The risks of the oral contraceptives taken in this light have been under continued surveillance of the Food and Drug Administration. It has periodically reviewed the labeling of these compounds, advocated increasingly strict surveillance by physicians, and recommended the accumulation of additional information about biological actions and clinical effects. As information increases concerning these compounds, both the benefits and the risks appear more precisely defined and quantitated.

Specific risks as well as requisite practices for followup of patients have been detailed in the labeling of all hormonal contraceptives. When the potential hazards and the value of the drugs are balanced, the Food and Drug Administration found that the ratio of benefit to risk was sufficiently high to justify the designation "safe" within the intent of the legislation.

Although this pronouncement by a governmental regulatory agency lends some confidence to the physician and to clinics in their continuing use of the oral contraceptives, it does not relieve them from the responsibility and the decision making inherent in the practice of medicine. As in all other decisions concerning health care, the choice of a contraceptive method rests with the physician and his patient or the clinic policy makers and their patients. It is derived from the knowledge of both physicians and patients and influenced by the complex interreaction between professional and layman. The decision as to which contraceptive to use may be wise or unwise, carefully considered or haphazard, relevant or not, depending on personalities, and on the knowledge possessed by both parties.

As already indicated, there is a vast body of information concerning the oral contraceptives. This information is sometimes divergent and by no means complete. It is, however, far more inclusive and more precise than it was even a few years ago. It does spell out comparative benefits as well as risks where these are known. It enunciates areas of concern and gaps in information. It makes transcendent the need for a high standard of medical practice in the prescription and use of the hormonal contraceptives. An adequate medical history, complete physical examination, including pelvic examination, and Papanicolaou smear, are essential. Annual, or better, semiannual reexaminations with repeated cervical smears are a part of good practice. Open and continuing contact between the giver and the user of contraceptive care are requisite, not only for safety but also for continuation of use. These points are so self-evident, that they seem trite. They are not always observed.

All knowledge and all decision making does not reside with the giver of contraceptive care alone. Increasingly, in all areas of medical care the consumer desires and has the right to information and knowledge about the benefits and risks involved in his treatment. This information is often complex and expressed in terms not always comprehensive to the layman. Especially in the area of the hormonal contraceptives, which are on the forefront of scientific development, knowledge is often incomplete.

Complete disclosure of all available information concerning the benefits and risks of the oral contraceptives would require much more than perusal of the labeling. It would necessitate the years of training and reading that are the hallmark of the professional. This course might be desirable in theory, but it is absurd in practice.

The physician solves this dilemma by conversation in which he attempts to interpret his scientific knowledge in the way that enables his patient to make some sensible choice regarding the preferred method of contraception. The clinic accomplishes the same objective through individual conversations reinforced by group lectures and demonstrations. In the best of situations, the clinic imparts a body of knowledge and fact sufficient for the patient to make an intelligent choice of contraceptive methods.

However, information is given to the user and whatever freedom of choice she may exert, the giver of contraceptive care cannot divest himself of responsibility. No signed release will free him. He can only do his best to impart sufficient information and provide the opportunity to the patient for complete freedom of choice. Meticulous medical care, knowledge and freedom of choice insure neither total satisfaction nor total safety, but they are the best that can be accomplished in an imperfect world.

I thank you for the opportunity to meet with you today. I shall be glad to try to answer any questions which the subcommittee may have.

Senator NELSON. This question of what the word "safe" means in the 1962 act is a difficult one, and I do not know the answer to it. But I