Even after a drug has been authorized as acceptable for use by practicing physicians throughout the country, there always remains some risk in this use. Not all patients react in exactly the same way, and what is entirely safe for one may produce adverse reaction in another. A drug which is highly potent in the treatment of disease is always suspect of causing occasional adverse effects in some patients. Even such a life-saving drug as penicillin can be dangerous for some patients, as some foods are not tolerated by some people.

In giving drugs to patients, the physician takes the responsibility for being familiar with all experimental work which has been done with the drug. Whether the drug is new, or tried-and-true, he does not give it indiscriminately. He prescribes only what he thinks will benefit the patient—the beneficial effect far outweighing possible, but very small, risk. Finally, he will continue to watch the patient to detect evidence of side effects to deal with them appropriately.

When your doctor gives you a prescription for a drug you have never used before, and accompanies it with a discussion of its possible risks, he does not intend to alarm you. He is, rather alerting you. He would not be giving you the medication at all if it were not presumed to be good for you. But he believes that you must share with him the awareness that there might be unforeseen reactions. If the disease being treated is a severe one or has been very resistant to treatment, the patient and the physician are usually more receptive to taking risks. But no significant risk to a patient is ever willingly incurred by the physician. Both physician and patient are, to some extent, at the mercy of the unpredictability of individual responses.

The patient or the parent of the patient should be aware that there is a price, because of these uncertainties, for all improvements in prevention and cure of disease. In explaining potential risks, the physician is seeking the "informed consent" of the patient. The patient must share the responsibility with the physician. When both are aware of this, the course of treatment is likely to go more smoothly.

Dr. WILLIAMS. These four documents, one is printed on two sides, amplify that paragraph on page 9.

Mr. DUFFY. Doctor, before we leave page 8 I am just curious about the last sentence before the first full paragraph:

"Post pill infertility was a worry for manufacturers. Otherwise they would not have alleged its nonoccurence in the early days."

Are you saying that a statement that something does not occur is the equivalent of covering up adverse data? That certainly is a fair implication that one may draw from that statement.

I just wanted to make sure what implication you intended for us to draw from that statement.

Dr. WILLIAMS. This is in the paragraph, Mr. Duffy, in which I am talking about areas of absent, tardy or incomplete research, and the matter of postpill infertility was a point of reassurance by the companies, and that is the implication I want you to draw.

Mr. DUFFY. In other words, adverse data has been covered up?

Dr. WILLIAMS. Either covered up or no effort made to uncover it.

Mr. DUFFY. Thank you.

Dr. WILLIAMS. So, Senator, to summarize on the subject of advertising and promotion, it seems to me that the promotion of the pill has had a great deal of very high placed help in recent days. I think it is strange that the Secretary of HEW, the Commissioner of the Food and Drug Administration, and the newly appointed Deputy Assistant Secretary have all made public statements in the midst of these hearings declaring, I would say safety by decree.

For example, the Secretary said there is no clear-cut evidence that the pill is harmful, and that many women want to keep from having children, and that when many women want to keep from having children the oral contraceptives are the best way to do this.