinyl Estradiol

Wyeth Laboratories
Box 8299, Philadelphia, Pa. 19101

Ortho-Novum	10 mg.	10 mg. Norethindrone	0.06 mg. Mestranol
Ortho-Novum	2 mg.	2 mg. Norethindrone	0.1 mg. Mestranol
Ortho-Novum	1 mg.	1 mg. Norethindrone	0.05 mg. Mestranol
Ortho-Novum SQ	14 tablets		0.08 mg. Mestranol
	6 tablets	2 mg. Norethindrone	0.08 mg. Mestranol

Ortho Pharmaceutical Company
Raritan, New Jersey

Provest	10 mg.	10 mg. Medroxyproges- terone Acetate	0.05 mg. Ethinyl Estradiol
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Upjohn Company
Kalamazoo, Michigan

C-Quens	15 tablets		0.08 mg. Mestranol
	5 tablets	2 mg. Chlormadinone Acetate	0.08 mg. Mestranol

Eli Lilly & Co.
P.O. Box 618, Indianapolis, Ind.

Oracon	16 tablets		0.1 mg. Ethinyl Estradiol
	5 tablets	25 mg. Dimethisterone	0.1 mg. Ethinyl Estradiol

Mead Johnson Laboratories Div. of Mead Johnson & Co.
2404 West Pennsylvania St., Evansville 21, Ind.

2 Intrauterine Devices

Birnberg Bow	Scheuler & Company 110 Fifth Avenue New York, N.Y. 10011
Gynecoll	Ortho Pharmaceutical Corp. Raritan, New Jersey
Hall-Stone Stainless Steel Ring	Goshen Instrument Corp. P.O. Box 102 Goshen, New York Glaxo-Allenbury's Can- ada, Ltd., 52 Barton Road Weston, Ontario, Canada
Lippes Loop	Ortho Pharmaceutical Corp. Raritan, New Jersey

Mejzlin Spring

Anka Research Ltd.
139-01 Archer Avenue
Jamaica, New York

Saf-T-Coil (Double Coil)

Julius Schmid, Inc.
423 W. 55th Street
New York, New York 10019

3 Diaphragm with Contraceptive Jelly or Cream

Most of the firms listed as manufacturers of contraceptive jellies and creams (see following—Products Not Requiring Prescription), also manufacture various types of diaphragms suitable for the varying needs of individual patients.

4 Cervical Cap

Milex Products
5915 Northwest Highway
Chicago 31, Illinois

Day, Baldwin & Co.
1460 Chestnut Avenue
Hillside, New Jersey

Products Not Requiring Prescription

1 Condom

Quality control is checked by the U.S. Food and Drug Administration; therefore reliable brands bought at drug stores are generally acceptable.

2 Chemical Contraceptives

All of the products listed in this group have been tested at the Margaret Sanger Research Bureau, New York City, for effectiveness against live human sperm. Products under "Vaginal foams, jellies, creams," are listed in descending order of in vitro spermicidal activity as determined by the International Planned Parenthood Federation test. Whenever two or more products have the same in vitro spermicidal activity, they are bracketed and listed alphabetically. The difference in sperm immobilizing ability between neighboring groups in the list is not great, but the difference between those at the top and those at the bottom of the list is considerable. It is not possible to determine what correlation may exist between these in vitro tests and the in vivo effectiveness of the products as observed under conditions of clinical use. An asterisk indicates those products advertised or designed for use without mechanical (occlusive) protection.

Vaginal Foams, Jellies, Creams

Vaginal Foams:		5 Koromex Jelly	Holland-Rantos Co., Inc. 393 Seventh Avenue New York, New York 10001
*Delfen Vaginal Foam	Ortho Pharmaceutical Corp. Raritan, New Jersey	Marvosan Jelly	Veritas Products Co., Inc. 1460 Chestnut Avenue Hillside, New Jersey
*Emko Vaginal Foam	Emko Co. 7912 Manchester Avenue St. Louis 17, Mo.	*Preceptin Gel	Ortho Pharmaceutical Corp. Raritan, New Jersey
Jellies and Creams:		Verithol Jelly	Veritas Products Co., Inc. 1460 Chestnut Avenue Hillside, New Jersey
1 *Delfen Cream	Ortho Pharmaceutical Corp. Raritan, New Jersey	6 Certane Jelly	Vogarell Products Co. Los Angeles 7, California
2 Certane Creme	Vogarell Products Co. Los Angeles 7, California	Lactikol Creme	Day Baldwin & Co. 1460 Chestnut Avenue, Hillside, N.J.
Contra Creme	Research Supplies Pine Station, Albany 3, N.Y.	Ortho Creme	Ortho Pharmaceutical Corp. Raritan, New Jersey
3 Creemoz Creme	Larré Laboratories Division Gynecic Laboratories, Inc. 474 Nepperhan Avenue Yonkers, New York	7 *Immolin Cream-Jel	Julius Schmid, Inc. 423 West 55th Street New York, New York 10019
Lactikol Jelly	Day Baldwin & Co. 1460 Chestnut Avenue Hillside, N.J.	Koromex Cream	Holland-Rantos Co., Inc. 393 Seventh Avenue New York, New York 10001
*Koromex-A Jelly	Holland-Rantos Co., Inc. 393 Seventh Avenue New York, New York 10001	*Locoro! "D" Jelly	Peck & Sterba Division, Inc. International Laboratories, Inc. Rochester 14, New York
4 Ortho-Gynol Jelly	Ortho Pharmaceutical Corp. Raritan, New Jersey	8 *Lanesta Gel	Esta Medical Laboratories, Inc. 902 Broadway New York, New York 10018

9	*Colagyn Jel	The Smith Laboratory, Inc. 811 Wyandotte Kansas City 5, Missouri	Vaginal Foaming Tablets:	
	Lanteen Jelly	Esta Medical Laboratories, Inc. 902 Broadway New York, New York 10018	*Durafoam Tablets	Day Baldwin & Co. 1460 Chestnut Avenue Hillside, N.J.
	Ramses Jelly	Julius Schmid, Inc. 423 West 55th Street New York, New York 10019	*Zeptabs	Larré Laboratories Division Gynecic Laboratories, Inc. 474 Nepperhan Avenue Yonkers, New York
10	Bilco Jelly	Veritas Products Co., Inc. 1460 Chestnut Avenue Hillside, New Jersey	Sponge and Foam:	
	*Cooper Creme	Whittaker Laboratories, Inc. 898 Washington Street Peekskill, New York	Durafoam Liquid with Sponge	Durex Products, Inc. 684 Broadway New York, New York 10012
	Cooper Creme Gel	Whittaker Laboratories, Inc.	Durex Foam Powder with Sponge	Day Baldwin & Co. 1460 Chestnut Avenue Hillside, N.J.
	Jellak Jelly	Larré Laboratories Division Gynecic Laboratories, Inc. 474 Nepperhan Avenue Yonkers, New York	Vaginal Suppositories:	
	Keml-Cream	Kemi Products Corp. Clifton, New Jersey	*Lorophyn	Eaton Laboratories 17 Eaton Avenue Norwich, New York
	Keml Jelly	Kemi Products Corp.		
	Locorol Jelly	Peck & Sterba Division, Inc. International Laboratories, Inc. Rochester 14, New York		
	Marvosan Creme	Veritas Products Co., Inc. 1460 Chestnut Avenue Hillside, New Jersey		
	Milex Crescent Creme	Milex Products 5915 Northwest Highway Chicago 31, Illinois		
	Milex Crescent Jelly	Milex Products		
	*Milex Jelly B4	Milex Products		
	*Veritas Kreme	Veritas Products Co., Inc. 1460 Chestnut Avenue Hillside, New Jersey		



Revised 1968
under the direction of
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Planned Parenthood-World Population
515 Madison Avenue, New York, N.Y. 10022

Modern Methods of Birth Control

Almost all people wish to decide for themselves how many children to have, and when to have them. Modern methods of birth control, or family planning, allow every couple to do just that—have babies when they want them, and avoid pregnancy when they don't.

Pregnancy takes place after sex relations, when the man's sperm or seed joins with the woman's egg and attaches itself to the lining of the womb, where the new baby grows. All methods of birth control are designed to keep this from happening: to keep the new life from starting *until the parents want it to*.

Just as there is no "magic" number of children ideal for all families, there is no one method of birth control that is perfect for every couple. There are a number of different medically approved birth control methods that work differently, and that are safe and inexpensive.

You can choose the one *you* like best. The method *you* will use regularly is the one that will work best.

Your private doctor, or the doctor at a Planned Parenthood center, local health department or hospital family planning center can help you choose. This is the most reliable and safest way to pick your method. Some methods can be gotten only by seeing a doctor first. These usually give better protection against pregnancy than those bought in a drugstore without seeing a doctor. This booklet describes both kinds.

If you cannot visit a doctor, or must wait for an appointment, see page 7 for a list of products you can buy at the drugstore without a doctor's prescription.

"Doctor Methods" of Birth Control

Available Only with a Doctor's Examination and Prescription

The Pill *Oral Contraceptives*

The Pill is now being used by about seven million U.S. women. It keeps a woman's body from releasing an egg (ovulating). If there is no egg, she cannot become pregnant. Pills have to be taken on a regular monthly schedule. When the doctor prescribes the Pill, he gives you the schedule. Only the full series taken regularly gives protection. Pills taken just "once in a while" will not help. To be sure, take the pill at the same time every day.

The Pill Works Well

If you follow your doctor's directions, the Pill has a close to 100 per cent record of preventing pregnancy. One big advantage about the Pill is that it can be taken at a time separate from the sex act.

Some women taking the Pill feel a little like women do in the early part of pregnancy. They feel sick at the stomach; their breasts are tender. These side effects usually don't last long. Sometimes spotting or bleeding occurs between periods.

Careful scientific studies over the last ten years indicate that the Pills are not safe for all women, and it

is too soon to be sure that there are no long-term ill effects. Your doctor can tell you if you have a condition which would make it unwise for you to take the Pill. If you are on the Pill, you should have an internal examination from a doctor at least once a year. If you have any problem you don't understand or expect, be sure to call the doctor right away.

If you decide you want to have a baby, just stop taking the Pill.

Intrauterine Devices IUDs

The intrauterine devices (IUDs), are small plastic or metal shapes which the doctor places inside a woman's womb (uterus). They come in several shapes and work very well in preventing pregnancy. IUDs have been tested since 1959 and are very safe. Although not quite 100 per cent effective, they are one of the best methods of birth control.

IUDs Need Little Attention

Once the doctor has placed the IUD inside the womb (a simple, not painful process), it can be left there for years, protecting you from unwanted pregnancy. It requires little attention. During sex, neither the man nor woman can tell it is there. An added advantage of the IUD is that it does not interfere with the sex act. The IUD user should visit the doctor at least once a year for a medical examination. Some women have cramps for a little while after the IUD has been put in by the doctor. Menstrual periods may be heavier, and bleeding or spotting may occur between periods. Discomfort usually stops after a few months. Menstrual periods proceed normally. Tampons may be used. If you wish to douche you can, but it is not necessary. Use of the IUD in no way changes your ability to have children. When you want to get pregnant, you go to the doctor and he quickly and simply removes the IUD.

Diaphragm with Jelly or Cream

A diaphragm is a thin sheet of soft rubber stretched over a metal ring that bends easily. It is placed in the birth canal (vagina) and covers the entrance to the womb (cervix). It does not interfere with sex relations and it will not hurt either sex partner. This was considered the most effective method of birth control by doctors until the Pill and IUD became available. It is very effective when used correctly. As with the Pill and IUD, you can put it in at a time other than when you are having sex. The diaphragm must fit between two places in the birth canal, and different women need different sizes. A doctor must first examine you to find out what type and shape diaphragm you need.

The doctor will also teach you how to put in the diaphragm (which can be bought, according to size, in the drugstore). Because women's bodies change, you should return to the doctor once a year to see if your diaphragm is still exactly the right size.

Jelly or Cream Necessary

Diaphragms should always be used with a contraceptive cream or jelly. These chemicals kill any male sperm which may get past the diaphragm, or are still alive after the diaphragm is taken out. About a teaspoonful of contraceptive jelly or cream is placed inside the diaphragm, with some spread around the rim. Then the diaphragm is put in the birth canal with the cream or jelly side up. This can be done at any time up to six hours before sex relations. If more time has passed or sex relations are repeated later, another applicatorful of the jelly or cream should be put into the birth canal; but don't take out the diaphragm.

You should leave the diaphragm in place for at least six hours after the last sex act. However, it can be left in for up to 24 hours. When you take it out, it should be washed and dried. Douching is not necessary. If you want to douche, be sure to wait until six hours after the sex act. Otherwise the douching may weaken the diaphragm's protectiveness.

Birth Control Methods Obtainable without a Doctor

Two very effective methods of birth control are available without seeing a doctor. One is for use by the man, the other by the woman.

The Condom

The condom or "rubber" is made to be placed over the male organ (penis) just before sex relations. It keeps the man's fluid (semen) with its sperm from getting into the birth canal. Condoms are safe, reliable and can be bought without a doctor's prescription at any drugstore. Condoms are highly effective and widely used. Some men report that they dull sensation somewhat. The condom must be put on after erection. Hence, its use interrupts the sex act. For couples who find condoms acceptable, the method is highly recommended.

There is a slight possibility that the condom may break during use, or slip off after the man "comes" and releases his semen. As a result, the man's fluid may spill into the birth canal. Slipping off can be avoided if the man holds onto the condom as it is taken out of the birth canal. Breakage usually occurs because the condom is dry, and can be avoided by using vaseline or any kind of cream.

The government Food and Drug Administration checks on condoms and destroys those found defective or inferior in quality. That is why most condoms are of high quality and breakage is rare. For greater protection, the woman may use a contraceptive jelly, cream or foam at the same time the man uses a condom. She places these in the birth canal before they have sex relations. (See below for information about contraceptive jellies, creams and vaginal foams.)

