Mr. Taxpayer as well, just what it's all about.

Last month, the NAS nominating committee finished its labors in a way that left no doubt about one essential point: the immediate future of science in the United States will be focussed on a concern for life. The NAS presidential nominee is Duke University biochemistry Professor Philip Handler.

Handler is famous for his research in biochemistry, ranging from amino acid metabolism in muscle to the mysteries of ammonia synthesis in the body, from the relationships between kidney function and high blood pressure to problems of skeletal growth and the role of vitamins in deficiency diseases.

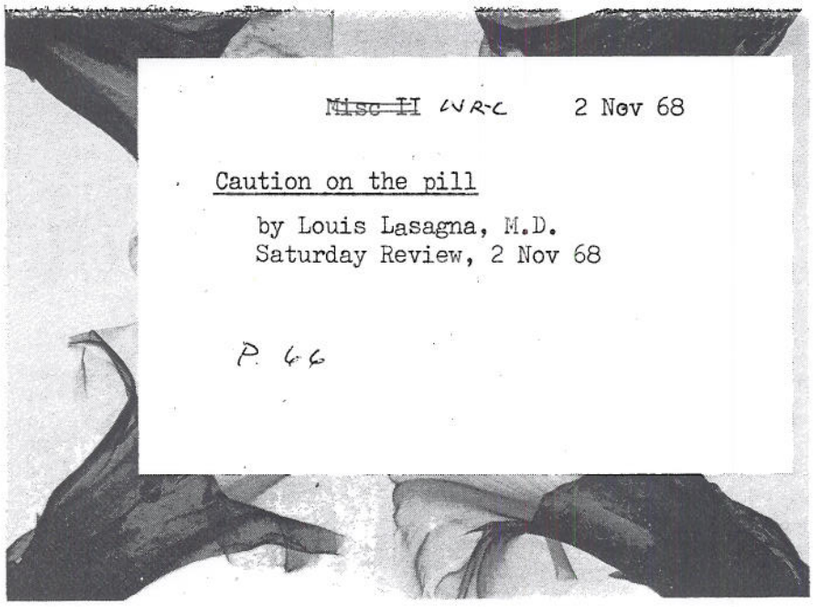
Within NAS, Handler already ranks high as a member of the governing council, the seventeen-man body that determines NAS policy. He is also chairman of an *ad hoc* committee that has been surveying the needs of research in all the life sciences.

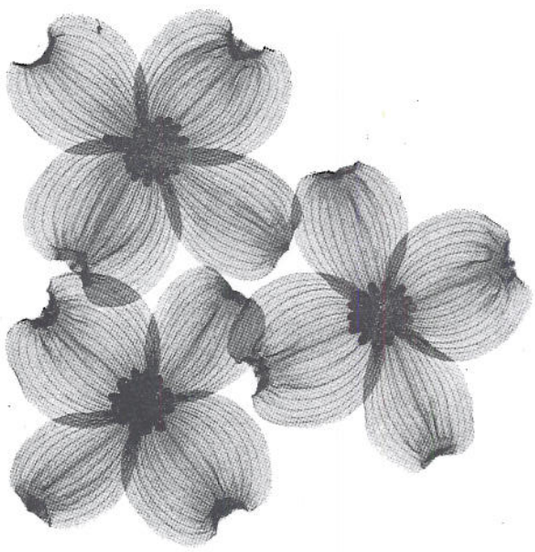
His political finesse has been demonstrated by a rapid rise through the scientific hierarchy in Washington. He was a member of the President's Science Advisory Committee and is now chairman of the National Science Board, the twenty-four-man policymaking group of the National Science Foundation, America's bank for basic science.

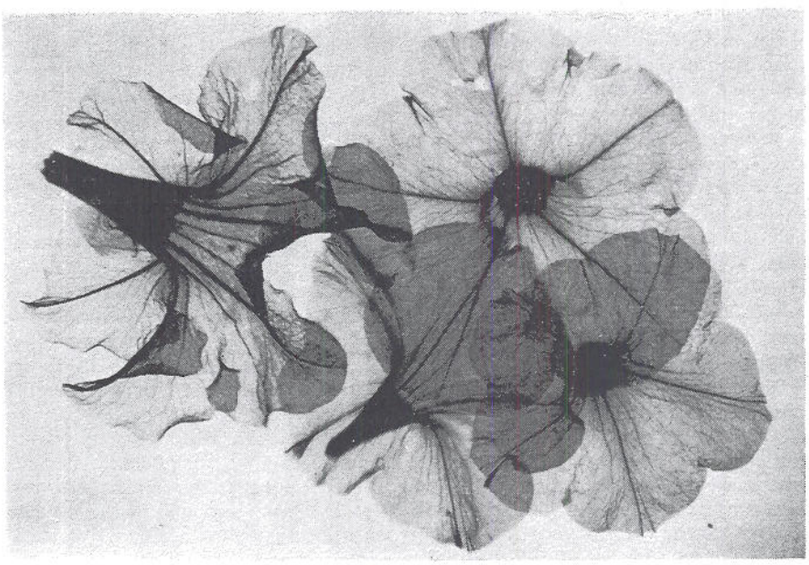
Nomination as president of NAS does not guarantee election for Handler. One of the most creative presidents in NAS history, Rockefeller University Professor Detlev Bronk, was elected following nomination from the floor of an NAS convention—in opposition to the slated choice of the nominating committee. Since that happened, however, the old floor-voting procedure has been supplanted by a mail ballot. Nominations rivaling that of the nominating committee of 1968 can be entered only by petitions signed by fifty persons each.

