CONTRACEPTIVE WARNING

FDA goes to the consumer

According to the Food and Drug Administration's last pronouncement on the subject, oral contraceptives are safe—at least by legal definition. But in its September report (SN: 9/13, p. 198), the outgrowth of three years of evaluation by the FDA's Advisory Committee on Obstetrics and Gynecology, the agency raised as many questions as it answered about the side effects of birth control pills, and by no means gave them a clean slate.

In the decade since oral contraceptives were first marketed, reports of known and suspected hazards have circulated through the medical literature and the press with steadily increasing frequency. Recent Senate hearings held by Gaylord Nelson (D-Wis.), provided a public forum at which experts recited accumulated data linking the pills to everything from weight gain to blood clots and cancer.

Moved by mounting evidence of danger and by public and political pressure, FDA Commissioner Charles C. Edwards first circulated a warning to doctors in a special letter (SN: 1/24, p. 93), then took the final day of the Nelson hearings as the occasion for announcing a virtually unprecedented action.

The FDA, Dr. Edwards said, will require drug houses to include in every package of oral contraceptives a pamphlet cataloguing in lay language the risks linked to their use. While it is standard procedure to have manufacturers supply physicians and pharmacists with details of side effects of prescription drugs, the information ordinarily goes to the patient only at the discretion of his physician.

At present, there is only one exception. Persons with bronchial asthma who inhale a drug called Isoproteronal receive a leaflet cautioning them against overdosing themselves and instructing them in the drug's proper use with every prescription. "However," says FDA's chief counsel William Goodrich, "the information is nowhere near as detailed as that proposed for birth control pills."

Further, Goodrich says, FDA has no intention of extending its requirement that information on risks go directly to the patient on other types of drugs. Though oral contraceptives are no different than other prescription drugs from a legal view, FDA considers them unique in that they are taken by overwhelming numbers of healthy individuals. An estimated eight and a half million women in the United States are or have been on the pill.

In spite of FDA's avowed intention to limit the warning practice to birth control pills, spokesmen for the Pharmaceutical Manufacturers Association and for individual drug companies fear it could set a dangerous precedent. A representative of G. D. Searle & Co., makes of Enovid, finds, for example, that it is not inconceivable that similar cautionary information might be proposed for individuals taking amphetamines or smallpox vaccinations from their physicians. On a risk versus benefit basis, amphetamines have long been and vaccinations (SN: 1/31, p. 129) are now under fire.

For the present, however, neither the drug makers nor the American Medical Association is raising a hue and cry against Dr. Edwards' plan. Generally, they say, they have no objection to informing patients directly about the side effects of the pill. And an official statement from the AMA goes as far as to say, "The medical profession regards the pill, in most cases, as a convenience rather than a traditional medication and hence the patient must bear her share of the legal and moral responsibility for taking it."

Nevertheless, it is naive to suppose that the proposed warning pamphlet will be included in packages within the next two months.

Delays are expected to occur when the process of establishing the precise wording of the brochure gets under way. Spokesmen for each of the affected drug manufacturers indicate that they have objections to portions of the wording of the proposed statement, which spells out a definite association between oral contraceptives and blood clots—"the risk is six times higher for users"—cites connections with mental depression, jaundice, high blood pressure and diabetes, and declares that while there is no evidence that the pill causes cancer in women, doctors will want to examine patients regularly on this score.

Goodrich and lawyers for the PMA affirm that at present the drug manufacturers have no plans to try to block FDA's move on legal grounds. However, if the final wording turns out to be too strong for their liking, the lawyers speculate that the issue could be taken to court on grounds that, because physicians inform their patients about birth control pills, the pamphlet is unnecessary or that it interferes with the physician-patient relationship.

While protesting any intention of interfering with that relationship, Dr. Edwards says, "I have come to the conclusion that the information being supplied to the patient in the case of oral contraceptives is insufficient."

And that, says Nelson, is why he held the hearings.

DOMESDAY BOOK

Cuts begin to hurt

Federal budgets for scientific research have been going down for several years. This year the decline is beginning to hurt; laboratories are closing and programs are being discontinued.

Rep. Emilio Q. Daddario (D-Conn.) chairman of the Subcommittee on Science, Research and Development of the House Committee on Science and Astronautics has gathered a list of those threatened.

Besides the Princeton-Pennsylvania Accelerator, which is scheduled to close, and the Cambridge Electron Accelerator, whose program is cut in half (SN: 3/7, p. 239), institutions being curtailed or closed according to Daddario include:

☐ The National Magnet Laboratory, possible 20 percent decline.

☐ The Haystack radio telescope at Lincoln Laboratory, Massachusetts Institute of Technology, which may have to close.

☐ The tandem accelerator at Florida State University.

☐ The Sloan-Kettering Institute for Cancer Research, where 7 out of 69 laboratories are being closed and 9 others are taking 50 percent cuts.

Beyond these major installations, programs in fundamental biological and physical sciences are declining drastically. The National Institutes of Health has less support for such things as genetics, plant physiology, biochemistry and nonpathogenic bacteria and viruses. The Department of Defense and the National Aeronautics and Space Administration are cutting support for astronomy and geophysics.

The National Science Foundation is being pressured to take up 50 biological programs being dropped by NIH and 25 astronomy programs being dropped by other agencies. The Foundation's budget does not call for generous increases in these categories, and it does not know where it will get the money.

Furthermore, organizations like the Haystack radio telescope and the Princeton-Pennsylvania Accelerator are now coming to the Foundation looking for operating money, a kind of grant that NSF has not often made in the past.

One of the ironies of all this, says Daddario is that the annual cost of basic research "would not pay the interest on the national debt for a week or Social Security payments for one day."