

Mr. GORDON. Dr. Ball, it has been estimated that perhaps around 10 percent of the adverse actions which result from the use of drugs, pharmaceuticals, are reported.

I do not know how accurate that 10 percent is, but let us assume it is a small percentage.

Would you say the adverse reports of the pill fall into that category also?

Dr. BALL. I am sure it does. Of course, you could be very direct and say how many have I reported to the FDA. Well, when the pill was first on the market and in general use, I reported to the FDA several cases of erythema nodosum and several cases of thromboembolic diseases, one life threatening and the other can be quite an illness. So I reported those. I am an internist. The reporting of those is rather a complicated bit of paperwork and there was no feedback. In other words, the paper went in and I heard nothing back from it. So from then on, I have not reported any further on the pill.

There has been plenty of literature, there have been plenty of statistical studies, presumably going on, and in fact, I considered it a closed subject in my mind in 1966.

Mr. GORDON. You do not report the adverse effects that you see?

Dr. BALL. Since that time, no.

Mr. GORDON. So the 10 percent, as far as you are concerned—

Dr. BALL. Is wrong. It is too high. It might be like .5 percent, I do not know. But it is probably very small.

Mr. GORDON. So you really do not know the occurrence, the percentage of occurrence of thromboembolic disorders or any of the other disorders?

Dr. BALL. Out in the boondocks, we do not.

Senator NELSON. I am now looking at the experience report on the reporting form that you get. Does it have all the information necessary?

Dr. BALL. Senator Nelson, as I say, it has been several years since I made out one of those blanks, but it required a quite a bit of secretarial time. It seemed to me it was not excessive but it took time to do it. If I had reported all of these I had seen, I am afraid the paperwork for the blank would have been greater than the history form I had on the patient. It has been quite a problem, a physical problem.

Senator NELSON. Thank you very much, Doctor. So that everyone will notice the balance in the record that is talked about so much, you are the first practicing physician who has recommended abandoning the pill. We have had no other such witness; they have all been pro to one degree or another.

Our next witness is Dr. Elizabeth Connell, associate professor of obstetrics and gynecology, director of Research and Development, Family Planning Services, International Institute for the Study of Human Reproduction, Columbia University, New York City.

The committee is very pleased to have you take the time to appear here today and present your statement, Dr. Connell. You may present your statement—it will be printed in full in the record. You may present it in any way you desire.