Polling of the 806 NAS members is now underway. Those who wish to name challengers to Handler must do so by December 1. On December 15, NAS Home Secretary Merle Tuve will send out the final list, which must be returned by January 15. Election is for a maximum term of six years, beginning next July 1. A shorter term is negotiable between the nominating committee and the nominee. Re-election to a second term is allowed. The salary is not a public statistic, but Dr. Frederick Seitz, who is now in process of moving from NAS in Washington to the presidency of Rockefeller University in New York, once told a reporter the figure was $45,000 a year plus residence in a quarter-million-dollar mansion.

Medium-tall, balding, with grey patches bordering the ears, Handler is dynamic, articulate, and able to talk the layman's tongue. —JOHN LEAR.







—Photos courtesy Oak Ridge National Laboratory News.

X-ray photographs of three flowers: morning glories (top), dogwood (middle), petunias (bottom).

year-old housewife. His report prompted a Sussex physician to describe two similar cases and to state that he knew of at least three others. A Newcastle physician announced that the autopsy on one of his young women on the pill showed clots in the arteries on both sides of the brain.

In April 1965, the Johns Hopkins neurophthalmologist, Frank Walsh, asked his fellow specialists (via the *Archives of Ophthalmology*) to report to him any cases they had seen with visual troubles similar to those he had observed in women on oral contraceptives. By November he had assembled some sixty cases in this way—seventeen with strokes, twenty-one with eye troubles, and twenty-three with other symptoms, including migraine. Without claiming a cause-and-effect relationship, he nevertheless wished to put the experience on the record and to ask for further study.

Meanwhile other physicians continued to report deaths as a result of compromise of the blood supply to the nervous system. One twenty-six-year-old Englishwoman died of a clot in her vertebral artery after a seven-week illness during which she had paralysis of all four extremities. In Ireland, a twenty-five-year-old patient expired with a large dead area in her brain caused by a clot in the carotid artery.

Dr. Sherif Shafey in Miami was at the same time accumulating his own series of thirty-four women, ranging in age from twenty to thirty-nine years and all receiving some form of oral contraceptive, who developed various sorts of neurologic complications, including migraine headache and clots in the arteries and veins of the brain.

NEXT, effects on the heart were reported. In January of 1965 a Norwegian pathologist described the sudden death of a thirty-two-year-old woman who had been taking oral contraceptives for five months. Postmortem examination revealed that the smaller branches of the coronary arteries were plugged with clots of various ages, with resulting death of the heart tissue. This was followed by a fatal case from England with clots in all of the major arteries of the heart; others have since been noted.

Why have these cases been put on record by physicians from various parts of the world? All the complications described are known to occur in people who do not use oral contraceptives. No new diseases have been seen. Why, then, the concern over the possibility of a cause-and-effect relationship?

It must be remembered that the suspicion of alert physicians is almost always the first indicator of pharmacotherapeutic mischief. Rarely can the doctor do more than suspect a cause-and-effect relation between drug and toxic effect, since hardly any drug's side effects are unique to that drug. Further, massive pulmonary embolism, strokes, and heart attacks are relatively rare in young women. This is a recurrent theme in the statements of concerned physicians, such as the British doctor who wrote:

> This cause of death [pulmonary embolism in a twenty-two-year-old woman on oral contraceptives for a few months] . . . in young people is extremely rare. In the few cases I have seen in young women there has always been some underlying explanation. . . . It is this feature which has been worrying me in my examination of an otherwise perfectly healthy woman. My own feeling is that [it] is just too much to be a coincidence. I have never seen a similar case . . . and I have seen many unexpected deaths in young people. This does not amount to proof.

Supporting this sentiment was a letter from a Cambridge scientist who disclosed the following information:

> From 9,280 consecutive autopsy reports . . . covering 1946-63, we have collected 27 cases [of massive pulmonary embolism] under the age of 70. Of 21 . . . females, only 3 women were under the age of 45, and they were either pregnant or had recently been pregnant. Thus we have no examples of non-pregnant women . . .

Other studies are in agreement. The coroner's records of Cuyahoga County in Ohio were reviewed in 1964 to see how often pulmonary embolism and unexpected sudden death occurred in supposedly normal persons between fifteen and forty-five years of age. Sixteen females had died in this manner during an eleven-year period. Five of these were pregnant at the time of fatal embolism, and eight of the eleven non-pregnant females were over forty. Thus, while such unexplained deaths are not unheard of in young women, they are decidedly rare.

In Hamburg, Germany, a study was made of fatal pulmonary embolism in a series of 5,200 autopsied cases. Of 500 consecutive cases of pulmonary embolism, half were in women, but their average age was seventy, and 95 per cent were over fifty.

A few cases have shown such unusual autopsy findings as to alert doctors to a generalized clotting tendency. In one case autopsied at the Johns Hopkins Hospital, for example, there were numerous clots in arteries and veins all over the body, without any actual disease of vessel walls.