Vaginal Foams, Creams and Jellies

Special contraceptive creams, jellies and vaginal foams can be bought without a doctor's prescription at drugstores. For couples who cannot use other methods or for women who can't get to a doctor, these are very good products. They are simple to use and no doctor's examination is needed. Special applicators which measure the right amount come in the box when you buy them. To be effective these must be used each and every time before sex relations. Next to the condom, the contraceptive foams, creams and jellies are the most effective birth control methods you can buy without a doctor's prescription. Because the foam is less noticeable, many women prefer it to jellies and creams. (See p. 8 for list of products on sale in drugstores.)

Chemicals in these foams, creams and jellies quickly kill the sperm. The jelly or cream is squeezed out of the tube into the special applicator. In the case of the vaginal foam, the bottle is first shaken well, then the applicator is placed over the valve at the top of the bottle and filled with foam. *Not more than one hour before sex relations*, the applicator should be placed gently but deeply into the birth canal. Pressing the plunger sends the foam where it provides protection. Each time sex relations are repeated, another applicatorful must be used. Douching is not recommended. If douching is desired, a six hour wait after the last sex act is a *must*.

Less Effective Birth Control Methods

Vaginal Foaming Tablets

Vaginal Foaming Tablets, also sold at drugstores, are simple to use. They only work when moist. For this reason the tablets are not suitable or effective for some women.

The tablet should be moistened with saliva or water and immediately inserted deep into the birth canal *at least five minutes before* each sex act so it can dissolve. The foam produced as the tablet dissolves covers the mouth of the womb. A new tablet should be used before each sex act. The tablets lose their effectiveness an hour after insertion. Douching is not necessary. If douching is desired it should be postponed until at least six hours after the last sex act.

Vaginal Suppositories

The Vaginal Suppository is a small, cone-shaped waxy material containing a sperm-killing chemical. A suppository is inserted into the birth canal *10 to 15 minutes before* each sex act so that it has time to melt at body temperature. They are simple to use and can be bought without prescription at any drugstore. However, they have not proven to be reliable enough to be recommended generally. Sometimes they do not melt quickly enough, or they may be incorrectly inserted. Like the foaming tablets, if the sex act does not take place within one hour after insertion, they lose their effectiveness. Products advertised for "feminine hygiene" are usually

worthless for birth control. When better methods are not available suppositories are recommended, since they do give some protection. (See p. 8 for a list of such products.)

The Safe Period Rhythm

It is advisable to consult a doctor familiar with the difficulties of this method if rhythm must be used. This method is based on the fact that a woman can become pregnant only during that part of her menstrual cycle when the egg is released from the ovary—around ovulation time. It is hard and time-consuming to determine the ovulation time each month for a particular woman. Only a very few women are regular every month. A menstrual record must be kept for from eight to 12 months. An exact record of her body temperature, taken each morning before rising, is also usually needed. A series of these carefully kept monthly charts shows a slight rise in temperature after ovulation and helps forecast when a woman will release an egg (ovulate). Also, because the time of ovulation is hard to learn in the menstrual cycle, several days must be added before and after and counted as part of the unsafe period when you cannot be sure you can have sex relations without becoming pregnant. *The fertile or unsafe period may last from 7-21 days. If a woman's period is irregular, her safe and unsafe days will also be irregular.*

For many women, the rhythm method may not be reliable, because they have trouble calculating the time of ovulation. A doctor can help you calculate your safe and unsafe period more effectively. Some women combine the safe period method with other family planning methods. They use contraceptives only during their fertile days. *For a pamphlet on the safe period, send 25¢ to Planned Parenthood-World Population, 515 Madison Avenue, New York, N.Y. 10022.*

Withdrawal Coitus Interruptus

Coitus interruptus, or "taking care," refers to the withdrawal of the male organ (penis) before the man "comes," so that sperm are not deposited in or near the birth canal. No drug or chemical is needed for withdrawal. This method is not completely reliable. Failures may occur because of poor control, carelessness or because sperm are sometimes released before the man's climax. Besides, worry that withdrawal will not take place in time may lessen the enjoyment of sex relations. Some couples find this method acceptable for regular use. For others it is useful when no other method is available.

Birth Control Methods Not Recommended

Sometimes women will use products or methods they think are useful for birth control but which are not.

Douches

The vaginal douche, taken after sex relations is one of

the *least effective* methods. It consists of washing out the birth canal with a solution of one kind or another in the hope of removing the sperm. The sperm enter the womb seconds after the man "comes," and cannot be washed out with a douche, even if taken immediately. This is not a reliable birth control method.

Feminine Hygiene Products

Many products are sold as aids to "feminine hygiene." In some cases, these widely advertised products hint at "birth control powers" in order to fool buyers. Many women buy these products in the mistaken belief that they will prevent pregnancy. *These are not useful for birth-control.*

The Truth about Birth Control

The methods listed in this booklet are the major birth control means known to medicine today. Any of those recommended in this booklet will give some protection from unwanted pregnancy. They must, however, be used regularly, according to the doctor's instructions and the directions provided. Remember, even the least effective method is better than no method. Other facts to be remembered about birth control are these:

Modern methods of birth control do not interfere with sexual enjoyment. Because they remove the fear of unwanted pregnancy, they often make married life happier.

The use of birth control in helping couples to plan their families is supported by nearly all Protestant and Jewish denominations. The Roman Catholic Church approves of birth control by the rhythm method.

Birth control does not interfere with life that has already started in the womb. It keeps pregnancy from starting.

Sterilization

Sterilization is a method of birth control involving an operation on either the husband or wife. Once done, it makes the man or woman unable to have children. Sterilization of the man (vasectomy) is relatively simple and may be done in minutes in the doctor's office. Complete recovery from the operation takes only a few days and the man experiences no change in his virility, his sex desire or in his sexual performance. Sterilization of the man involves tying off the tubes through which the sperm travels.

Sterilization for the woman involves an operation in a hospital. It is often performed just after childbirth. For this reason, if the operation is to take place, it should be planned several months before the baby is born. Sterilization does not involve the removal of any sex gland and it does not change the woman's sexual desire or femininity in any way. Sterilization of the woman involves tying off the tubes through which the egg travels.

Additional information on sterilization may be obtained from any Planned Parenthood Center, from hospitals, private doctors or from the Association for Voluntary Sterilization, Inc., 14 West 40th Street, New York, N.Y. 10018.

Birth Control Products

Birth Control Products

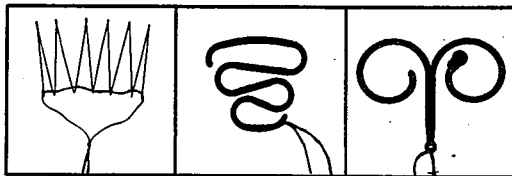
Available only with a Doctor's Prescription

1. Oral Contraceptives

The products for oral contraception approved thus far by the Food and Drug Administration are: C-Quens, Enovid, Enovid-E, Noriday, Norinyl, Norlestrin, Norquen, Oracon, Ortho-Novum, Ortho-Novum SQ, Ovral, Ovulen and Provest. Your doctor will tell you what is best for you.

2. Intrauterine Devices

Intrauterine devices have been given extensive testing and are available to physicians. These devices have been given names which describe their shapes: Spirals, loops, springs, bows and double coils. Three are illustrated below.



3. Diaphragms

Many firms manufacture types of diaphragms suitable for the varying needs of individual patients. Your doctor will prescribe the one best suited to you.

Birth Control Products Not Requiring a Doctor's Prescription

1. Condoms

Quality control is checked by the U.S. Food and Drug Administration; therefore, reliable brands bought at drug-stores are acceptable.

2. Jellies, Creams and Vaginal Foams

All of the products listed in this group have been tested at the Margaret Sanger Research Bureau, New York City, for effectiveness against live human sperm. Products listed first under headings A and B are those which were the strongest in the test tube trials. Products of equal strength are listed under the same number. The difference in sperm-killing ability between products close to each other on the list is not great; but the difference between those at the top and those at the bottom of each list is. In choosing the product that best meets your own special needs, you may wish to try several; ask your doctor for advice. Many of these products are available at your local drugstore:

A. Vaginal Foams:

- *Delfen Vaginal Foam
- *Emko Vaginal Foam

B. Jellies and Creams:

- 1 *Delfen Cream
- 2 Certane Creme
Contra Creme
- 3 Creemoz Creme
Lactikol Jelly
*Koromex-A Jelly
- 4 Ortho-Gynol Jelly
- 5 Koromex Jelly
Marvosan Jelly
*Preceptin Gel
Verithol Jelly
- 6 Certane Jelly
Lactikol Creme
Ortho Creme
- 7 *Immolin Cream-Jel
Koromex Cream
*Locorol "D" Jelly
- 8 *Lanesta Gel
- 9 *Colagyn Jel
Lanteen Jelly
Ramses Jelly
- 10 Bilco Jelly
*Cooper Creme
Cooper Creme Gel
Jellak Jelly
Kemi-Cream
Kemi Jelly
Locorol Jelly
Marvosan Creme
Milex Crescent Creme
Milex Crescent Jelly
*Milex Jelly B4
*Veritas Kreme

3. Vaginal Foaming Tablets:

- *Durafoam Tablets
- *Zeptabs

4. Sponge and Foam:

- Durafoam Liquid
with Sponge
- Durex Foam Powder
with Sponge

5. Vaginal Suppositories

- *Lorophyn
- *Indicates those products designed for use alone
(without a diaphragm).*

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Senator DOLE. I agree with Senator Nelson that the little booklet called "So Close to Nature" leaves something to be desired. It may not be very realistic at least in the first few sentences that the Chairman read from that document.

Dr. GUTTMACHER. Of course, this testimony of mine has been so interrupted, I really do not know where to take it up, but we have not discussed two things, I believe.

One is that for certain individuals, particularly certain married couples, the pill has emancipated them from the onus and chore of contraception. I think that, I trust that you gentlemen have read these excerpts from this letter which I received, which moved me very much, because I think this woman puts in rather simple English statements which I would have difficulty putting in more complicated English.

To them, to her marriage, the pill is almost a saving factor.

Senator NELSON. I want to just finish the discussion of this pamphlet. One of the issues we are concerned about is informed consent. The question raised here is, as a matter of public policy, are we entitled to withhold information that is known about a prescription drug which gets the stamp of approval of the Federal agency under a statute passed by Congress? There are all kinds of complicated questions.

We debated on the floor of the Senate at great length the antibalistic missile, which is an incredibly complicated mechanical device, which probably nobody in the Congress could explain from a technical standpoint. Should that be discussed although it is complicated and the public may not be able to understand it, or should it not?

This is the kind of question we are dealing with here. Do we have a right not to have public hearings and not to make the information available on the ground that all the press may not carry it the way some people think they ought to carry it? Or that it is too complicated for the public to understand? Is this the kind of decision that we have a right to make, to withhold knowledge developed by the Federal Government itself through research and studies and conferences like the NIH, or should these matters be made a matter of public knowledge, counting, as it seems we always have to do, upon the ultimate good judgment of the public to come to a reasonable conclusion?

Very frequently, in a free country, people do not come to reasonable conclusions. That is no reason for substituting an arbitrary system such as you have in other countries, where you tell them what you want them to know, no more and no less. This is one of the risks, it seems to me of having a free society in which there are many risks.

This is the fundamental question raised here from time to time. I am one of those who happens to favor planned parenthood. I would like to see the perfect pill. I think the rapidly multiplying intrusion of human beings upon the limited resources of the planet is a catastrophe already. And I think there is not any question but what, with our present situation, the United States is overpopulated now with 200 million people, because we have demonstrated our incapacity to dispose of the waste of 200 million people. What will happen when we have 300 million?

I believe all those things. I also believe that the public is entitled to have the facts. The facts are being presented by all sides. We have invited witnesses who are qualified to make a contribution to come here. We have invited every drug company to suggest witnesses and come themselves.

We are trying to see that there is a record presented on all aspects of this problem, on my theory, at least, that the public is entitled to know.

Now, that is the fundamental question. If, as a result of the public acquiring knowledge, some of them misunderstand it and some of them panic from it, some of them are disturbed by it, so be it. That is part of the democratic process.

These hearings are presenting everything that experts can tell us about this pill. Nobody to this day has questioned the qualifications of the experts who appeared here, though they have had different viewpoints.

Now, you raised the point that nothing has been raised in these hearings that has not been in the FDA report. What would your view have been if you had been a lay person? The difference is that the information in the FDA report was not put in the papers and only now is being publicized. I have perused the material. It was in some of the medical literature, although much of that was slanted to the final conclusion that the pill was safe within the meaning of the law, with no explanation of what the 1938 law meant.

Now, let us assume that when the FDA report came out, the findings in that report had been put on the front page of the papers? Would not your reaction have been about the same as it is now?

Dr. GUTTMACHER. I think people would have read it and then come to the final conclusion, which I admit is framed in verbiage which is difficult to define. But at least it is verbiage which does create a certain sense of complacency in the user. I think that if this committee has the power and the wisdom to perhaps issue a statement at the end of the hearings to put this whole thing in proper perspective, to grant the fact that the pill has magnificent and necessary use for many segments of the population, that there are other birth control methods for some which may be substituted with equally good effect, perhaps this will help a great deal.

I think that the American public is leaning on this committee for guidance. My hope is that if you agree with me that there has been a lot of material which perhaps has been misinterpreted and has become inflammatory, you will attempt in an honest and perhaps even cautious way to undo this, I think it would be a great service.

I do not know whether I am making my point clear to you, sir.

Senator NELSON. I at least do not have the qualifications to draw up a summary of what the experts have said and enconsions on it, and present it to the public as a valid position respecting the pill, its side effects, and its uses. I have no such qualifications. That is the reason we have called upon distinguished experts such as yourself and many others to state the case for the record.

