them. Unfortunately, these women cannot all be recognized by the tests and exams that we use today. In other words, some of the diseases are so latent that unless one does extremely extensive testing, they are not recognizable. What the doctor can do, however, is notice that this group becomes overtly abnormal very quickly, so for example that the patient with underlying vascular disease develops here hypertension very soon after starting on the pill. Therefore I believe that the first visit after beginning the drug has to be relatively soon so that this group that is abnormal is recognized and the drug stopped. I would recommend that this exam be at 3 months after starting the drug. Then after that, we are dealing with a very low yield of abnormal things occurring, and we could place the next repeat visits somewhere out between 6 and 12 months.

Senator NELSON. Several witnesses over the period of the hearings had commented in one way or another about the question of how many people do go through the examination, and cannot get very firm figures on that with the estimates being that in good clinics, the examination is done regularly and good procedure is followed. In other parts of the country probably not. It appears, although we have not taken testimony on it, but from conversations with a couple of pharmacists, they occasionally get a prescription which is renewable upon request. That was a problem also mentioned in testimony here about people who are in countries where there is no availability of physicians to do the examining.

What kind of an issue are we raising when in this country, where we either are not informed that we must have an examination or cannot afford it that regularly, and other countries where there is no medical facility available and they are taking the pill?

Dr. SPELLACY. In this country, we have a physician manpower problem. However, I believe there are enough physicians to do this type of examination. One of the problems is keeping physicians informed of the tremendous expanding literature on this particular subject. This is one area that a central organization with expertise in the scientific interpretation of this expanding literature could be helpful by periodically sending to all physicians reviews in succinct form describing the pertinent complications, the tests to be performed, and the intervals that these tests should be repeated in the subjects taking these drugs.

Senator NELSON. Where should that responsibility lie?

Dr. SPELLACY. I am not in a position to say where that should lie, but probably some Federal organization such as FDA. This should be current information sent not every 5 years, but perhaps once a year.

Senator NELSON. Dr. Wynn testified yesterday that because of the great prestige of the pharmaceutical industry and the medical profession and the fact that we have a highly regarded regulatory agency, the FDA, that all over the world, South American, for example, they simply rely upon the fact that if it is manufactured in this country and distributed in this country that it is safe, and he said the pill is being widely used in these other countries without adequate supervision.

Dr. SPELLACY. We certainly have responsibility to monitor this in our own country and also to disseminate the information to the world as it appears.