But there are other compelling reasons for suspecting the oral contraceptives as a causative factor in these vascular catastrophes. Many of the scientists who have worked with the pill have compared the endocrinologic state induced by these synthetic steroids with pregnancy. While this view is not universally held, there are at least certain parallelisms between normal pregnancy and drug-induced pseudo-pregnancy. As stated above, pregnancy carries with it a definite risk of clotting difficulties, related in part at least to the hypercoagulable state associated with the hormonal alterations undergone by the expectant mother. Both during pregnancy and the taking of oral contraceptives, there is also a reduction in blood-flow velocity in the extremities, which favors the formation of sludge in the vessels of the limbs.

Although the pill buffs tend to ignore them, a substantial number of studies have now been performed to determine whether oral contraceptives affect the clotting capacity of the blood. They have been conducted in such diverse places as Oslo, Norway, and Manchester, England, and in the United States in Washington, D.C., Minneapolis, Brooklyn, Philadelphia, New York, and Seattle. The majority agree on the fact that there are changes from the normal, even in asymptomatic women taking oral contraceptives. These scientists have not all used the same tests, but in general there have been increases in four blood fractions including fibrinogen (the precursor of fibrin, which eventually forms the clot). Blood platelets, in the two studies focusing on this blood constituent (which helps clots to start), were also increased in number. Only one index of blood clotting—the so-called fibrinolytic system—possibly changes in a direction that might impede normal clotting. *All the other changes are such as to encourage the clotting of blood.*

There are other reasons for worry. In several studies in men and women who have been given female sex hormones as treatment for atherosclerosis of the brain or heart, or for cancer of the prostate, there have been significantly more deaths in the treated patients than in

---

" 'That kills my faith in the pill. I think I'll picket the company.' —Victor Millar, father of quadruplets born yesterday in Ottawa [Canada, after Mrs. Millar, 30, had taken birth control pills for about a year]."

—The New York Times
QUOTATION OF THE DAY,
SEPT. 21, 1968.

---

the control (untreated) patients, with more strokes, heart attacks, or both.

Studies of blood fats have shown changes in women on the pill that resemble those seen in post-menopausal women, who have a higher risk of heart attacks than younger women. One extremely provocative report involved a Mead Johnson oral contraceptive that was under trial in 7,000 American women. Trials were suddenly halted when British workers giving "massive doses . . . daily and continuously for several months" to dogs reported thromboemboli in the animals.

A number of researchers have been intrigued by the relationship between hard-water areas and the decreased occurrence of hypertension and other cardiovascular diseases. It has even been suggested that a diet deficient in magnesium may be partially responsible for the high incidence of arteriosclerosis in Western nations. In 1966, Doctors John and Naomi Goldsmith reported serum magnesium concentrations to be lower in non-ovulating women and women on Enovid than in ovulating women. The finding calls only for speculation at present, but it supplies another bit of evidence to remind us of the multiple effects of hormonal agents.

WITH such highly suggestive data, how can one explain the unwillingness of many physicians even to consider the possibility of clotting troubles in some women taking oral contraceptives? One major reason for this apathy is the now famous report of the 1963 Advisory Committee asked by the FDA for guidance in evaluating thromboembolic morbidity and mortality.

The committee decided to focus only on fatal complications, because of the difficulty in tracking down nonfatal cases. (A patient whose lungs were riddled with clots and who survived only because of heroic cardiopulmonary surgery, or who suffered a disabling but nonfatal stroke, thus did not enter into the committee deliberations.)

It was necessary to know how many women had died while on Enovid, the drug under investigation. For this purpose, they relied completely on the files of G. D. Searle, the manufacturer. This was the first and most appalling mistake. No drug manufacturer can possibly have complete records of the deaths occurring among patients taking his drug. To have such complete records would require that every such death be associated in the attending doctor's mind with the possibility of its being caused by Enovid, that he always know whether patients have been on Enovid, and that he report every such case to the manufacturer. All experience is contrary to these assumptions. Even in hospitals where drug reactions theoretically must be reported by the medical staff, and simple cards are provided for such purpose, the true incidence of drug toxicity varies from ten to fifty times the incidence calculated from voluntary reports.

The committee also relied on photostats of death certificates for knowledge of what was occurring in the population at large. Regrettably, death certificates are notorious for their inaccuracies, especially when autopsies are not performed. As Professor L. M. Schuman, a member of the committee, said on a later occasion: "In view of the fact that one of the greatest sources of error in hospital statistics is the glib assignment of a clinical diagnosis to pulmonary embolism . . . , epidemiological studies utilizing mortality sources should confine themselves to autopsy . . . [findings]."

THERE was also no clear information on how many women were taking the pills. It was known roughly how many prescriptions had been filled and renewed for Enovid, and after some crystal-ball gazing, it was decided to subtract 300,000 (primarily to exclude duplicate prescriptions) from the maximum estimated numbers of users to give a tidy—but possibly inaccurate (guesses on the total number of women using the pill range from 3,800,000 to 6,000,000)—figure of 1,000,000 women. No one on the committee seemed to worry, however, about the fact that it was important to know not only how many women took Enovid during a given year, but also how long they were on Enovid. (A lady on for only one month is obviously not at risk from the drug for the whole year; to assume so is to make the drug look safer than it is.)

Next, the committee decided to throw out some of the Enovid deaths, for a variety of reasons. Unfortunately, such selective discarding of cases could be done easily for the Enovid cases, but not for the control group. The latter were studied only by analyzing death certificates, whereas the Enovid files contained autopsy reports, clinical information, charts, etc., solicited by the manufacturer or voluntarily supplied by interested doctors.