The problems still remain, if the FDA report, as I said, covered most of the things which have been covered in this hearing, with some exception—some of the material in here has been in much more

detail than in the FDA report—but if the press and the journals had looked at this and given the same visibility to these grave reservations that were expressed, the indications of various effects and the concerns about the long-term use, and if that had been on the front page of all the papers, the result would have been exactly the same as the result from taking the same testimony and having it in this committee.

You would be reaching the same conclusion.

Dr. GUTTMACHER. Yes, but I think it is pretty obvious that the spoken word is more likely to be paid attention to than the written word. I think that these hearings, of course—as you say, the same materials can be brought out, but when they are spoken with an authoritative voice, it means much more than between the pages of a rather sterile document.

The newspapers are likely, obviously, to pay attention to the spoken word, not the written word. This is human nature, sir, and this is no exception to it.

Senator NELSON. Does that not still raise the question whether or not the FDA report by a committee appointed by the Government, a committee of distinguished gynecologists and clinicians of various kinds, to evaluate the pill should be a matter of public knowledge? Should it not be disseminated to the people of this country, where we have 8,500,000 women using the pill, 10 million in other countries?

Is this not something they ought to have a chance to see and read?

Dr. GUTTMACHER. I think you misinterpret me. I have not attacked the hearings, sir. I do not think I have. I am unhappy about the results on our patients in my clinics. This distresses me because I do not think that anything has changed materially.

I think they could wait a little longer, but I think there has been a very sudden kind of stampede. This, of course, I regret.

Now, whether the hearings could have been differently tailored so that this was not the result, it is certainly not within not my competence to tell you. You are much more experienced at this than I am.

I am not attacking the hearings. I believe in free speech. I believe everybody has a right to be heard. But unfortunately, when it comes to medical matters, the negative is so often more clearly understood than the positive by lay people. This is just the nature of the problem, sir. I have not the solution to it.

Senator NELSON. Well, my own view is that this is about the only solution that there is. My own view, furthermore, is that you will conclude, yourself, after a couple of years that the greatest benefit to the pill and the development of more effective devices, or one of the great benefits, is the effect of these hearings. But what we faced here was a situation in which the drug manufacturer's literature is being promoted, the literature that is promoting the pill. You reject the statement in the literature. But that is what the users get. What is the responsibility of the Government, which does the studies, licenses the pills, approves the package insert which goes to the druggist and most of the time does not get to the physician because he does not

get the package? The literature that is going out is inaccurate. It is misleading 8,500,000 women in this country and it has been doing it for 10 years. It has not been corrected by the Food and Drug Administration, it has not been corrected by the medical profession; it has not been refuted by anybody. Here it stands. You refute it; I reject it.

You would not use this in your clinics. Yet it is being passed to women all over the country. At what stage do you consider the women's rights?

Dr. GUTTMACHER. I see your point. Well, I suppose if you had the, if the FDA had the, medical manpower and the budget, they could have submitted such literature, I am sure that if they criticized it, the drug company that put this out, I should think would make the changes which are suggested.

I think that you probably have no right to impose what should be written in such a pamphlet. But if there were some way of clearing all medical throwaway data with the FDA before publication for their criticism, it might be a very salutary thing.

Senator NELSON. I think it would be, but they do not have the personnel, nor, at this stage, so far as I know, the authority which is another thing that ought to be corrected.

Dr. GUTTMACHER. That is correct. But I do not think you can impose it.

I turn our attention to one other aspect of this situation, and that is what is happening the world over because the impact of these hearings has washed up on the shores of almost every country.

Senator NELSON. May I interrupt you? I apologize for interrupting you, but I wanted to get the—

Dr. GUTTMACHER. I am hurrying myself along and you are slowing me down.

Senator NELSON. I just have one more line of questioning. I read to you the statement of the Sallhanick study sponsored by NIH. I suppose each individual has to judge himself, and you feel that the statement would not mean anything to women, and I assume you mean men, too. Let me read that once more. I do not think there is anything in there that any average person in America would not understand. I understand it; I have no medical training.

Dr. GUTTMACHER. You are the son of a doctor, sir.

Senator NELSON. But you do not get any genes or chromosomes for that.

Until recently, the metabolic effects of the sex steroids have been inadequately investigated, or ignored. These accumulated data and others suggest that no tissue or organ system is free from a biological, functional, and/or morphological effect of contraceptive steroids. Many of these changes appear to be reversible after short periods of treatment. But it is impossible to form judgments on the reversibility of some of the changes resulting from prolonged administration. This question becomes more important daily for the many patients who have already had long-term contraceptive steroid treatment.

Nevertheless, the consistency of such reports on such findings rejects the possibility that they are of no consequence and requires that certain questions be answered.

Now, that is not any medical statement to cause anybody any trouble. Perhaps the word "morphological" may be difficult but, as a

whole, this is a very, very clearly, simply stated paragraph that gives warning about the long-term systemic effect, which is quite a different thing from what is going to the woman, which says:

And it works without upsetting the delicate balance of your normal bodily function.

Compare this authoritative statement with the statement going to the woman.

Dr. GUTTMACHER. Now, I do not think that statement—I agree with it in part, but I think, for example, it could lead one to the impression that it is universal, that every woman on the pill has such changes. As far as I know, it is 8 percent in one series; 20 percent in another.

Also, these chemical changes often clear up during the time the patient is on the pill. Also, so many of these changes are reversible when the patient concludes it. I think if this were added to the statement, perhaps—then there are words in there that I just have the feeling that a lot of people do not understand.

“Morphological”, I dare say if you took that word to half the population in Washington, the number of people who do not understand that word would be higher than I anticipate. I think it is fine, but I think it needs a good deal more writing. I think it has to add that it is not universal, that it reverses itself even when patients are on the pill; when they come off, most of these disappear.

I think also we need to state in there that so far, we do not see any evidence of sustained systemic damage. There is nobody, I think, that thinks, so far as I have been able to read that volume or other volumes—and Dr. Carrington is going to follow me, and she can answer me—that the pill is going to cause diabetes. Nevertheless, it causes changes in sugar tolerance.

I just have a feeling that you are trying to oversimplify your message to the American public. It is a complicated message and this does not do it all.

Senator NELSON. I did not suggest that. I was just saying, as contrasted with the comments on metabolic effect here——

Dr. GUTTMACHER. Oh, I will buy the book against the pamphlet. There is no problem about that.

Senator NELSON. And this statement, save a word or two, which could easily be rephrased, is perfectly understandable by any eighth grader, I think, in the country.

That is my point. On one side is the information that the woman is getting; that there are no metabolic effects. On the other side is what a most distinguished committee has gathered on the metabolic effects. It has summarized all the literature here and elsewhere in the world and here is the conclusion they come to. The woman is being told exactly the opposite. That is why I raise the question, should it not be told?

Senator JAVITS. Mr. Chairman, a point of interest to me. The Chair said he was reading from an official document. What is the official Government document?

Senator NELSON. It is an NIH-sponsored conference. This is the book that came from the conference sponsored by the NIH, considered to be——

Dr. GUTTMACHER. I think it is an excellent book, Senator Javits.

Senator JAVITS. Do you consider it an official Government document?

Dr. GUTTMACHER. No, I do not. I think it is an excellent study. I think the people who contributed to this are among the leaders in the field.

Senator JAVITS. But as far as you are concerned, it is not an official Government document?

Dr. GUTTMACHER. No, that is true.

Senator NELSON. It is sponsored by the NIH, held in Boston, Mass., in 1968. According to the witness before us, it is the best compilation of authoritative material on metabolic effect of steroid hormones any place in the world. Is that not so?

Dr. GUTTMACHER. It is the best I know.

Senator JAVITS. With all due respect, it is far from an official Government document. I just wanted to know what you meant by those rather heavy words.

Senator NELSON. It is quite unimportant, sir.

Senator JAVITS. I think what you are saying is that the book "So Close to Nature" is deceptive because it is at variance with an official document. I have no lack of indictment for the little book; however, I think it is very important not to let that impression go abroad, that the United States has found the facts that the Chairman has read.

Senator NELSON. Let me read into the record so that the Senator from New York will know what it is about. It has the Library of Congress catalog No. 789792. The workshop upon which this volume is based was held in Boston, Mass., December 1 to 5, 1968, and was sponsored by the National Institute of Child Health and Human Development, in the Center for Population Studies of Harvard University School of Public Health. It was conducted pursuant to contract No. PH43681456, with the National Institutes of Health, Department of Health, Education, and Welfare.

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Senator JAVITS. Mr. Chairman, I would like to ask the witness some questions, if I may, because I think they ought to come at the same point as the Chairman's questions.

May I do that?

Senator NELSON. Go ahead.

Senator JAVITS. Dr. Guttmacher, please let me welcome you to the committee and let me state my own purposes. I have no preconception about this matter whatever. I think that Congress has a right to conduct these hearings and the chips must fall where they may.

We realize that lots of drug companies are interested in selling this pill but that does not make it bad. Lots of drug companies were interested in Salk vaccine, and antidiabetic material—many, many wonderful medicines. That does not make it bad. It does not make it good, either.

Until the United States manufactures all the drugs, we have to run a private enterprise system and we have to regulate the best way we can.

Now, just a question or two, because you are a distinguished

expert in this field. One, do you prescribe the pill? It is not sold over the counter, is it, without a prescription?

Dr. GUTTMACHER. It is against the law, and I hope this law is very seriously enforced.

Senator JAVITS. So you prescribe it?

Dr. GUTTMACHER. We do.

Senator JAVITS. Are you continuing to prescribe the pill in your clinics?

Dr. GUTTMACHER. We absolutely are, sir.

Senator JAVITS. Do you distribute any booklet for that?

Dr. GUTTMACHER. We have publications about methods of contraception. We include, of course, not only the pill in these booklets, but other methods of contraception to help patients make a rational choice. These are written in very simple English, which we anticipate the patients understand.

As I said before you came, Senator Javits, we plan to furnish the committee with these booklets so they can inspect them.

Senator JAVITS. Are they the same booklets to which the Chairman referred?

Dr. GUTTMACHER. No, sir; we write our own.

Senator JAVITS. Do you know anything about the practice of other clinics like your own?

Dr. GUTTMACHER. Well, of course, we are a national organization and we sell these booklets in bulk to various—sometimes the U.S. Army for their hospital uses, and we sell them around the country and around the world.

Now, we are not the only people who write such booklets, but we have a very wide distribution of them.

Senator JAVITS. Can you give us any factual light on what part of the market, which the Chairman has said was over 8 million people, what part of the market is filled by your particular organization?

Dr. GUTTMACHER. About 275,000, sir.

Senator JAVITS. Do you have any idea as to what part of the market is occupied by other similar clinics.

Dr. GUTTMACHER. Of course, what we are talking about, our group is primarily what we call the medically indigent. As we know, the President, in his message to Congress, said that there were approximately 5 million women of fertile age among the medically indigent group who were not seeking pregnancy currently. Of this group, there are about 800,000 getting effective birth-control advice. Forty percent is given by health departments—county, State.

Twenty-seven percent are given advice by Planned Parenthood, and 27 percent are given advice by the great hospitals of this United States. Five percent get their birth control advice from other sources.

Now, in addition to that, we assume that perhaps another 100,000 get their birth-control advice through medicaid, so that probably the number of medically indigent getting effective birth-control advice may be in terms of a million people out of the 5 million who need it.

Now, whether they get the pill or not depends upon their preference, but in most of our installations, three-quarters of the patients choose the pill, and one-quarter other means.

Senator JAVITS. I was particularly concerned about the information which the Chairman feels they are not getting.

I was wondering about the extent of the distribution of information about the pill. How many are getting proper information regarding its use?

Dr. GUTTMACHER. In absolute honesty, Mr. Javits, I cannot tell you of the million women in the medically indigent group getting birth control through subsidized sources, what percentage are given actual insight into the potential dangers of the pill. I cannot tell you. We certainly know our doctors are thoroughly instructed in these potential dangers. We assume that in conversation with patients, they pass on this information to them. Certainly, if questioned, they would. If they are not questioned, whether they would point out the dangers, I cannot in all frankness say.

Senator JAVITS. Now, do you know whether this booklet to which the Chair referred—

Dr. GUTTMACHER. You mean the Salhanick booklet?

Senator JAVITS. No, the little one, "So Close to Nature." Do you know whether this is still in distribution? I see it is copyrighted in 1965, Meade, Johnson and Co.

Dr. GUTTMACHER. I do not know.

Senator JAVITS. Mr. Chairman, I would respectfully suggest that a request be made of this company to find out if it is in distribution, or what are the conditions of its distribution, the size of its distribution, and so on, that that may be made a part of the record.

Senator NELSON. Yes. I would assume you would want it from all companies, because each of them puts a piece of literature out. I have seen other pieces of literature in doctors' offices myself.

(The subsequent information was received and follows:)

MEAD JOHNSON LABORATORIES,
Evansville, Ind., February 26, 1970.

HON. JACOB K. JAVITS,
U.S. Senate,
Old Senate Office Building,
Washington, D.C.

DEAR SENATOR JAVITS: During the hearings of the Senate Small Business Monopoly Subcommittee which were in progress February 25, you asked Dr. Alan F. Guttmacher, President, Planned Parenthood if our booklet, "So Close to Nature" was still being given to patients. Dr. Guttmacher replied that he did not know.

You asked that we inform the committee whether or not the booklet is currently distributed so that information might be placed in the record.

We withdrew "So Close to Nature" from circulation in November, 1968. No additional copies have been printed nor distributed by us since that time.

We do appreciate your interest and hope this letter will answer satisfactorily your question to Dr. Guttmacher.

Sincerely, DONALD G. HARRIS,
Marketing Administration.

Senator JAVITS. I think, if I may say so to my own chairman, I think we ought to base this solidly in fact and be sure that the facts support the conclusions which we make. I think the distribution of information is really something of great importance that this committee has a duty to go into, since we have undertaken this investigation. It is this committee's duty to give the pertinent information which they develop. Do you agree with that?

