

Dr. GOLDZIEHER. Senator McIntyre, I serve as an investigator for the National Institutes of Health, the National Science Foundation, the Southwest Foundation for Research and Education. I am a consultant to the U.S. Air Force and to the U.S. Army, and I am a consultant at various times to various drug companies.

Senator McINTYRE. And you receive remuneration from the drug companies for this work?

Dr. GOLDZIEHER. Among others. Also from the Air Force, the Army, the Southwest Foundation, and also from my patients, I might add.

Senator McINTYRE. I don't wish you to take any umbrage or any offense at this line of questioning, because you mentioned it, and it is a problem to try to get what we would call unbiased testimony.

Now, the major thrust of the early part of your testimony, Doctor, as I understand it, is that the questioning of patients concerning their experience with the pill is not a highly reliable way to determine the frequency of side effects, is that correct?

Dr. GOLDZIEHER. With certain reservations, yes.

Senator McINTYRE. But is it not a fact that the really serious potential effects of the pill, such as thromboembolic disease or carcinogenesis are not the kinds of conditions which could be detected through this kind of subjective response?

Dr. GOLDZIEHER. There are two classes of side effects that we have to deal with: those which occur with some degree of frequency, like nausea, which can be evaluated by fairly simple statistical designs. There are extremely rare side effects, such as thromboembolic disease, which are not picked up by this type of study.

Now, what is the process by which such a rare condition as thromboembolic disease can be picked up? There are two aspects of it.

First of all, somebody has to say, "I had a patient who developed something or other, and I wonder if it was related to the fact that they were taking an oral contraceptive?"

This is a raw adverse-reaction report of a rare, perhaps lethal, event in a woman taking a particular drug, oral contraceptive or otherwise. Reports of this kind are a raw material, an unevaluated raw material, because they are in effect a numerator without a denominator, and the only purpose of such reports—though unfortunately it is not the only purpose to which they are put—is to alert us that here is a matter for concern, and that it is required that we now sit down and devise an experiment, a study, an investigation, a protocol, which will enable us to reach a conclusion which is statistically meaningful as to whether this was or was not coincidental.

Senator McINTYRE. I take it that you agree generally that the testimony you gave relative to side-effects complaints and their unreliability still does not depreciate one bit the fact that the most serious things that are worrying some of us are really not developed under a side effect sort of complaint.

Dr. GOLDZIEHER. If you mean the metabolic effects, obviously, metabolic effects are not developed by questioning.

Thromboembolic disease turns up because you follow the patient. She will tell you yes, she has a pain in the calf, and you find a thrombophlebitis. You will turn it up if the patient does not show up at the