There were many other assumptions as well, but these are perhaps the most disturbing. What, then, could anyone conclude from such an analysis? Nothing, of course, which is exactly what the report says:

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

Unfortunately, the report also included the statement that "no significant increase in the risk of thromboembolic death from the use of Enovid in this population group has been demonstrated." The FDA, the pill enthusiasts, and most physicians have since then acted as if the report, which is based on incomplete data of dubious quality inappropriately analyzed, actually proved for all time that there was no risk.

This attitude has been encouraged by several other factors. The manufacturers of Enovid, for example, have periodically informed the world that the cases reported are not in excess of those "anticipated." In 1965, their medical director published a paper with the astonishing news that the thromboembolic morbidity was actually less than a quarter of what might have been expected. He conceded that the discrepancy "is very likely a reflection of inadequate reporting" but concluded with the unequivocal assertion "that massive use of Enovid has not increased the incidence of thromboembolic disease in women."

A second source of misconception is the group of experts who for one reason or another have decided that the pill's advantages must not be sullied by any doubts. One argument is that pregnancy is risky, too, and that the troubles women get into on the pill must be balanced against the medical risks of pregnancy. Such an argument is reasonable, of course, only for those women who cannot possibly use any other effective contraceptive technique.

Dr. Erik Ask-Upmark, head of the Department of Medicine at the University of Uppsala in Sweden, reviewing his own and others' experiences with thromboembolism in women on oral contraceptives, pointed out the highly suggestive recurrence of trouble in several women as they took repeated courses of pills. His report ends: "If any female member of my own family applied to me to get oral contraceptives I would most certainly not dare to give it to her."

In 1965, a World Health Organization (WHO) Scientific Group came in with their own report. There was a cer-

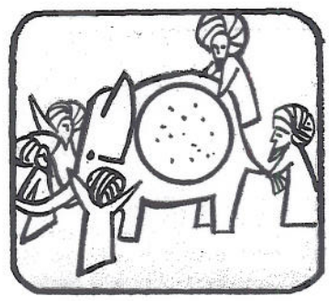
WARREN REPORT?

tain friction in the committee, especially from an American expert who bridled at the need—spelled out in WHO rules—for unanimous recommendations. The report pointed out that incidence of thrombophlebitis is highest not in pregnant women, but right after delivery, when hormonal levels are lowest. This was meant, presumably, to exonerate the pill, which is said to produce a "pseudo-pregnancy." It might be argued, however, that women on the pill have a "pseudo-delivery" once a month, as they suddenly stop the pill in order to menstruate. (Such an argument presumes that the pill produces a menstrual cycle more like pseudo-pregnancy than normal menstruation.) Recent studies also suggest that much of the clotting troubles seen after delivery are not "spontaneous" but due to estrogens given to suppress lactation in non-nursing mothers.

The report also made an interesting and subtle point: Many doctors will not prescribe oral contraceptives in women with a history of thromboembolic disease. Thus in a sense the pill is being given to healthier women than the average population, possibly biasing present risk estimates in favor of the pill. The committee concluded that oral contraceptives were extremely effective and that no cause-and-effect relationships had been established for serious adverse effects. Nevertheless, it listed twenty unmet research needs, including the effects of the pill on the pituitary, "higher nerve centers," thyroid, adrenals, carbohydrate metabolism, ovaries, cancer development, genetics, uterus, vagina, lactation, infants, liver, blood, weight, emotions, congenital anomalies, and a variety of diseases!

In 1966, the Food and Drug Administration came up with still another report on oral contraceptives. Unfortunately, the expert committee was no more able than its predecessor to make factual statements about serious risks from the pill. It acknowledged that deaths from thromboembolism were of concern, and that "the present system of reporting deaths and adverse reactions relies on either the cooperation of physicians or the haphazard filtering of rumors to detail men. The latter route is patently unreliable, and the former not much better. Physicians are becoming increasingly fearful of reporting deaths or adverse drug reactions because of possible legal reprisal." (I know of two deaths in Baltimore—from strokes in twenty-one- and twenty-six-year-old girls – unpublicized for this very reason.) The report reiterated that available data could neither confirm nor refute the role of the pill in thromboembolic disease. No progress, in other words, since the 1963 FDA report.

The committee expressed worry about



the carcinogenic effects of estrogen taken for long periods, admitted that long-term studies to tell whether the pill might cause cancer were unavailable, but concluded that no maximum limits should be set for how many years the pill might be taken.

Other risks were also discussed, but the important conclusions reached were as follows:

> The committee finds no adequate scientific data, at this time, proving these compounds unsafe for human use. It has nevertheless taken full cognizance of certain very infrequent but serious side effects and of possible theoretic risks suggested by animal experimental data and by some of the metabolic changes in human beings.
>
> In the final analysis, each physician must evaluate the advantages and the risks of this method of contraception in comparison with other available methods or with no contraception at all. He can do this wisely only when there is presented to him dispassionate scientific knowledge of the available data.