Dr. GUTTMACHER. We have to separate fact from conjecture, and this is a realm of difficulty. We know the facts about thromboembolism. I think this is pretty uncontested. We know the facts about

development of high blood pressure in a certain small proportion of patients. We know the fact that certain patients get depressed on the pill.

These are facts we are all privy to.

But when it comes to cancer, for example, you are dealing then with a wholly conjectural structure, because we have no evidence to date that the pill causes cancer in the human. When we talk about chromosomal damage to the ovary and perhaps to the offspring, we are talking about conjecture and not fact.

This is the thing that I think has a tendency to confuse the public, because the public does not separate fact from conjecture. When you are talking about cancer in such a meeting, in such a forum as this, they do not take Dr. Roy Hertz's statement that no cancer that he knows of in either a monkey or in a human being can be attributed to the pill. Dr. Hertz is concerned that the hormone estrogen may cause cancer in two target organs in women on the pill, the breast and the uterus.

This is highly inflammatory to the public.

Senator JAVITS. The doctor's first responsibility as to whether he will allow the patient to use the pill and as to what information he will give the patient about the pill is to the patient? That is the first responsibility?

Dr. GUTTMACHER. Absolutely.

Senator JAVITS. And the first responsibility?

Dr. GUTTMACHER. Yes, sir.

Senator JAVITS. So a patient has a right to assume that the doctor is going to be fair and honest with that patient.

Dr. GUTTMACHER. I hope so. I expect so.

Senator JAVITS. That is true of many other medicines?

Dr. GUTTMACHER. That is true. If the doctor is going to recommend surgery, he has to do it from the patient's point of view, because it is necessary.

Senator JAVITS. Dr. Connell's implied criticism—and I think she was rather soft in this—of the hearings was that the presentation should have been very carefully balanced at every stage so that the public does not get hit on the head with a sandbag. This has caused many serious problems, which I understand has resulted in a number of unwanted pregnancies, some of which have been terminated by abortions. What is your comment on that? That was my understanding of the implication of her testimony.

Dr. GUTTMACHER. It would have been certainly preferable, if feasible. I am not sure you know how a witness is going to testify before he comes on the stand, and perhaps many of the witnesses were uncertain even when they were called. But I think a balanced picture is very valuable, and unfortunately thus far this has not been a balanced presentation. I do not think it is by design of the chairman; I think it is a matter, perhaps, of happenstance that this has been an overwhelmingly negative type of hearing in regard to the safety of the pill. I do not think that people have emphasized the vast and tremendous importance that the pill has to certain segments of our population.

When one says more or less carelessly that other methods of contraception can be easily substituted, he is really not talking out of

fact, he is talking, I think, out of misinformation. It can be in some instances, but certainly not in the vast proportion.

The fact that our clinics have grown so magnificently since the pill was introduced, I am sure, is not due to the fact that other social factors have made deep impact. The fact that we now have a product which is extraordinarily acceptable to our type of patient, and if we did not have this product and if we deny them this product or scare them to death from using it, unfortunately, we are going to revert back to situations which are most unhealthy in America.

Senator JAVITS. Has anything happened in the testimony or otherwise to change your view as an authority that this is a landmark and historic development in population control?

Dr. GUTTMACHER. I think that the two methods, the pill and the intrauterine device, have been significant contributions. I think we are still in the horse and buggy day of effective contraception. I am optimistic in feeling that in 5 years, we shall have methods that are infinitely superior and safer than either.

Senator JAVITS. I would like to tell you just by way of confirming your own view that Dr. Guy Iman, who has just won the Nobel Prize for medicine, addressed the session of trustees of the Salk Biological Institute of La Jolla. I am a trustee and I heard it. His appraisal was precisely yours, that within 5 years, we should have as marked an advance in this science as we have had up to now. It is very interesting. I thought you might be interested.

Dr. GUTTMACHER. I am happy to be confirmed by such a distinguished person.

Senator JAVITS. Is he not one of the most distinguished individuals in this field?

Dr. GUTTMACHER. Yes, he is.

Senator JAVITS. He is beginning to be a fellow at Salk and undertaking his research there.

I noted with great interest in your statement—I do not know whether you have come to it or not in your prepared remarks—but your press release quotes the following:

"It is against these risks that the proven annual mortality of three deaths per 100,000 pill users must be weighed," and the risks which you outline, I gather, are the toll, as you put it, of unwanted pregnancy, between 200,000 and a million illegal abortions a year, with a resulting estimated 100 deaths per 100,000 such abortions.

Dr. GUTTMACHER. When done by nonmedical personnel.

Senator JAVITS. No less than 300,000 illegitimate children born in 1970, based on the experience of the last decade; at least three-quarters of a million children born each year are unwanted at the time of birth—conception is your statement.

Then you give the international problems which are involved. You say millions of women use the pill in other countries.

Now, are those the effects to which you just—as against these risks that the proven annual mortality of three deaths per 100,000 pill users must be weighed—is that right?

Dr. GUTTMACHER. That is my feeling, sir. I think that the situation, of course, is quite different abroad because of a maternal death rate in much of Asia and Africa and Latin America which is so much greater than the United States that you would probably con-

trast three deaths from the pill per 100,000 in America against 900 deaths per 100,000 childbirths in Africa. Three against 900 is quite a considerable difference.

Senator JAVITS. Could you give us, Dr. Guttmacher, as part of your analysis of such a situation, the documentation which Planned Parenthood distributes to the taker of the pill?

Dr. GUTTMACHER. I unfortunately did not do my homework; I did not bring it with me, sir. As I have said, I have promised to send it.

Senator JAVITS. Good.

Dr. GUTTMACHER. In my written testimony I went into detail with regard to the rules we impose on physicians prescribing the pill, that they must take an annual Pap smear, they must make an annual breast examination, a pelvic examination, and so on. What I am lacking is the material we give to the patients. We shall certainly submit that. Some of my staff is here and I am sure they will call up New York and get it.

Senator JAVITS. I ask unanimous consent that that become a part of the record.

Senator NELSON. It will be printed in the appropriate place in the record.

Senator JAVITS. Now, could you make any recommendations to us—this will take a little time, but I hope you can do it—as to what must be done in law or at the Food and Drug Administration to more nearly present the dangers and the benefits with the greatest accuracy possible to the patient?

Now, the chairman, I think, said that the United States authorized the pill, or words to that effect. Of course, as I understand the operation of the Food and Drug Administration, it may permit a drug to be distributed, but it does not authorize it in the manner that the chairman uses the word. I do not think we would want to be put in that position.

Did FDA approve the pill? Is that your understanding?

Dr. GUTTMACHER. They approved it after considerable research.

Senator JAVITS. For use as a prescription drug.

Dr. GUTTMACHER. As you know, the pill was started experimentally in 1956 by Pincus in Puerto Rico, and 4 years later, was approved by the Food and Drug Administration for prescription.

Senator JAVITS. Would you give us your recommendation as to whether the approval should be withdrawn?

Dr. GUTTMACHER. I am 100 percent certain that approval should not be withdrawn. That requires no thought on my part, sir.

Senator JAVITS. Therefore, the area in which you can help me—I do not want in any way to speak for the committee—the most is to give me your idea as to any changes, which will, in your judgment, more nearly present the case so that the choice of the individual—because it is choice, even though the doctor is ready to prescribe and even recommend it—is as free as possible?

Dr. GUTTMACHER. Well, number one, I would say that the physician should be made to understand and appreciate that unless he can see the patient who is on the pill at least every 6 months, he should not prescribe it for her. I think there is danger in allowing a patient to go for an indefinite period without examination.

I think second of all, the doctor should be sufficiently well

equipped to answer honestly and authoritatively the facts that have been presented about the pill—not conjectures but facts, and I think that he should be made to recognize the necessity for him to take the time from the busy life of a doctor to answer these questions, and if he feels that he cannot do this, then I think he should not dispense the pill.

We must recognize that for many situations, the pill may not be the ideal contraceptive. I have often said, and I would say it again, that I think that nothing can be substituted for the pill when it comes to premarital sexual relations. I think nothing can be substituted for the pill in early marriage, where couples are making a good physical adjustment. But I think after marriage has matured and a good sexual adjustment has been made, then I think the intelligent patient should go to an intelligent physician and discuss methods of contraception. She may find that other methods may be quite satisfactory to her.

Some couples have become so dependent upon the pill, because to them its great virtues would not permit them to substitute other methods. Since sexual response and satisfaction is so largely psychic and so little organic, it is what one's attitude is that counts. If couples wish to reject other methods of contraception, I think they have the right to. On the other hand, if they can make a trial of other methods and find them entirely satisfactory, I think perhaps other methods should be substituted.

Now, of course, I get back to what I told Senator Nelson. The primary responsibility, I think, is to educate the medical public, not the lay public. And this is a tough assignment.

Senator JAVITS. I think the Government can play a very significant role in this. I think, therefore, any additional help you can give us on that score would certainly be welcome, very constructive.

Mr. Chairman, I would like to thank the Chair particularly for its indulgence in allowing me to break in with this rather lengthy questioning.

Senator NELSON. Thank you, Senator.

I have just one minor observation on the question that was raised on the balance of the hearings. For example, we called Marvin Legator, Chief, Biology Branch, and Director of Pharmacology and Toxicology, Bureau of Science, Food and Drug Administration, on the first day, because of the distinguished work he has done.

On the second day, we called Dr. Roy Hertz, Assistant Medical Director, Biomedical Division, Population Council, Rockefeller University, and a member of the Food and Drug Administration panel and a member who signed the so-called Hellman Report. Dr. Hertz made an important contribution to the FDA report. Dr. Hertz' testimony got widespread publicity because he was critical of many aspects of the pill. But of course, that was his testimony.

Then we called Dr. Kistner on the second day because he is a very distinguished gynecologist, wrote a book on it—a very good book—which I read and in which he, for all practical purposes, unqualifiedly endorses the pill. He is a strong proponent, so he was on the second day.

On the third day, we had Dr. Hellman, who is the chairman of the Advisory Committee of the Food and Drug Administration. He had very critical things to say about the pill. He was chairman and

he wrote the language, in fact, along with Mr. Goodrich, in which they concluded that the pill was safe within the meaning of the law. Dr. Hellman was widely quoted as being critical of some aspects of the pill.

So I would just like to point out to Senator Javits and you that some of the broadest coverage was given to members of the FDA panel. We did not even know what Dr. Hellman would say, but we thought that those who wrote the report for the FDA ought to be witnesses very early.

Go ahead, Doctor.

Dr. GUTTMACHER. I think the only influence we have not covered by question is the influence these hearings are leaving in their path throughout the world. I state in my testimony that Professor Alvarez from Montevideo and Professor LaVergne from Panama actually came to the United States because they are members of the Medical Committee of the International Planned Parenthood, to talk with me and others about these hearings because they are so terribly upset and because patients throughout Latin America are upset. I received from one of them yesterday—

Senator NELSON. Who are these two gentlemen?

Dr. GUTTMACHER. Professor Alvarez is Professor of Obstetrics and Gynecology in Montevideo. Professor LaVergne is Professor of Obstetrics and Gynecology in Panama. You see, we have a worldwide committee of physicians for International Planned Parenthood.

Senator NELSON. They came for what reason?

Dr. GUTTMACHER. They came to discuss this problem with us here in America.

Senator NELSON. What problem?

Dr. GUTTMACHER. The problem of the bad publicity the pill was getting in Latin America, how much was fact and how much was fancy, and because there was panic among their people in Latin America due to publicity which had come from these hearings.

Senator NELSON. Are these two gentlemen part of Planned Parenthood's organization?

Dr. GUTTMACHER. They are members of the Central Medical Committee. We have eight physicians throughout the world who are members of this committee, of which I am one. These two gentlemen are two of the other seven.

Senator NELSON. I am puzzled as to why they would come to the United States to find what was fact and what was fancy when you have testified that everything that was presented here was in the FDA report. Did they not have that report?

Dr. GUTTMACHER. I am not sure they have had it.

As a matter of fact, I received from London an editorial in one of the Pakistan papers, in which the editorial ends with the admonition that they should discontinue the pill in Pakistan. This, of course, is a very serious problem, because I know you, Senator Nelson, are among the great protagonists of world population control. Unfortunately, the pill is being depended upon more and more throughout the world for population control, and I feel that this setback has been most unfortunate.

Now, I am not blaming you. I think you are taking it for granted that I am trying to levy a certain amount of blame, and I am not blaming you at all. I just cannot help but decry that this has gotten

so much adverse publicity in the press. I cannot help but say that nothing really has materially changed. Millions of people were on the pill before the hearings were held, and nothing has happened, really, to their knowledge about the pill.

Facts and conjectures have been ventilated to physicians who had less knowledge of the pill and ventilated to a lay public which is allergic to all kinds of scare propaganda. I feel our task is to try to put the thing in perspective so that people realize that the pill is still, to me, a magnificent therapeutic agent which has tremendous necessity, until, as Senator Javits says, this 5-year span can be passed and we have much better and safer methods.

Senator NELSON. There is no use going back into that. It is just a question of whether you believe the people of the United States should have all the facts or whether they should not. In my view, I think they should. Many people concerned about the question are concerned that the facts are out; some people may decide not to use the pill and therefore raise the problem about population control. I do not think we ought to use individual persons for sociological purposes.

Would you agree with the letter sent out by Dr. Edwards, Acting Commissioner of Food and Drug Administration, sent about the 18th of January, in which he states:

In most cases, a full disclosure of the potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risk associated with this method.

Dr. GUTTMACHER. I am sorry, not admitting the patient? Is that what you said?

Senator NELSON. No, I am sorry. The quote I read is that in this letter sent to 324,000 doctors. The last sentence reads:

In most cases, a full disclosure of the potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risk associated with this method.

Do you agree or disagree?

Senator JAVITS. Do you not think the witness ought to see the letter?

Dr. GUTTMACHER. I can evaluate that. I have not seen it, but we have discussed it before. I think it places a great burden on the patient. I think it is impractical, sir. I think the physician has to make the decision.

