

experts far more capable of giving you the epidemiological requirements for such studies.

But when we talk about the numbers Dr. Seigel and Dr. Corfman have presented, as referred to by Mr. Duffy previously, there is a vast amount of biomedical support that will have to go into any particular enterprise. So I say this, gentlemen—such studies are very expensive, I am sure you know it—but as an investigator I think this fact has to be laid face up on the table.

Senator, this is the end of my testimony.

Senator McINTYRE (presiding). May I say, Doctor, that Congress will be facing that issue very, very shortly.

Dr. BOLE. I understand, sir. That is why I said it.

Senator McINTYRE. Doctor, is it a fair summary of your position to say that although one cannot conclude from the present evidence that the oral contraceptives do cause rheumatic disease, it is a possibility which physicians should be aware of in prescribing the pill?

Dr. BOLE. I would modify that to some degree, sir, to state that laboratory tests that we use in helping to make the diagnosis in early cases can be rendered abnormal in some instances. By stopping oral contraceptives these tests become normal and clinical symptoms may disappear, and we can say they have disappeared for as long as 2½ years, because that is the longest case we have followed.

But I also would interject that you cannot do anything to stop rheumatic disease with 100 percent certainty by stopping oral contraceptives in any one of the cases.

Now, the question is obviously are they provokers. I left out of my testimony, for the sake of time, the fact that isoniazid, a tuberculosis treatment, procainamide for cardiac abnormalities can produce similar abnormalities—and expert rheumatologists in my field will debate for hours whether the patient has unrecognized disease, and all that the drug is doing is triggering this unrecognized disease.

I think to some degree this is of no great consequence, but it is saying to us that there are things that these drugs are able to, that will, provoke illness, and in that sense these drugs in some cases of rheumatic disease may need to be looked upon as something that can provoke a problem. I do not wish to leave the impression that these drugs can necessarily trigger progressive disease.

Senator McINTYRE. Well, to help me, Doctor, is it or is it not possible to detect which apparently healthy individuals may be predisposed to rheumatic disease?

Dr. BOLE. It is not at the present time, sir.

Senator McINTYRE. Doctor, do you know whether the present labeling of oral contraceptives includes any information indicating a possible relationship between the pill and the development of rheumatic disease?

Dr. BOLE. You have to look at the individual statements. It speaks in terms of backache, it speaks in terms of some other symptoms. One of the arthritic syndromes is listed (erythema nodosum) as having been associated with use of the pill, but other direct statements are not presently available.

But I would point out, sir, that these preliminary reports that I have cited, both our own studies and all others, have accumulated in the literature only in the last 18 months.