DR. ROY HERTZ, a National Institutes of Health endocrinologist and cancer specialist, filed a minority report for the committee that took a much graver view of the pill-cancer problem. He reminded people that all known human carcinogens show a long latent period—most of them about ten years, but ranging up to forty years—and that in most instances there is no way of detecting this fact during the period when the cancer is "cooking," as it were. Hertz also pointed out that all known human carcinogens are also carcinogens in animals and that therefore animal data are not irrelevant, as some have claimed. (It is ridiculously easy to produce tumors of all kinds in rats, mice, rabbits, hamsters, and dogs given estrogen, and early in 1966 an investigational drug of this class under study by Merck Sharp and Dohme was hastily removed from clinical trial when dogs developed breast cancers after a year of treatment.)

He then reviewed the accepted evidence that a young woman's own estrogen or estrogen in pill form can make breast cancer worse, and observed that most breast cancers are probably in existence for years before they become clinically apparent. Hertz derided the claims that use of estrogens in women over the last twenty-five years had not changed the incidence of breast cancer, because most of the women so treated have not been young women, but were post-menopausal, and there is clear evidence of a difference between these ages in response to female hormones—estrogens are even used successfully to treat breast cancer in older women. He further revealed that the entire world literature on the risk of prolonged estrogen therapy causing breast and genital-tract malignancy is based on a pitifully small sample of less than 1,000 women, of whom only eighty-five were under forty years of age. He then performed a similar analysis of the worrisome situation with regard to uterine and cervical cancer, and the possible effects on ova and children ultimately born from the eggs of women who have taken the pill. In none of these situations could Dr. Hertz find reason for complacency. He ended with this unequivocal recommendation: "In view of the serious limitations in our knowledge of the potential long-term effects of estrogen-progestogen combinations, it is mandatory that further clinical experience be gained under properly controlled conditions of observation and follow-up."

The FDA report elicited predictable reactions in the interested parties. Physicians suspicious of the pill saw cause for alarm, and found no reassurance. The drug manufacturers saw the report as an exoneration of the drug. Dr. Louis M. Hellman, chairman of the FDA Committee, said the report was a "yellow" caution light. Dr. Alan Guttmacher of Planned Parenthood read it as "a complete green light." One could only recall the story of the blind men describing the elephant.

The British at first did no better than the Americans. In a country with a highly organized National Health Service with allegedly good record-keeping on drug usage, they relied on voluntary reporting by doctors instead of careful detective work on women in the child-bearing years who died of strokes, heart attacks, pulmonary emboli, etc. The results were as inconclusive and unsatisfying as might be expected: "At present the number of deaths [voluntarily] reported is small and does not differ remarkably from expectation . . . [however] the deaths reported . . . may represent an underestimate . . . no firm conclusion can be drawn . . ."

A week earlier, in the *British Medical Journal*, which carried the above report, a distinguished Oxford professor wrote on "Adverse Reactions to Drugs," pointing out that the actual incidence of toxicity with a new drug with which he had worked was twenty-five times higher

than one would guess from voluntary reporting by practitioners, and that one could, temporarily at least, quadruple the reported incidence by sending official requests for information to all British doctors. Obviously the hazards of under-reporting are universal, as is the likelihood that official government committees and drug manufacturers will neglect these hazards.

In the spring and summer of 1967, however, three independent British studies were reported that finally began to clarify the thromboembolic danger. All delivered an affirmative answer to the question, "Can oral contraceptives cause thromboembolism?" In the words of a Medical Research Council Subcommittee: "The sum of evidence . . . is so strong that there can be no reasonable doubt." It remains to be seen what impact, if any, these findings have on the prescribing habits of physicians.

ALTHOUGH the blood-vessel abnormalities have received the greatest publicity, other potentially serious complications of the pill have been reported. In 1964, some Finnish scientists reported abnormal liver function in seven postmenopausal women who consented to take oral contraceptives for a month. Despite dissents from some experts and manufacturers, there has now been convincing confirmation of this phenomenon in different parts of the world, including the United States, and involving women in their twenties as well as older females. Particularly at risk of developing jaundice are those rare women who develop the unexplained "jaundice of pregnancy," which is probably also attributable to hormonal changes. It is not reassuring to learn that mestranol, present in most oral contraceptives, can cause severe liver damage and even liver cancers in rats taking the drug in high doses for prolonged periods.

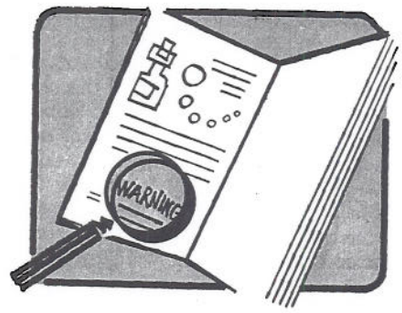
Others have observed decreased tolerance for glucose in some women taking oral contraceptives, with "chemical diabetes," a phenomenon again reminiscent of what occurs during pregnancy. Whether this is related to the changes in blood concentration of adrenal or thyroid hormones that occur in women on the pill is not clear.

A few letters have appeared in the British journals describing strange muscle pains or symptoms of neuritis associated with the taking of oral contraceptives, and diarrhea related to structural changes in the lining of the small intestine. American doctors have seen dilatation of the ureters in women taking oral contraceptives.

Gynecologists have occasionally observed severe uterine bleeding in women who have stopped the pill after prolonged cyclic therapy for contraceptive purposes. The bleeding is thought to be due to overgrowth of the lining of the uterus secondary to disturbance of normal feedback mechanisms among the ovary, the hypothalamus, and the pituitary. Other gynecologists have been troubled by the development of an "obstinate" form of vaginitis due to the yeast Monilia in women taking oral contraceptives, curable in many cases only after the pills are discontinued.