As I have told you, in 35 years of active practice, I cannot pass decisions to patients. Patients pass decisions to me. It is very confusing to her when she tries to interpret my testimony and what went before. How is the poor patient to make the decision?

I think the doctor has to make the decision. I do not think such a disclosure is going to do much good. I think it is going to do great harm. But if Dr. Edwards wants to do it, I think he has a perfect right to do it. I do not want to build optimism that this is going to solve all our problems, because I think the patient, after she has read all of this, is going to come back to the doctor and say, what shall I do?

Senator NELSON. I was just asking for your observation. He sent it to 324,000 doctors.

Senator JAVITS. Could that go into the record? He said he has not read it.

Senator NELSON. It has been in. I assumed, since it was a "Dear Doctor" letter, Dr. Guttmacher had read it.

Dr. GUTTMACHER. Unfortunately, I do not get all my mail.

Senator JAVITS. May I ask unanimous consent that if the letter is not in the record, it be put in the record?

Senator NELSON. We can put it in the record at this point in the hearings.

(The letter referred to follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., January 12, 1970.

DEAR DOCTOR: I am enclosing revised labeling for oral contraceptives to reflect the latest findings on safety and efficacy, as reported by the Obstetrics and Gynecology Advisory Committee in August 1969. An American study confirms previously reported studies in Great Britain which show a relationship between the use of oral contraceptives and the occurrence of certain thromboembolic diseases. These carefully designed retrospective studies show that users of oral contraceptives are more likely to have thrombophlebitis and pulmonary embolism than non-users. Studies in Great Britain also show increased risk of cerebral thrombosis and embolism in users of oral contraceptives. A British study found a hospitalization rate (an index of morbidity) in women age 20-44 to be 47 per 100,000 in users compared to five per 100,000 in non-users.

The American study, although not designed to evaluate differences between products, also suggests there may be an increased risk of thromboembolic disease in users of sequential products. This difference in risk cannot be quantitated, and further studies are needed to confirm the observation.

The British Committee on Safety of Drugs recently advised practitioners in that country that only products containing 0.05 mg. or less of estrogen should normally be prescribed because reports of suspected adverse reactions indicated there is a higher incidence of thromboembolic disorders with products containing 0.075 mg. or more of estrogen than with products containing the smaller dose. This finding has not been confirmed by other studies.

The FDA is planning studies that will determine, among other things, the thromboembolic effect of various products. You will be kept informed as results become available.

Other aspects being investigated in separate studies underway or pending are cervical cytology, carbohydrate metabolism, serum lipids, urinary tract function, blood coagulation, effects on endocrine function in adolescents, breast pathology, outcome of pregnancy, and cytogenetic effects.

In the United States during 1969 an estimated 8.5 million women took oral contraceptives monthly. The unsurpassed clinical efficacy of these products is well established. Although reported pregnancy rates vary from product to product, the effectiveness of sequential products appears to be somewhat lower than that of the combination products.

I strongly urge you to familiarize yourself with the labeling, particularly with the cautionary material contained in the sections headed Contraindications, Warnings, Precautions, and Adverse Reactions. As the prescribing physician, you are in the best position to determine the extent of your discussion of this material with your patient. In most cases, a full disclosure of the potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risk associated with this method.

I also request your assistance in continuing our assessment of the safety of A supply of the standard reporting form (FD 1639), shown in facsimile below, may be obtained from the Bureau of Medicine, Food and Drug Administration, Washington, D.C. 20204.

Sincerely yours,

CHARLES C. EDWARDS, M.D.,
Acting Commissioner of Food and Drugs.

Attachment:
Revised labeling

ORAL CONTRACEPTIVE LABELING

DESCRIPTION

This section includes generic name, amount, chemical name and the structural formula of each active ingredient.

ACTIONS

Combination oral contraceptives: The mechanism of action is inhibition of ovulation resulting from gonadotropin suppression. Changes in cervical mucus and endometrium may be contributory mechanisms.

Sequential oral contraceptives: The mechanism of action is inhibition of ovulation resulting from gonadotropin suppression.

SPECIAL NOTE

Oral contraceptives have been marketed in the United States since 1960. Reported pregnancy rates vary from product to product. The effectiveness of the sequential products appears to be somewhat lower than that of the combination products. Both types provide almost completely effective contraception.

An increased risk of thromboembolic disease associated with the use of hormonal contraceptives has now been shown in studies conducted in both Great Britain and the United States. Other risks, such as those of elevated blood pressure, liver disease and reduced tolerance to carbohydrates, have not been quantitated with precision. Long term administration of both natural and synthetic estrogens in subprimate animal species in multiples of the human dose increases the frequency for some animal carcinomas. These data cannot be transposed directly to man. The possible carcinogenicity due to the estrogens can neither be affirmed nor refuted at this time. Close clinical surveillance of all women taking oral contraceptives must be continued.

INDICATIONS

The Obstetrics and Gynecology Advisory Committee considered the following indications acceptable: contraception, endometriosis, and hypomenorrhea. These indications may be used in the labeling when efficacy has been demonstrated in each case. Any other claims will be evaluated on the basis of oral contraceptives. Your reports of adverse reactions will help us to do this. efficacy data available to support each.

CONTRAINDICATIONS

1. Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions.
2. Markedly impaired liver function.
3. Known or suspected carcinoma of the breast.
4. Known or suspected estrogen dependent neoplasia.
5. Undiagnosed abnormal genital bleeding.

WARNINGS

1. The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately. Retrospective studies of morbidity and mortality in Great Britain and studies of morbidity in the United States have shown a statistically significant association between thrombophlebitis and pulmonary embolism and the use of oral contraceptives. There have been three principal studies in Britain¹⁻³ leading to this conclusion, and one⁴ in this country. The estimate of the relative risk of thromboembolism in the study by Vessey and Doll³ was about sevenfold, while Sartwell and associates in the

¹ Royal College of General Practitioners; Oral Contraception and Thromboembolic Disease. J. Coll. Gen. Pract., 13:267-279, 1967.

² Inman, W. H. W. and Vessey, M. P. Investigation of Deaths from Pulmonary Coronary and Cerebral Thrombosis and Embolism in Women in Child Bearing Age, Brit. Med. J. 2:193-199, 1968.

³ Vessey, M. P. and Doll, R. Investigation of Relation between Use of Oral Contraceptives and Thromboembolic Disease. A Further Report. Brit. Med. J. 2:651-657, 1969.

⁴ Sartwell, P. E., Masi, A. T., Arthes, F. G., Greene, G. R., and Smith, H. E. Thromboembolism and Oral Contraceptives; An Epidemiological Case-Control Study. Am. J. Epidem., 90:365-380, (November) 1969.

United States found a relative risk of 4.4, meaning that the users are several times as likely to undergo thromboembolic disease without evident cause as non-users. The American study also indicated that the risk did not persist after discontinuation of administration, and that it was not enhanced by long continued administration. The American study was not designed to evaluate a difference between products. However, the study suggested that there might be an increased risk of thromboembolic disease in users of sequential products. This risk cannot be quantitated, and further studies to confirm this finding are desirable. Retrospective studies in Great Britain have shown a statistically significant association between cerebral thrombosis and embolism and the use of oral contraceptives. This has not been confirmed in the United States.

2. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be withdrawn.

3. Since the safety of *** in pregnancy has not been demonstrated, it is recommended that for any patient who has missed two consecutive periods, pregnancy should be ruled out before continuing the contraceptive regimen. If the patient has not adhered to the prescribed schedule the possibility of pregnancy should be considered at the time of the first missed period.

4. A small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs. The long range effect to the nursing infant cannot be determined at this time.

PRECAUTIONS

1. The pretreatment and periodic physical examinations should include special reference to breasts and pelvic organs, including Papanicolaou smear since estrogens have been known to produce tumors, some of them malignant, in five species of subprimate animals.

2. Endocrine and possibly liver function tests may be affected by treatment with ***. Therefore, if such tests are abnormal in a patient taking ***, it is recommended that they be repeated after the drug has been withdrawn for 2 months.

3. Under the influence of estrogen-progestogen preparations, pre-existing uterine fibromyomata may increase in size.

4. Because these agents may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation.

5. In breakthrough bleeding, and in all cases of irregular bleeding per vaginam, nonfunctional causes should be borne in mind. In undiagnosed bleeding per vaginam, adequate diagnostic measures are indicated.

6. Patients with a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree.

7. Any possible influence of prolonged *** therapy on pituitary, ovarian, adrenal, hepatic or uterine function awaits further study.

8. A decrease in glucose tolerance has been observed in a significant percentage of patients on oral contraceptives. The mechanism of this decrease is obscure. For this reason, diabetic patients should be carefully observed while receiving *** therapy.

9. The age of the patient constitutes no absolute limiting factor, although treatment with *** may mask the onset of the climacteric.

10. The pathologist should be advised of *** therapy when relevant specimens are submitted.

11. Susceptible women may experience an increase in blood pressure following administration of contraceptive steroids.

ADVERSE REACTIONS OBSERVED IN PATIENTS RECEIVING ORAL CONTRACEPTIVES

A statistically significant association has been demonstrated between use of oral contraceptives and the following serious adverse reactions:

Thrombophlebitis
Cerebral thrombosis
Pulmonary embolism

Although available evidence is suggestive of an association, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions.

Neuro-ocular lesions, e.g., retinal thrombosis and optic neuritis.

The following adverse reactions are known to occur in patients receiving oral contraceptives.

- Nausea
- Vomiting
- Gastrointestinal symptoms (such as abdominal cramps and bloating)
- Breakthrough bleeding
- Spotting
- Change in menstrual flow
- Amenorrhea during and after treatment
- Edema
- Chloasma or melasma
- Breast changes: tenderness, enlargement and secretion
- Change in weight (increase or decrease)
- Changes in cervical erosion and cervical secretions
- Suppression of lactation when given immediately postpartum
- Cholestatic Jaundice
- Migraine
- Rash (Allergic)
- Rise in blood pressure in susceptible individuals
- Mental depression

Although the following adverse reactions have been reported in users of oral contraceptives, an association has been neither confirmed nor refuted:

Anovulation post treatment	Fatigue
Premenstrual-like syndrome	Backache
Changes in libido	Hirsutism
Changes in appetite	Loss of scalp hair
Cystitis-like syndrome	Erythema multiforme
Headache	Erythema nodosum
Nervousness	Hemorrhagic eruption
Dizziness	Itching

The following laboratory results may be altered by the use of oral contraceptives:

Hepatic function: Increased sulfobromophthalein retention and other tests	Thyroid function: Increase in PBI, and butanol extractable protein bound
Coagulation tests: Increase in prothrombin, Factors VII, VIII, IX, and X	iodine and decrease in T' uptake values
	Metyrapone test
	Pregnanediol determination

DOSAGE AND ADMINISTRATION

This section includes routine administration and specific instructions on handling problems such as breakthrough bleeding, amenorrhea, etc.

CLINICAL STUDIES (AN OPTIONAL SECTION)

If any clinical data are included, the following paragraph must be used: Different pregnancy and adverse reaction rates have been reported with the use of each oral contraceptive. Inasmuch as these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision. Furthermore, pregnancy and adverse reaction rates tend to be lower as clinical experience is expanded, possibly due to retention in the clinical study of those patients who accept the treatment regimen and did not discontinue due to adverse reactions or pregnancy. In clinical trials with *** patients completed *** cycles, and a total of *** pregnancies was reported. This represents a pregnancy rate of *** per 100 woman years. Please see the special note in this labeling.

Senator NELSON. You are going to send us the literature that you distribute?

Dr. GUTTMACHER. That we shall, sir.

Senator NELSON. What do your clinics tell the user of the pill?

Dr. GUTTMACHER. I think I have said in my testimony that I cannot say, because I do not visit the clinics and see them operate, so I cannot tell you how much time is spent by each physician or nurse who is instructing patients as to the adverse reactions that might stem from the pill. I am moderately certain that if a patient asks questions, they are answered as frankly as the respondent can do it. But at the same time, I think I would be dishonest if I tried to tell you that every time a patient is given a packet of pills, the dispenser tells the patient about the difficulties. I cannot tell you this.

Senator NELSON. I thought you referred, when the literature was handed out—

Dr. GUTTMACHER. I think the literature covers this. This is covered by the literature. I am certain that if a doctor is terribly busy and the patient does not ask questions, he does not pause too long to tell her about the potential dangers. Perhaps he should.

Senator NELSON. I really think I should have said what is the patient told, what is the patient given orally, or—

Dr. GUTTMACHER. They are given both oral and written information. Of course, the oral information helps them choose what method of birth control they are going to select.

Senator NELSON. In your own judgment, if a woman decides to use the pill, should she be told anything about the side effects, number one?

Number two, should she be advised of any untoward symptoms which should cause her to consult a doctor?

Dr. GUTTMACHER. I strongly feel that if you are prescribing a pill to a patient who is not knowledgeable, you have the necessity to tell her that in very rare instances, there are clots formed in vessels which apparently are due to this drug, and that sometimes very dangerous situations may develop. I would tell her that this is mathematically most unlikely to occur. I would tell her that if there is any departure from her normal health picture, the pill might be responsible for these changes in her feeling of well-being, and that under all such conditions, she should promptly get in touch with the proper medical authority who dispensed the pill.

I would not, probably, tell her about cancer, because I think this is totally unproved. I do not think I would tell her about genetic changes, because this is totally unproved. I doubt very much whether I would tell her that her blood lipid are going up or there are going to be changes in liver—

Senator NELSON. Would you tell her that the incidence of thromboembolism, according to Dr. Lynd's study in England, was 9 times as great?

Dr. GUTTMACHER. Oh, yes, I think that is well documented. I am not sure I would use—it is 5 against 45.

Senator NELSON. That is right.

Now, would you tell her about the symptoms to observe? That is, if she experienced temporary blindness, migraine headaches, erythema, swollen legs, all of these things—would you tell her about those symptoms and advise her that, upon the showing of a certain set of symptoms, she should consult a doctor?

