

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS.
Washington, D.C., May 7, 1970.

THE HEARING CLERK,
Department of Health, Education, and Welfare,
Rockville, Md.

DEAR SIR: I am writing to comment on the proposed package insert that will be a part of each package of oral contraceptives received by the user.

Dr. Charles Edwards, Commissioner of the Food and Drug Administration, is to be commended for his positive recognition of the importance of the concept of informed consent in the use of oral contraceptives. This prescription drug differs from all others in that it is very widely prescribed for healthy users and in that for a substantial percentage of users, at least, there are effective alternative methods of birth control.

The issue is whether the user is entitled to be informed about the benefits, risks, and side effects of oral contraceptives and alternative methods. This is the essence of the matter. It is my view that users are entitled to know what the government and the experts know.

Obviously this poses difficult practical problems. The fundamental responsibility rests with the prescribing physician. Nevertheless, a simple, direct reminder notice should be available to the user at all times since it cannot be expected that millions of people are going to remember their physician's advice for long periods of time. Furthermore, it is clear that a substantial percentage of users were not given any advice on risks and side effects at all.

It seems to me that contra-indications ought to be listed since the scientific community is agreed that those with certain histories should not use the oral contraceptive. This will help assure that they do not.

One sentence in the proposed reminder notice raises, I think, a serious question. That sentence is, "Rare instances of abnormal blood clotting are the most important known complication of the oral contraceptives." The word rare is a subjective term that means something different to each reader. In my own subjective judgment, the word rare is inaccurate as used here, since the hospitalization rates due to thrombo-embolic disease in users is one in two thousand.

Serious questions are also being raised concerning the metabolic effects of long-term use. In the comprehensive volume edited by Drs. H. A. Salhanick, D. M. Kipnis, and R. L. Vande Wiele, the editors state in the preface, "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 a 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."

All of these matters pose serious, difficult medical and public policy questions. It is doubtful whether any individual has at his fingertips the final best answer.

I would suggest, therefore, that public hearings be conducted on this issue so that the collective wisdom of the scientific community and the public may be focused on the issue. It would, I think, be a valuable source of information and opinion for developing the most useful and practicable reminder insert.

Sincerely yours,

GAYLORD NELSON,
U.S. Senator.

[From Science News, March 14, 1970]

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