Psychiatrists have been upset by the unpredictable mental effects of the pills. Some women on them claim an increase in sexual desire and pleasure, but others become frigid, a situation reversible by stopping the pills and using mechanical devices. Dr. William Masters, co-author of *Human Sexual Response*, said that when referring physicians or marriage counselors ask him to see a woman for secondary frigidity, his first question is: "Has she been taking the pill?" There has been an increasing awareness of depressive reactions, with crying spells or suicidal ideas, in women taking these hormones. Some believe that the pills can make a latent depressive state overt or aggravate an existing melancholia. Remission may not follow promptly on withdrawal of the drug. (However, it must also be stressed that some women, such as those who suffer from severe premenstrual tension, may be helped remarkably by oral contraceptives.)

FEARS about the long-range effects of oral contraceptives on fertility have ranged from apprehension about ultimate infertility when the pills are stopped after years of use to the possibility that oral contraceptives, by preventing ovulation, may prolong the period of potential childbearing so that pregnant fifty- and sixty-year-old grandmas will be possible. One Canadian physician has even suggested the possibility of a new specialty of "geriatric obstetrics" to care for such aged parents. There are no convincing data at present to support either notion, although both American and Australian physicians have suggested that some women may suffer long-term interruption of their ovulatory cycling as a result of the pill, with prolonged failure of menstruation (and infertility) after stopping the medication. Proponents of the pill promptly labeled the reports "misleading" and the conclusions "unwarranted."



In view of all the side effects reported with the pill, and the clear evidence that some 10 to 25 per cent of women refuse to go on with oral contraceptives because of dissatisfaction of one sort or another, it is confusing to have their enthusiasts deny such defects. In April 1966, *The New York Times* ran a "gee-whiz" type of article about the pill entitled "Three Men Who Made a Revolution." In it, Dr. Gregory Pincus commented on the medical advertising for some newer-type sequential and low-dosage pills: "These ads are creating a false emphasis. There may be a minute lessening in side effects, but since all present side effects are insignificant, I see absolutely no advantage in sequentials."

Such a remark stands in strange juxtaposition to the drug ads. One for Ovulen, for example, reads: "A significant advance over older progestins . . . a new measure of freedom from undesirable effects . . . extremely low incidence of breakthrough bleeding . . . low average weight change . . . extremely low incidence of nausea . . . extremely low incidence of amenorrhea . . ." If these statements do not imply a better performance than with older drugs, what are they saying? And if Ovulen is so remarkable, one wonders why the ad explains, in tiny print to be sure, "the following adverse reactions have been reported with Ovulen: headache, dizziness, depression, breast complaints, amenorrhea, chloasma, vomiting, allergy, edema, migraine, pulmonary embolism, thrombophlebitis, visual difficulties, nervousness, rash, itching, decrease in libido, tiredness and malaise. A small incidence of nausea, spotting and breakthrough bleeding has been reported."

What is a sensible, conservative, scientific attitude toward the use of the pills? On occasions when I have taken a public position emphasizing the possible dangers of their use, it has been obvious that the emotions of both patients and doctors are highly charged when it comes to a discussion of oral contraceptives. Doctors have accused me of everything from a Catholic-tainted bias against contraception (I left the Church at the age of twelve) to having canine ancestry on my maternal side. These

doctors are understandably annoyed because such discussions upset their patients. But is it really defensible to assure women—as many doctors do—that the pill has been proved as safe and harmless as water? How can a doctor say that he "can think of no condition in which these pills would not be safe to take"? (The FDA labeling warns against their use in certain situations.) How can Dr. Rock, in an article entitled "Let's Be Honest About the Pill!," dismiss those who worry about its dangers as "irresponsible, and uninformed . . .zealots"? Does he really believe that all women who find themselves unable to tolerate any brand of oral contraceptive on the market are, in his words, "guilt-aroused neurotics"? Is it really desirable to produce diabetes temporarily with the pill because this merely unmasks a condition that would have become manifest years later and is therefore "a prophylactic blessing"? Surely such questions deserve serious discussion, not supercilious dismissal.

"Brassiere designers are having to accommodate an ever-expanding American bust. . . . Undergarment makers attribute the increase in bust sizes to improved diet and the hormonal effects of birth control pills."

—NEWS ITEM,
The Wall Street Journal.

THESE pills should certainly not be taken off the market. On the other hand, they cannot possibly be considered the contraceptive technique of first choice for all women desiring birth control. They are not necessarily the best or the only way. The pills are indicated for many women, including those who will not or cannot use mechanical devices because of anatomic, psychological, or religious reasons. Since it is my firm conviction that these pills can kill—rarely, to be sure—and that other techniques, properly used, which do not kill, are almost as effective in preventing conception, I believe it bad medical practice not to recommend mechanical contraception to those who can use it. I recognize the tremendous importance of the pills for certain women who apparently find condoms and diaphragms impractical despite the great need some of them have for means to avoid pregnancy, and I appreciate the Planned Parenthood Association's interest in avoiding hysterical condemnation of the pill. But it is ethically and morally wrong to take the decision out of a patient's hands by assuring her that these powerful chemicals are completely free of risk.