Dr. GUTTMACHER. I would certainly tell her about the possibility of headache. I would certainly tell her about the possibility of mood changes such as depression.

I doubt very much whether I would go into greater detail about other things, but I would try to make her understand that any departure from health should be reviewed by the physician so that he can make the determination whether or not the pill may be responsible for it.

Senator NELSON. But do you think, as the former Commissioner of FDA, Dr. Ley, suggested sometime back, and also a number of witnesses have testified, that some literature of this kind indicating what untoward symptoms to look for ought to be included with the pill package? Would you agree with this or disagree?

Dr. GUTTMACHER. I think it might be well to do it. I would prefer to have the doctor do it, but since we cannot depend upon him 100 percent, some literature, assuming it is accurate, might be valuable to put in. I think the patient might read it.

Senator NELSON. You are aware, I assume, that in the survey done for Newsweek, two-thirds of the women in that survey stated that they were told nothing about side effects by their doctors?

Dr. GUTTMACHER. No. I do not remember that.

Senator NELSON. Well, that is in the article. As a matter of fact, the article stated that that is one fact these hearings have dramatically demonstrated.

Dr. GUTTMACHER. Yes.

(The article referred to follows:)

[From Newsweek, Feb. 9, 1970]

POLL ON THE PILL—18 PERCENT OF U.S. USERS HAVE RECENTLY QUIT

For two weeks last month in hearings that headlines blazoned throughout the U.S., a roster of experts testified on Capitol Hill about the possible hazards of oral contraceptives. Most of the headlines were scary—more frightening, indeed, than any balanced perspective of informed medical opinion would justify. But just how scared were the women who are actually taking the Pill? To find out, NEWSWEEK commissioned The Gallup Organization last week to take a reading of the latest attitudes and actions among U.S. women using the pill.

The result was an eye opener. Largely because of all the recent publicity, 18 per cent of the 8.5 million U.S. women on the pill—nearly one in five—say they have stopped using it altogether. In addition, 23 per cent say they are giving serious consideration to quitting.

What makes the proportion of women who are defecting even more remarkable is the fact that many of them also say that they have had entirely satisfactory experiences with the pill. Fully 76 per cent of users say they have been "very satisfied" with oral contraceptives, and another 11 per cent were "fairly satisfied." Moreover, two-thirds of U.S. users continue to believe that the advantages of oral contraceptives outweigh the risks. Forty-one per cent of the women say they have had no side-effects or complications, and 38 per cent attribute their approval of oral contraceptives to their unquestioned effectiveness. "They protect me against something I don't want to happen," said a Grand Rapids, Mich., woman.

Quitting the pill—Have you stopped using birth control pills, or are you considering stopping, for any reason?

	Percent
Have stopped.....	18
Considering stopping.....	23
Neither.....	59

To conduct the NEWSWEEK poll, the Gallup researchers assigned women interviewers last week to telephone a representative national cross section of 895 women between the ages of 21 and 45. About one-fourth of the women reported they had been using the pill during the last three months, and these were interviewed further on their current use of the pill as well as their experience with it and their latest views on it. The results are therefore projectable, says The Gallup Organization, to all U.S. women 21 to 45 who have used the pill during the past three months. About 28 per cent of them are college graduates, and 65 per cent hold high-school diplomas. Forty-four per cent are married to men in white-collar jobs with incomes above \$10,000.

Doubts: Of the total of 41 per cent who have now quit or who are thinking of quitting the pill, a quarter say they have had doubts and anxiety because of side effects they have experienced themselves, or because friends of theirs have had side effects. A 26-year-old Whittier, Calif., college graduate, for example, told an interviewer of "a girl friend who almost died from a blood clot which was attributed to birth-control pills." A small number of women say they have given them up for no particular reason. But the biggest single group of defectors—roughly a third—said their doubts about the pill were directly related to the hearings of Sen. Gaylord Nelson's Monopoly subcommittee, where some experts testified about a possible link between the use of the pill and scores of disorders including blood clots and cancer.

Most of the women who quit because of the hearings were especially alarmed about clotting problems and cancer. A 22-year-old Mission, Texas, housewife quit the pill after five years of use because "I heard that it could cause cancer and heart disease, so I talked it over with my husband and he told me to stop." "I guess with all the talk about clots," said the 24-year-old wife of an East Keansburg, N.J., manual laborer, "I'm beginning to suffer from imaginary symptoms."

The influence of the recent bad news about the pill is easy to understand. An astonishing 87 per cent of American women have heard or read about the Senate pill hearings, a degree of awareness rare on public issues or events. And no matter what their own personal reaction, more than a third, on the basis of the reports, are prepared to believe that the pill is linked to cancer, blood-clotting problems, diabetes and heart trouble. There remain, however, a good many women who are not particularly frightened by what they have heard. Twenty per cent of the users believe that the relationship between the pill and cancer, or between the pill and blood clotting, has yet to be established, and another 14 per cent believe that conflicting testimony has made it impossible to reach positive conclusions about the hazards. "It seems to me most of the people who testified stressed the detrimental effects," said a wary housewife in Morristown, N.J. "You could die in childbirth just as easy as taking the pill," noted the wife of a Hastings, Neb., laborer.

Concern: One of the main purposes of the Nelson hearings was to determine whether women are being adequately informed by their doctors about the suspected dangers of oral contraceptives. And in the light of the survey, the subcommittee's concern was well founded. A startling two-thirds of pill-taking women say they have never been told about possible hazards by their physicians. On the other hand, only 16 per cent of women have taken the trouble themselves to discuss the dangers of the pill with their doctors as a result of the Senate investigation. Most of these were reassured by their physicians that the pill is safe and that they have prescribed it for a considerable time without noting serious side effects. An Omaha woman quoted her doctor as saying that he had prescribed the pill "long before they were called birth-control pills and never had any patient get cancer or anything else."

Less than 1 per cent of women have found their doctors to be totally against the pill. A Norfolk, Va., woman reported that her physician told her oral contraceptives were "not natural." And still other physicians seem evasive to their uneasy patients when asked about the risks of the pill. A 26-year-old Denver woman reported that her physician "couldn't be tied down to an answer."

The poll's findings of widespread alarm among women who have been on the pill proved consistent with soundings by NEWSWEEK correspondents among leading gynecologists across the U.S. Some said that, unfortunately, they could foresee an increase in unwanted pregnancies. "I've seen three pregnant women

this week who discontinued the pill about a month ago," said Dr. R. Elgin Orcutt, a San Francisco gynecologist. "Two of the three are applying for a therapeutic abortion."

Senator NELSON. Two-thirds of the women are not being told about side effects. I do not know how you persuade the physician to do it. Do you not think, then, that there is some obligation to see that they are informed?

Dr. GUTTMACHER. Yes, I would agree with that. I do not think that is too good a substitute. I would like to get the two-thirds of doctors who are not doing it to do it.

Senator NELSON. I would agree with you, but since the fact is that that is what they found—

Dr. GUTTMACHER. I think maybe these hearings have created a different attitude among physicians. I think a new Gallup Poll would not give you that figure.

Senator NELSON. But about the suspected dangers of oral contraceptives, and in the light of the survey, the subcommittee's concern was well founded, a startling two-thirds of pill-taking women say they have never been told about possible hazards by their physicians.

This is another reason why, in my judgment, the hearings are necessary.

Dr. GUTTMACHER. Yes, sir.

Senator NELSON. On these statistics, in the first page, Dr. Guttmacher, you state that according to a Gallup Poll reported in Newsweek, February 9, 18 percent of women using the pill had abruptly stopped using it and an additional 23 percent were giving serious consideration to quitting. That would leave the impression that, which I am sure you did not intend, that the Gallup Poll indicated that 18 percent were quitting because of something they had read about these hearings. That was not your intent, was it?

Dr. GUTTMACHER. I assumed that was the reason. Otherwise, either these hearings or what they had read in the literature, the Ladies Home Journal and various other publications in the previous 12 months. I do not think they make it quite clear as to the source, but certainly they took the Gallup Poll, because they assumed this was probably going to be the result.

I think it is naive to feel that some of this 18 percent, or most of this 18 percent did not stop because of the hearings.

Senator NELSON. Just going by memory, and I want the record to be correct, my memory is that in the survey 18 percent of the women stopping the pill, 6 percent attributed it to the hearings. So the other 12 percent were quitting it for other reasons.

Dr. GUTTMACHER. I see.

Senator NELSON. Of course, I am sure you will agree that that does not mean that that 6 percent, or even that 18 percent, are not going to go to some other method, is that not correct?

Dr. GUTTMACHER. A certain proportion will. I do not think you can tell exactly what proportion. I hope the vast number will, but we cannot prove it.

I think Dr. Daly found that the prescription of the pill in the tremendous Health Department Birth Control Clinics that they have in New York dropped from 67 percent to 47 percent among new patients. That is Dr. Edmund Daly.

Senator NELSON. All new patients?

Dr. GUTTMACHER. All new patients. 67 percent were choosing the pill. After the hearings, it went to 47 percent.

Senator NELSON. They went to other methods?

Dr. GUTTMACHER. Or are not taking, not using anything, I do not know.

Senator NELSON. I would just like to point out that without any hearings at all, if you surveyed the women who started the pill today, according to this Chicago study of Dr. Franks, 2 months later, 40 percent will have quit the pill.

Dr. GUTTMACHER. I do not know that study. I know the study by Frank & Tietze on 15,000 patients of Planned Parenthood. 70 percent were still on the pill after 30 months of use. That is a very distinguished study. I do not know this study that you referred to. But that is an excellent study. And the number of people on the pill is surprisingly high in that study. It is the highest continuation rate that I know of, sir.

Senator NELSON. Well, this is the testimony of Dr. Hugh Davis:

In a Chicago study, Frank found that 40 percent of those patients started on oral contraceptives abandoned the method within two months.

Dr. GUTTMACHER. Well, I hate to dispute my friend, Hugh, but I would love to see that article. Because if you got out the Frank-Tietze article, it is black and white that 70 percent or 15,000 patients were taking the pill 30 months after they had started it. This, to me, is an extraordinary figure.

Senator NELSON. He goes on to say:

In the Maryland Planned Parenthood Clinic—

Which he knows of first-hand—

half of the pill patients abandoned the method in less than a year.

So you have a massive dropout of pill users going on at all times without any reference to these hearings.

Dr. GUTTMACHER. Overseas you have more losses with the IUD, the patients discontinuing IUD, than pills. This has been the Korean results.

Senator NELSON. I just wanted to have it in the record, because most people do not realize that over half the people quit the pill in less than twelve months.

Dr. GUTTMACHER. This is true of all methods of contraception. One of the problems which we have is attempting to study the intellectual mechanisms that make people enthusiastic about contraception. We give them one or two good methods, then, for some reason or other, they abandon it. It is very strange. We have not solved this problem. But it is true of IUD, it is true of the pill, it is going to be true of the diaphragm as well. So they are not dealing with anything absolutely unique with the pill, sir.

I hate to be discourteous, but I have to catch a plane. I wonder whether it is going to be much longer that you wish me to stay.

Senator NELSON. You can run out on us any time you want. But I am all through. Senator Dole would like to ask some questions.

Senator DOLE. I would like to place in the record this Newsweek article with the poll on the pill.

Senator NELSON. We just asked to put that in.

Senator DOLE. That is fine.

The article does point out that a third of the ladies sampled did stop the pill because of publicity about these hearings. Maybe it is a good thing; maybe they should have all stopped, I do not know.

But I would hope, Doctor, that a man with your broad experience and expertise would be able to allay the fears of some people, with reference particularly to charges about cancer and some of the more serious side effects. You may have made the point, in my absence, that the pill is not perfect—not 100 percent safe. But you still feel, even after the testimony you have given on cross-examination, that it is still an effective contraceptive device or method.

Dr. GUTTMACHER. I think these hearings are the best argument in favor of the Tydings-Yarborough bill of anything I know. I think the Chairman agrees with me, because he is the best protagonist of that bill that I know.

Senator NELSON. I am happy to hear you say that, because I just testified on that bill, and I think these hearings will be very helpful in getting that bill passed and in getting substantial increases in funds for planned parenthood research.

One of the criticisms made in my appearance on the Tydings bill was that I thought the money asked for in the bill was inadequate.

Dr. GUTTMACHER. Thank you, sir.

Senator DOLE. Thank you, Doctor.

(The complete prepared statement of Dr. Guttmacher follows:)

STATEMENT OF DR. ALAN F. GUTTMACHER, PRESIDENT, PLANNED PARENTHOOD/
WORLD POPULATION; EMERITUS PROFESSOR, MOUNT SINAI SCHOOL OF MEDICINE;
LECTURER, MATERNAL HEALTH, HARVARD SCHOOL OF PUBLIC HEALTH; FORMERLY
CLINICAL PROFESSOR, OBSTETRICS AND GYNECOLOGY, COLLEGE OF PHYSICIANS AND
SURGEONS, COLUMBIA UNIVERSITY

Mr. Chairman and Members of the Select Committee on Small Business, I appreciate the invitation to appear before you in the hearings on the birth control pill, the invitation tendered me as a physician of long standing and as President of the Planned Parenthood Federation. In the latter capacity, I probably have one of the largest birth control practices in the world, since in 1969 slightly more than 350,000 women attended 525 centers conducted by Planned Parenthood in 130 cities of this country (1). I assure you this is a responsibility which neither I nor my organization, particularly its National Medical Committee and its capable Medical Staff, take lightly.

Senator Nelson, I believe that the primary consideration for these hearings was the health of American women. I interpret your more specific goals to be twofold—to have potential users of the pill forewarned of its risks and to make the medical profession more cognizant of their responsibilities in its prescription. Unfortunately, and I assume you share my apprehension, there have been undesirable side-effects from these hearings. They have created a sense of great alarm. According to a Gallup poll reported in *Newsweek*, February 9, 18 percent of women using the pill had abruptly stopped using it and an additional 23 percent were "giving serious consideration to quitting." Nineteen highly qualified physicians, members of Planned Parenthood's National Medical Committee, described at a meeting at our headquarters on January 28, that the hearings had caused great distress among patients. One is forced to ask why?

