I believe that relying solely on the pharmaceutical industry to inform the physicians of these things is shedding our responsibility as a medical group to keep ourselves informed.

Senator NELSON. But what about the problem of it being widely used in other countries where, in fact, even if the user wanted to have a physical exam and understood it was necessary, facilities are not available? Perhaps every doctor in this country would say that you must have a physical exam; sound medical practice requires it to protect the user. But yet it is being used all over the world where there are no medical facilities under circumstances which any doctor in this country would say, "I will not permit my patient to have it if they are not going to take the exam."

Dr. SPELLACY. We should strive for the ideal practice of medicine by doing these regular examinations and in certain select groups very detailed in-depth research studies on these drugs. This cannot be done for all 18 million ladies but it can be done in selected countries and in select groups. With this information we can recognize these complications earlier and direct our efforts toward new means of conception control, be it different steroids or different combinations of steroids or completely different modalities, we can then introduce these safer methods into the world population control centers.

Senator NELSON. But it is being introduced now, some 10 million, 12 million women, many of whom do not live in developed, highly sophisticated societies such as the Scandinavian and the British, the German and the French, but do live in South America and do live in India, and do live in all kinds of countries without a sophisticated medical profession, and there is no answer to that question. It seems to me to raise a serious question that a device which we say medically in this country requires a physical examination, is sent to a place where a physical examination simply is not available because they do not have personnel.

Dr. SPELLACY. But it becomes a choice of the lesser of evils for that particular population in say South America. The risks, though minimal, from taking the drug without medical supervision are probably considerably less than those of not taking the drug at all. Again the United States should seek the ideal, establish the standards, protect our women, and help others to follow our methods.

Senator NELSON. It might be a decision they ought to make for themselves, and I am afraid they are.

Well, are there any other questions?

Senator DOLE. Just briefly.

I think you raise a dilemma at page 5 and page 9. On page 9 you state that an immediately striking conclusion we are drawing comes from very small sample sizes. On page 5 you make reference to a study in 1966 by Dr. Wynn and Dr. Doar reported an elevation of free fatty acids in the blood of women taking oral contraceptives, and then in 1969 they were unable to confirm this finding. I assume what you are saying to us, in effect, in many areas we are just dealing with uncertainty because there has not been an adequate sampling, there is no statistical certainty. You pointed out the study in Los Angeles involving 176. There are some 18 million, I assume worldwide, who are using the pill, and you point up that it is very difficult and also expensive to have a controlled group.