It has been argued that even if one recognizes some small risk from the pill, its advantages far outweigh the dangers. One Baltimore obstetrician argued that a million women not using any contraceptives would experience 360 maternal deaths per year, since most would become pregnant (not pregnant every year, however, a fact ignored in the calculations, which also do not jibe with the more recent British data), and some women die in pregnancy. His guess about oral contraceptives was that a million women taking them would show only one or two maternal deaths, and that a few additional deaths from thrombophlebitis and related vascular troubles would still be acceptable. A main point of his argument is the assumption that use of the condom or diaghragm would result in fifty maternal deaths per year because of a high failure rate with these devices.

How valid is such an argument? Another Baltimore obstetrician, equally well known and experienced, pointed out that the failure rate of the condom or diaphragm—properly used—is very low. The higher figure obtains in couples with low motivation—for example, those who have one child and are not quite sure when they want a second. An excellent batting average is seen in highly motivated women—those who have completed their families, for example, and are sure that they don't want another child. In his opinion, most failures "are simply an expression of 'I don't care.' " And one thing is reasonably certain—condoms and diaphragms are not going to produce breast cancer, or diabetes, or any of the other ills that are at least a theoretical hazard of oral contraceptives, which can affect the whole body, not just the uterus.

It would be wonderful if doctors could predict which women would get into trouble from the pill, but at the moment it is possible only to avoid its use in certain women, such as those with obvious vein disease, past or present, and a history of migraine or of jaundice during pregnancy.

Louis Lasagna, born in New York City forty-five years ago, received his M.D. degree from the College of Physicians and Surgeons, Columbia University. He is an associate professor of medicine and associate professor of pharmacology and experimental therapeutics at Johns Hopkins University Medical School, and a consultant to the National Institutes of Health. His cautionary statement on birth control pills is taken from *Life, Death, and the Doctor*, a Borzoi book published by Alfred A. Knopf and copyright 1968 by Louis Lasagna.

LETTERS TO THE SCIENCE EDITOR

On Social Science

IN HIS ARTICLE, "Public Policy and the Study of Man" [*SR*, Sept. 7], John Lear clearly summarizes the debate over the questions of how, and to what extent, the federal government ought to support social scientific research, and over the means by which social scientists can increase their influence on the determination of public policy.

Mr. Lear devotes most of his piece to a report prepared by a committee chaired by Dr. Donald R. Young for the National Academy of Sciences. The Young report suggests the establishment of a National Institute for Advanced Research and Public Policy, an independently endowed institution which would conduct policy-oriented behavioral research. The objectives of this institution, if not its operating procedures, evidently would be similar to those of the National Social Science Foundation, which I have proposed, and the Presidential Council of Social Advisors proposed by Senator Walter F. Mondale and co-sponsored by me.

The Young report also endorses several other means of increasing the prestige and elevating the role of the social sciences within the federal establishment, but, as Lear points out, these recommendations "were quietly but firmly against creation either of a separate National Science Foundation for the Social Sciences or of a separate White House Council of Social Advisors." This is unfortunate, in my opinion.

Unquestionably, greater involvement of social scientists in the federal government, as suggested by the Young report, is a step in the right direction. But the incremental improvements contemplated by Young's panel seem to me unlikely to alter substantially the established institutional arrangements between the scientific community and the federal government, which presently ensure that the natural and physical sciences command all but a small share of federal research money, and which make it difficult for social scientists to play a greater advisory role in policymaking. What is needed is a distinctive and separate institution within the government for the social sciences, one which possesses a clear political mandate to support imaginative and innovative research and to encourage the development of each discipline in the field, and with sufficient status to represent effectively the needs of the social sciences and to increase their ability to assist the government in dealing with the difficult social problems which confront us.

The twin crises of Vietnam and of our cities lend a special urgency to this argument. Moreover, recent reductions in appropriations for scientific research in general—necessitated by overall cuts in federal spending—lessen the prospect that the government will soon reorder its priorities to provide the social sciences with a more equitable share of federal research funds.

In short, the need for a National Social Science Foundation appears even more es-

sential today than when I first proposed the institution two years ago.

The [U.S. Senate] Subcommittee on Government Research, which I chair, has identified the following issues that would begin to be resolved by such an independent governmental agency concerned exclusively with the support of social science research.

1) The social sciences need federal support for research and development far in excess of what they now receive. This implies not only sufficient funds, which are essential, but a recognition of their potential contribution to society and a strong legislative base. In 1966 basic research of all types funded by the Federal government amounted to $1.84 billion, of which the social sciences received $44,000,000 or 2.4 per cent. The estimated obligations for 1967 and 1968 were about the same, 2.5 per cent for both years. The portion of federal support for applied social science research out of total applied research funds is not much different—3.5 per cent in 1966, 3.6 per cent in 1967, 3.7 per cent in 1968. Further evidence of inadequate support is pointed up by the fact that while the social sciences received 24 per cent of total government expenditures for research in 1938, by the early 1950s the percentage had diminished to about 8 per cent and for the last ten years it has varied between only 3.5 per cent and 5 per cent.