NOTE.—Numbered references at end of statement.

Certainly, nothing fundamentally has changed in respect to hazards from the pill since the hearings began and well-informed physicians found nothing revealed by the hearings which was not previously recorded in the published literature or presented at scientific meetings. The Second Report on the Oral Contraceptives, issued by the Obstetrical and Gynecological Advisory Committee of the Food and Drug Administration (FDA), completed six months ago and based on 189 references to the current literature, covered the same data as presented in the January hearings of this body. In many instances, these data were written by those who appeared as witnesses before you.

The FDA Advisory Committee, composed of 14 of this country's most eminent, unbiased physicians, public health experts, and highly qualified research scientists, all fully cognizant of this same data, concluded its report with the important sentence which I feel has not been given sufficient emphasis: "When these potential hazards and the value of the drugs are balanced, the Committee finds the ratio of benefit to risk sufficiently high to justify the designation safe within the intent of the legislation."

On January 15, 1970, the American College of Obstetricians and Gynecologists, in the name of its 12,000 members, said in its statement that it "considers that the oral contraceptives are accepted therapeutic methods" and deplored inaccurate and sensational reports concerning these drugs. At the January 28 meeting referred to above the distinguished physicians who form the National Medical Committee of the Planned Parenthood Federation issued a memorandum from which I quote the key sentence, "The Committee continues to recommend the prescription of oral contraceptives."

Why do I quote the report of the F.D.A. Advisory Committee, the American College of Obstetricians and Gynecologists, and the National Medical Committee of Planned Parenthood? Not to whitewash the pill. But I have compelling interest to place this matter in proper perspective in the hope, with which I am sure you will agree, of stemming unwarranted and dangerous alarm.

The pill is, in my opinion and that of many of my colleagues, a prophylaxis against one of the gravest socio-medical illnesses, unwanted pregnancy. Let us tally the results of unwanted pregnancy, a condition tragically common in the U.S.:

Experts estimate that between 200,000 and 1,000,000 illegal abortions are performed each year, with a death rate estimated to be 100 per 100,000 illegal operations when performed by non-medical persons (2).

At least one out of six U.S. brides is pregnant when married. Half of the brides are pregnant when the couple are teenagers (3).

No less than 300,000 illegitimate children will be born in the U.S. during 1970, based on the experience of the past decade (4).

A recent study shows that at least 750,000 children born each year were unwanted at the time of their conception (5). Undoubtedly a significant proportion lead to unloved, neglected, and abandoned children. Perhaps even worse, some become abused or battered children, children physically assaulted by parents or parent substitutes. This tragic condition is being reported more and more frequently in the current pediatric and psychiatric literature (6).

With all this evidence of social pathology associated with unwanted conception, I believe it is inaccurate to belittle the importance of the contraceptive pill by stating it is a potent drug given to healthy women. What is omitted from such a statement is the fact that the pill is the most effective means yet known to prevent a very serious affliction, unwanted pregnancy. It is a serious affliction for the parents, but far more for the children.

Now I should like to attempt to separate fact from conjecture concerning the safety of the pill.

I believe that it has been indisputably proven that patients taking birth control pills are more prone to the formation of blood clots than those not on the pill (7). Nine times as many women—45 per 100,000 women per year—will be hospitalized as a consequence of this complication than women not on the pill. There is a death rate of 3 per 100,000 per year from the fatal clots in the lungs or brain, among contraceptive pill users, a rate approximately 10 times that of non-pill users from the same conditions. These rates, established by British research, have been corroborated by American studies (8).

The British scientists who presented these data also prepared separate analyses for women aged 20 to 34 and 35 to 44 and, to give a frame of reference

and a perspective to these figures, they compared the death rate from blood clots to deaths from all conditions associated with pregnancy and with deaths from motor accidents.

They noted that among the younger women 22.8 of every 100,000 healthy married women would die as a consequence of pregnancy, compared with 1.5 of every 100,000 women who would die as the result of a fatal clot associated with the pill.

Among the older group, 57.6 of every 100,000 women would die as a result of pregnancy, compared with 3.9 who would die of a clot associated with the pill.

DEATH RATES PER 100,000 HEALTHY MARRIED FEMALES

Age-----	20 to 34	35 to 44
Thrombosis, lungs or brain pill users-----	1.5	3.9
Thrombosis, lungs or brain nonpill users-----	.2	.5
Pregnancy, all causes-----	22.8	57.6
Motor accidents-----	4.9	3.9

These data show that the risk of death from clots among the younger group of pill users is about one-fifteenth the risk of death from pregnancy and about one-third the risk from auto accidents.

I recognize that fact that not all women who will cease the pill will necessarily become pregnant. But were all the women to switch to the next two most effective contraceptive methods—the Intrauterine Device (IUD) and the diaphragm—the pregnancy rates would be two to four times higher with the IUD and 10 to 30 times higher among users of the diaphragm (9). Therefore, the risk of death would rise proportionately. To further complicate the picture, use of the IUD also carries a risk of death, of about 1 or 2 per 100,000 (10).

I should like to point out also that the death rate associated with pregnancy is even higher in the U.S. than in Britain, especially among poor women (11).

These are some of the considerations that must be weighed when assessing the safety of oral contraceptives.

In my interpretation of the published data, the only other established fact in this area is that other serious adverse reactions may occur in occasional patients. The more common are high blood pressure, headache, depression, interference with vision, and nervousness. Usually, these side effects are reversible and disappear if contraceptive pills are discontinued promptly. These rare adverse affects are well known to physicians and appear in the labelling of the drugs.

Now, as to metabolic changes: I recognize that fact that there are extensive changes in the body chemistry of some women taking the pill. But no proof exists in the medical literature, nor has any been presented before this Committee, that these changes are or will be harmful. Furthermore, in some patients the changes revert to normal while they continue on the pill; in others, when the oral contraceptive is discontinued.

In addition to these facts, there are *conjectures* about the pill. In underscore *conjectures*. First, that it may be carcinogenic, cause cancer.

Dr. Roy Hertz has stated before this Committee that to date *no* case of cancer in either a monkey or in a human being can be attributed to the pill. Many physicians and investigators believe that the fact that cancer can be produced in five species of animals (rodents and one breed of dog) by relatively huge daily overdosages with estrogen, comparing their body weight with that of a woman, produces little evidence that the contraceptive pill is likely to cause human cancer.

Dr. Hertz is concerned that the hormone, estrogen, a component of the pill, may cause cancer in two target organs in women on the pill: the breast and uterus. This is *conjecture*, by Dr. Hertz' own testimony.

It is of interest, I believe, that the American Cancer Society reports that there has been no increase in breast cancer mortality in the decade since the pill has been in use in the U.S. (12). This does not negate the possibility there may be an increase in the future in breast malignancy from the pill, but I believe the *fact* cited above deserves mention along side of Dr. Hertz' conjecture.

As to cancer of the cervix, the scientists who have done the most extensive study of this problem to date concluded that their findings do *not* establish that the pill causes the condition (13). And they stated unequivocally, "It is our conviction that death and disability from cervix cancer in any population can be eliminated, regardless of the method of contraception used, if a program of yearly Pap examination is established and all cases of carcinoma *in situ* (early cancer) are treated." The scientists concluded with this highly significant observation, "So long as regular visits to a physician are mandatory for women who are using the steroid contraceptives (the pill) in order to obtain a prescription, there is a possibility for them to have better medical care, with less danger from cancer of the cervix, than any other group of women."

The American Cancer Society verifies, as a matter of fact, that as a consequence of early detection by means of the Pap smear, death from cervical cancer has dropped in the past decade. This is not conjecture, this is fact.

The second *conjecture* I should like to deal with is that the pill, particularly if taken over a long period of time, may in some cases cause irremediable sterility. As the FDA report pointed out there is evidence that "resumption of ovulation is usually prompt, within 4 to 8 weeks in most cases." Some few women, however, have difficulty in becoming pregnant *perhaps* though not certainly as the result of the pill. Their problem fortunately can be corrected by appropriate therapy. It is strange how the medical pendulum swings; for years it was believed that there was heightened fertility after one stopped the pill. Perhaps this still may be true.

A third *conjecture* is that taking the pill may damage the chromosomes of ova within the ovaries. It may. But if this were true with the millions of American women having stopped the pill to achieve pregnancy, one would expect a sharp increase in congenital abnormalities. This has not happened.

I should now like to turn attention to the allegation that physicians do not forewarn recipients of the potential hazards of the pill, nor follow them with sufficient care. This may be true in some few instances; but in my experience physicians have behaved responsibly and with the best interests of their patients in mind.

This is certainly true in organized clinic programs where careful attention is paid to the instruction of patients in the use of various contraceptives. In Planned Parenthood clinics we have provided careful guidelines for the responsible prescription of oral contraceptives since they were introduced in our clinics. Earliest notices to our medical personnel regarding the oral contraceptives called attention to side effects and urged careful medical supervision. We have monitored research findings meticulously and have made these findings available to our Planned Parenthood physicians.

More than four years ago, on January 26, 1966, the National Medical Committee of Planned Parenthood issued a directive to all Affiliated centers outlining the following procedures for prescription of oral contraceptives:

1. *Initial Examination:*

Prior to receiving oral contraceptives a patient shall receive a complete pelvic examination including visualization of the cervix, a Papanicolaou smear, and examination of the breasts. The examination of other systems, including appropriate laboratory investigations, shall be determined by medical history.

2. *Follow-up Examination:*

a. *One month following initial prescription:* Consisting of an interview for teaching and instructional purposes and for assessing complaints. If the latter are severe or unusual the patient should be seen by the physician.

b. *Six months following prescription:* An interview for assessing complaints and a complete pelvic examination.

c. *Annual examination:* Subsequent to the six month examination, all patients should be seen annually and receive a complete pelvic examination, including a Papanicolaou smear and a breast examination.

I am proud to say my organization has not deviated from this policy.

I also wish to state that new patients attending Planned Parenthood Centers are and always have been offered a wide latitude of choice in the selection of

a contraceptive method. The several available methods are described to them either in groups or individually, depending upon the volume of patients, by either a doctor or a nurse. Ordinarily, questions are answered freely and honestly. Quite frankly, I cannot say whether potential risks of the pill are *always* presented by the discussant or only in answer to questions. I would assume this varies, depending upon the practice of the individual discussant.

After a long career in private, full-time practice of obstetrics and gynecology, I have little faith in the value of detailing the hazards of a drug, as printed on a label, to a patient. In the final analysis, for all but the most well-informed and intelligent patients, therapeutic decisions are made by the physician. Undoubtedly, in most instances, even after a patient reads a label or a printed insert about risks of the pill, she would turn to her physician and ask, "Is it safe?"

The physician who has just studied the patient's medical history and completed a thorough physical examination is best qualified to answer her question in consideration of her special needs.

Another area I should like to explore is, How necessary is the pill, I think it is very necessary. Of the 350,000 patients who attended our centers in 1969, 76 percent chose the pills. Its acceptability is mirrored in patient growth figures. The pill was introduced by us in August 1960, but few of the 122,498 women that year who sought our services received it. In the year previous to the introduction of the pill, increase in patients had been 4,000; but in 2 years, 1960-1962, we added 60,000 to our rolls. The number of patients has doubled since 1962. Undoubtedly, the growth is due to multiple factors, but among them all I feel quite certain introduction of the pill has been the most important.

Why is the pill so acceptable. First, it is so protective against pregnancy—almost as protective as celibacy—resulting in less than one unplanned pregnancy among 100 women using it for one year (14). This is no small consideration. We are all aware that fear of pregnancy can have serious adverse effects on the stability of a marriage. Second, the pill is simple to take, requiring little effort on the part of the user. Third, the birth control pill permits wholly spontaneous marital relations, since no contraceptive measures have to be instituted to achieve full protection from impregnation before, during, or after the sex act. This has tremendous psychic advantage to a host of women and to their husbands.

Some witnesses have assumed that some other equally effective contraceptive method can and will be readily substituted and accepted by anyone. I challenge this assumption. In the first place, no other birth control method equals the pill's protection against pregnancy. An IUD (nearest the pill in effectiveness) carried an annual failure rate of 3 per 100 users, while the diaphragm in a clinic population results in approximately 18 unplanned pregnancies per 100 users per year (15). Even among college educated women the diaphragm shows a substantial failure rate. Failures in contraception are of grave importance, particularly since state laws prevent correction through safe, legal abortion.

In the second place, I am extremely concerned that many women who abandon the pill through fright will not substitute another contraceptive because no other method has the high degree of acceptability for them.

Dr. Philip Sarrel, in his excellent Yale-New Haven Medical Center studies (16), has shown that recidivism in illegitimacy among high school students can be almost wholly prevented by the combination of humane counselling, education, and careful prescription of the pill. I fear that if these same adolescents were to abandon the pill, through fear of the health risk, few would be able to find a replacement method.

The pill is to date by far the best contraceptive for sexually active adolescents, judged by the experience of private physicians and by physicians in teen clinics in Baltimore, New York, San Francisco, among other places. In my estimation no other method compares with it. Apparently even Dr. Hugh Davis of Johns Hopkins who so thoroughly castigated the pill before you in January, agrees with this opinion. Dr. Davis is the clinician for Maryland's Planned Parenthood Youth Relationship Project which, among other services, provides contraceptive services for sexually active teenagers, many of whom have not yet become pregnant. He placed 23 on the pill while inserting IUD's in 14.

Dr. Arthur Lesser, Director of the Maternal and Child Health Service in the

Department of Health, Education, and Welfare, estimated that if current national trends continue, during 1970 approximately 70,000 girls under 18 years of age will have a child out-of-wedlock (17). If the pill scare continues unabated, I fear that figure will become a gross underestimate.

Nor are the harmful consequences of alarm over the pill likely to be confined to unmarried women.

I feel that insufficient recognition is being given to the pill's singular contribution to the happiness of married couples and the stability of their marriages. Rather than theorize and quote statistics, I should like to read excerpts from a letter received February 3 from a woman living in Alma, Michigan:

"Being a voluntary user of the pill for six and one half years, I feel that I should say something in defense of the birth control pill, because I feel it is possible that only those persons who are speaking out against the pill will be listened to. . . .

"The men I know of whose wives take birth control pills, my husband included, enjoy their wives more because they don't have to worry about getting their wives pregnant each time they make love, or worry about supporting a large family, or worry about not being able to give each child enough individual love and some of the material joys of life. There is the joy of being able to make love more often, if the couple so desires.

"But I feel that just because these pills are harmful to some, they shouldn't be banned from all women. The women I know who have had troubles are few, whereas the women who take them without any difficulty are many. I have discussed the possibilities of dangers with women after the frightening articles in a national magazine, and we all agreed that the best advice anyone could be given is to find a doctor you trust, follow his directions for taking the pill, and have frequent check-ups.

"The thought of banning oral contraceptives just because some people cannot take them would be as frightening as banning the use of penicillin or other drugs, just because they are harmful to some.

"I truly hope the few people who are fighting the birth control pill will lose their battle, so that the many of us who want to take it and have an easier and safer way of controlling the size of our families, may do so."

The third matter I should like to discuss is use of the contraceptive pill abroad, especially in the developing nations. I can speak to this issue from extensive personal experience. As Chairman for four years of the Medical Committee of the International Planned Parenthood Federation, and now as a member of that Committee, I travel three months of every year observing birth control clinics all over the world.

Both the IUD and the pill are used abroad. In Singapore, where a significant reduction in birth rate has been achieved through birth control programs sponsored by the Ministry of Health, the oral contraceptive is used exclusively. In Hong Kong and Egypt the pill and IUD are both employed. In Taiwan and South Korea the oral contraceptive is used as a back-up mechanism in patients who cannot tolerate the IUD. In the birth control clinics of Latin America the pill is used more widely than the IUD.

It concerns me that the alarming reports emanating from these hearings have burst the confines of American news media and have gained prominence all over the world. Distinguished physicians from Uruguay and Panama, in behalf of colleagues working in the family planning movement in Latin America, have been in consultation with me seeking advice.

Should we caution our colleagues to cease prescribing the pill? I answer with a strong, No! We support the use of the pill abroad for the same reasons we support its use here: It is an important preventive health tool.

Maternal mortality is hideously high in many of the developing countries—estimated at several hundred maternal deaths per 100,000 birth in Africa and much of Asia and Latin America, for example (18). Infant mortality, too, reaches almost unbelievable figures—in some countries as many as one-quarter of all babies die in the first year of life (19).

It is against these risks that the proven annual mortality of 3 deaths per 100,000 pill users must be weighed.

Sound programs of maternal and child health are a necessary essential component of population control programs.

Surely, with world population soaring and bringing in its wake malnutrition and starvation, overcrowding and increasing illiteracy, joblessness and hope-

lessness, it would be foolish to abandon use of this particular contraceptive and other methods such as the IUD because of the infrequent health risks attendant upon their use. Effective conception control is an important remedial effort the world over.

These hearings can have one important, positive effect: To highlight the desperate need for much more research in the area of contraceptive technology and reproductive physiology. We do not have the perfect contraceptive. Both the pill and the IUD, while vast improvements over older methods, leave much to be desired. In addition to the safety factor, these methods require medical supervision and are therefore costly and unavailable to many women around the world. Sizeable numbers of women cannot use one or another or both. The continuation rate after two years for our best methods is not good enough. What we need is new methods that are safe, free of side effects, cheap, require little medical supervision, act over a period of time, and are reversible when a woman wants to become pregnant.

A massive research program must be undertaken not only to document the true health status of the present oral contraceptive, to remove the issue of their safety from the current polemic status to the status of incontrovertible scientific fact. Research must also be undertaken to develop as rapidly as possible a multiplicity of safe and effective birth control methods to be used either by the female or the male.

To carry out such a broad and complete research program two elements are necessary: Talent and Money. Scientific talent is available. But the field of conception control research must be given the same glamour, urgency, and long-term funding now assigned to cancer, stroke, and heart research, to attract first-rate minds to the field.

Money has not been available from the Federal government in anywhere near the amount needed. Contraceptive research has been the stepchild of medical research, starved, ignored.

What is required is sizeable, long-term funding of a magnitude that is possible only from the Federal government. The sums thus far allotted have been totally inadequate. For this fiscal year, for example, only about \$5,000,000 has been requested by Federal agencies for both contraceptive development, and research into the safety and effectiveness of existing contraceptives.

Over the years, a variety of voices have raised the issue of adequate funding for contraceptive research. In 1967, a group of experts recommended to the Department of Health, Education and Welfare an expenditure of at least \$150,000,000 a year for research in reproductive biology; expansion of support for social research and training in population problems; a family planning and research demonstration fund of at least \$10,000,000 a year. Needless to say, these funds were not forthcoming (20).

In 1968, the President's Committee on Population and Family Planning recommended that a minimum of \$30,000,000 be allocated for biomedical and social science research and training in population in Fiscal 1970 and \$100,000,000 in 1971. Needless to say, these sums have not been made available (21).

I would like to call to the attention of members of this Committee action pending before Congress which can change this state of affairs.

A bill sponsored by Senators Joseph Tydings and Ralph Yarborough, and co-sponsored by 86 Senators and Representatives from both parties, urges a five-year authorization for "medical, contraceptive, behavioral and program implementation research in the area of family planning." The cost of this research would range from \$35,000,000 in Fiscal 1971 to \$100,000,000 in 1975.

It is my strong plea that the distinguished Senators forming this Committee support the Tydings-Yarborough bill when it comes to the floor of Congress. This will be a positive way for you to show your concern for the health and well-being of the women of our country as well as women all over the world—and for the population problem that poses such a threat to the well-being of all mankind.

Thank you.

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17. Lesser, Arthur, J. paper delivered Los Angeles, California, Feb. 8, 1968.
18. *Africa's Population Problem*, Victor-Bostrom Fund, Report #11, Spring, 1969.
19. Population Reference Bureau, 1969 World Population Data Sheet.
20. Harkavy, O., Jaffe, F., Wishik, S. M. *Implementing DHEW Policy on Family Planning and Population*, Sept. 1967.
21. *Population and Family Planning*, Report of the President's Committee on Population and Family Planning, Nov., 1968.

(A subsequent statement submitted by Senator Nelson follows:)

STATEMENT BY SENATOR GAYLORD NELSON

During the hearings on the oral contraceptives, there was some discussion as to how many women stopped taking the pill as a result of the hearings. Extravagant claims were made that a considerable number of women went off the pill, and this would result in many unwanted pregnancies.

The history of the pill indicates that the vast majority of women would have gone off the pill over the years, hearings or no hearings. Studies indicate that 25% to 50% of women who start to use the pill have over the years stopped its use within 3 or 4 to 24 months. In fact, as far back as April 1, 1963 the Director of Marketing Research for Searle and Company in a memorandum to the firm's medical director stated that:

"We discovered that as high as 70 to 75 percent of all patients who take Enovid do not continue its use beyond three months."

Indications are that a substantial percentage of those who go off the pill do so because of undesirable physiologic reactions they experience. This necessitates initiating an extensive research and development program which has been neglected during the last 10 years while the pill has been on the market.

A recent survey released on April 29, 1970 indicated a small drop in the use

of the pill. Whereas a year ago 72% of their patients desiring contraception were using the pill, the present level was about 65%, a drop of 7%. The survey indicates, however, that almost all those who have discontinued the pill have gone to other methods of contraception.

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PUBLIC RELATIONS DEPARTMENT—AO 312-782-3618—PRESS RELEASE FOR
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Since the Subcommittee on Small Business, chaired by Senator Gaylord Nelson of Wisconsin, began hearings on "The Pill," sensational headlines have appeared in newspapers across the country and physicians have been busy handling inquiries from concerned women on the subject of oral contraception.

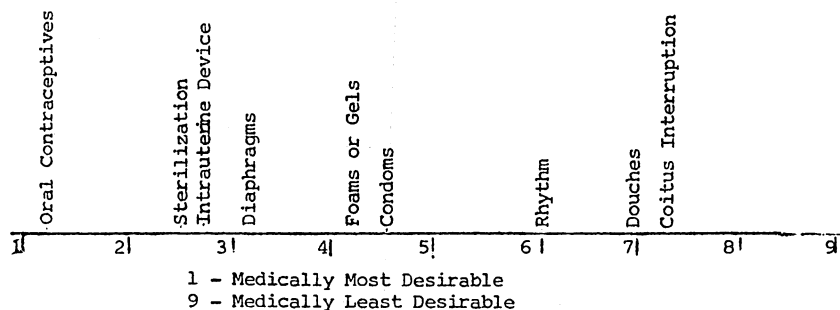
In addition, statements have appeared recently in the public press on the effect of the news reports emanating from the Hearings. Many statements have indicated that a significant percentage of users of oral contraceptives were sufficiently worried to discontinue this method of fertility control.

At the North American Conference on Fertility and Sterility held in late February at Dorado, Puerto Rico, clinicians were again warned that there were possible adverse effects from the use of The Pill, such as amenorrhea, infertility, and electroencephalographic changes. On the other hand, they frequently cited the lack of objective evidence for cause and effect relationships between The Pill and certain alleged side effects, pointing out that in many cases impressions are being taken as facts. All of these events are of serious concern to the practicing physician.

At the February executive meeting of the American Association for Maternal and Child Health, it was decided that the practicing obstetrician/gynecologist could make a valuable contribution to knowledge in this area. Accordingly, the Board of Directors asked the Association's executive secretary, Harold J. Fishbein, to conduct a survey among the approximately 13,000 obstetrician/gynecologists to determine their attitudes and recommendations concerning birth control methods. There was a high interest in the aims of the survey, and over one fourth of the physicians replied to the lengthy questionnaire.

Summarizing the responses, 3,240 (97%) physicians believe oral contraceptives are medically acceptable; 61 (2%) believe they are not, and 51 (1%) are undecided. This vote of confidence for The Pill is the result of a careful balancing of the risks and benefits involved. The survey asked physicians to rank contraceptive modalities, considering pregnancy risk, general user health, and patient convenience. The results of the process appear below: oral contraceptives, with a ranking of 1.6 on a scale of 1 to 9 (where 1 indicates high desirability and 9 indicates low preference), are still the preferred method of birth control. Next, with a ranking of 2.7, was sterilization, followed by the intrauterine devices at 3.0.

PHYSICIAN RANKINGS OF BIRTH CONTROL METHODS



Though practicing physicians continue to endorse oral contraceptive use, many women have reacted to the recent publicity about the safety of The Pill. Obstetrician/gynecologists report that new patients asking for oral contraceptives have declined by 20% since the recent publicity. Further, established patients using oral contraceptives asking about safety tripled in the same period. Usually these patients are just seeking reassurance. After a discussion with their physician

about the comparative risks and benefits of all the available birth control methods, 82% elect to remain on The Pill.

Despite current observations of a 20% drop in oral contraceptive use among new patients and 18% among especially concerned patients, these physicians report that when all patients under their supervision are considered, the decline in the Pill's use is much smaller. A year ago, 72% of their patients desiring contraception were using The Pill. Now they estimate this level at 65%, a drop of 7%.

[In percent]

Percent of patients using—	Now	Last year
Oral contraceptives.....	64.5	72.0
Diaphragms.....	6.7	4.8
IUD.....	8.9	6.3
Rhythm.....	3.9	3.4
Condoms.....	3.1	2.6
Foams or jellies.....	5.5	4.6
Sterilization (husband or wife).....	2.3	2.2
Douches.....	.3	.3
Coitus interruption.....	.6	.5
No method.....	2.7	2.7

Apparently physicians have no strong preferences for other modalities than the oral contraceptive. Gains for the other birth control methods, as a result of declined Pill usage, have been across the board. One possible exception noted was that when physicians opt to change a patient from oral contraceptives for health reasons, they tend to avoid giving intrauterine devices.

Based upon the findings that practicing physicians consider the oral contraceptive to be the most desirable method of birth control, the Board of Directors of the American Association for Maternal and Child Health, Inc. voted to release the findings of the survey at a public press conference at 3 P.M., April 29, 1970, to send the press release to all interested agencies, to present the report to all practicing obstetricians and gynecologists in the United States, through the bi-monthly Newsletter of the AAMCH, and to lay readers through Mothers-to-Be, and the American Baby, Inc., the Association media for parent participation membership.

Senator NELSON. The next witness is Dr. Mary Lane, clinical director, Contraception Service, Margaret Sanger Research Bureau.

Dr. Lane, I apologize to you and to the rest of the witnesses for having proceeded so slowly this morning, as sometimes happens in hearings of this kind. We did want Dr. Guttmacher and everybody else to have the time they need. Now I see we are up against a schedule problem. We have to abandon this room at 2 p.m., and I did not know that before now.

STATEMENT OF DR. MARY E. LANE, CLINICAL DIRECTOR, CONTRACEPTION SERVICE, MARGARET SANGER RESEARCH BUREAU, NEW YORK, N.Y.

Dr. LANE. Senator Nelson, I was very happy to have been invited to appear before this committee. I would like to point out that I am responding to an individual invitation to me. I am not simply accompanying Dr. Guttmacher.

Senator NELSON. That is correct. We are very pleased to have you.

Dr. LANE. Thank you.

Your letter to me suggested that I speak of the pill as I see it from the standpoint of a practicing physician. This is one of the things I like to talk about most, not necessarily the pill, but contraception in general and what my general ideas are about the way contraceptive care should be given.

My experience in this field really antedates my appointment to the Sanger Bureau. In my general practice of medicine for some 8 years, I, of course, rendered contraceptive service to my patients.