2) The National Science Foundation has given very little or no support at all to certain disciplines and methodologies within the social sciences. For example, the NSF did not start a political science program until eleven years after beginning formal support of social science. In fiscal year 1966, NSF funded only seventeen proposals for political science research totaling only $335,650. Law is an even more extreme case. No funds are earmarked for legal research and education in universities in any federal program, and yet there is substantial opinion within the legal professions and the social science community which recognizes law as a social science.

3) The social sciences have suffered from insufficient attention to their development, visibility, and prestige, partly because of the low level of federal funding, the tenuous statutory authority for their encouragement, inadequate support by the NSF and the operating agencies, and the failure to recognize fully the potential importance and significant contribution they can make to the achievement of national goals. A new foundation with specific authority would encourage a quantum leap in funding for the social sciences and revitalize social science research conducted by other federal agencies.

4) Innovative and perhaps controversial thinking and research must be encouraged in the social sciences if the nation expects to meet the challenges of the pressing and growing social problems which face it. With its natural science orientation, NSF will, I believe, continue to find it difficult to promote such research in the social sciences, which now accounts for less than 10 per cent of its basic science research support, so as not to jeopardize the other 90 per cent devoted to the support of the natural and biological sciences which tends to be noncontroversial, at least in the short run. A strong legislative mandate to encourage the support of innovative research will provide the social sciences with the confidence they need and deserve and the authority they must have.

5) Interdisciplinary and multidisciplinary research must be conducted on a much greater scale in universities and other research organizations. Many modern problems do not fall neatly within the boundaries of a single discipline. One of the barriers to collaboration and cooperation between the natural and social sciences has, in the past, been the inferior status of the latter. A new foundation will, by enhancing the status of the social sciences, serve to foster interdisciplinary research and, in the long run, to unify the sciences. Administrative "unity" is not necessary to achieve this goal, and evidence clearly indicates that it has served the social sciences poorly.

At such time in the future as the social sciences achieve status and acceptance as co-equals, a "one agency for all sciences" concept might be reconsidered by Congress to the mutual advantage of all science. Multiple-agency support for the physical sciences has been of obvious benefit to the nation. No reason is perceived why we should not expect a similar outcome from diverse agency support for social science as well. The Subcommittee does not conceive of NSF becoming the exclusive federal supporter of social science research. It is intended that all agencies of the federal government now supporting social science reseach, including NSF and the National Foundation for the Arts and Humanities, will continue to support and, indeed, increase their level of support for the social sciences.

6) The nation cannot adequately confront its myriad social problems without a significant increase in social science knowledge. Social conditions are constantly being altered, by rapidly developing science and technology, population growth, the hastening deterioration of urban America further exacerbated by continued outward migration of people from rural America seeking opportunity in already overburdened cities. The need is great for a critical assessment of our social goals, our priorities, and the existing national programs and approaches for implementing them. This assessment will not come easily but it will come more quickly if support for social science research is sharply increased and if the social sciences are encouraged to probe to the root causes of social problems.

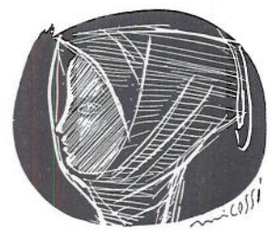
On the international scene, shifts in the balance of power, changes in regional coalitions, erosion of the foundations of postwar treaties, and the ever-widening gap between the developed and the developing countries force to the surface new issues that must be identified, understood, and resolved and, therefore, subjected to increased scrutiny by the social sciences on a much larger scale than is presently the case.

I believe that attempts thus far to define a proper role for the social sciences within the federal government have made clear just how vulnerable they are to budget cuts and to unpredictable changes in politics and policy. This is especially true when social science research is housed in agencies whose research funds are committed almost entirely to the physical, natural and life sciences— or to carrying out specific government missions. The National Social Science Foundation would provide the social sciences with an institutional base that would permit them to develop more rapidly, and to be represented more effectively before the Congress and within the executive branch.

I do not anticipate Congressional action this session on my bill to establish a National Science Foundation, but I will introduce the measure again at the beginning of the next session, with considerable hope of favorable action.

I congratulate *SR* for publishing John Lear's incisive review of the debate in this field, and I appreciate his consideration in making public my response.

FRED R. HARRIS,
U.S. Senator for Oklahoma,
Washington, D.C.



Earthquake Disaster

FOR SOME YEARS, I have attempted to bridge the gap between C. P. Snow's two cultures by teaching physical science ("poet's physics") to college students who are oriented toward the literary-historical-social science culture. More recently, it was my privilege to help develop Harvard Project Physics, a new high school course designed to appeal to students with both non-technical and technical orientations. In both efforts we refer students to *SR*'s well-subtitled Science & Humanity Supplement, which is so imaginatively edited by John Lear.

But the text of "How to Predict Earthquakes" [*SR*, Oct. 5] is a disaster. The earth's axis does indeed precess in a 26,000-year conical motion, but the precession is due to the combined steady (average) pull of the sun, the moon, and the other planets —not to alternating gravitational pulls of the sun and the moon. Precession has nothing whatever to do with the 365-day calendar. Nor is precession in any way related to the Chandler wobble, which is not a punctuation or perturbation of the motion of the earth's axis.

According to Newton's law of inertia, only an external force can change the direction of the earth's axis (the sun and moon exert such external forces in causing precession). To understand the postulations of Mansinha and Smylie, we must consider the earth's axis to be fixed, absolutely rock-steady in space (as it is, except for the well-understood and predictable precession and