I would like to ask your view about the status of reporting to the FDA on side effects, which you would like to know about. But first, let me read what Dr. Best said before the committee, about 2 years ago.

This is from a statement of William R. Best, chief, Midwest Research Support Center, Veterans Administration, Edward Hines, Jr. Hospital, Hines, Ill. He said:

> I am not sure how much effect the reporting system would have itself. It would produce a universal reporting system . . . that would have a little more meaning than those I have written about that I related to voluntary reporting.
>
> In other words, we would have a better feel for what the total number of cases are. I think we still would not have the whole picture.
>
> I know that in a recent study in Philadelphia, for example, five of the medical school affiliated hospitals tried to set up their own reporting system to catch all the adverse reactions occurring in all of these hospitals. People being people, the way they are, when they went back to check and see how complete their reporting system was, even though the chief of every service told all of his residents and internes to report every case that came through, I think they reported somewhere in the neighborhood of 5 percent. About 95 percent still did not get reported, even though this was the rule of the particular hospital.

This would seem to have been a case where there was a conscientious, specific effort, and according to Dr. Best, about 5 percent of the side effects were reported.

Do you think in your experience, in your judgment, that figure is anywhere near in the ball park of any kind of voluntary reporting the FDA gets on side effects?

Dr. EDWARDS. I do not think I am in a position to give you an absolute figure. I would say without any hesitation our reporting system is poor. As long as we continue to have a reporting system that is voluntary, as it is right now, where we have very little access to the medical records in both hospitals and in doctors' offices, I think the likelihood of our establishing a really accurate, up to date reporting system is not going to be very encouraging.

I think that we have to move in this direction for all drugs, not just for the oral contraceptives. I think a complete adverse reporting system has to be established in this country eventually, if we are really going to provide the surveillance for these powerful drugs that is necessary.

Senator NELSON. I bring this up just to make the point that if the Philadelphia study and the five hospitals with the chiefs of all the services cooperating produced only a 5-percent reporting result, all of your reports on the incidence of deaths and other side effects from the pill, would have to be multiplied by 20 to get an accurate figure.

Dr. EDWARDS. I have some reservation as to whether this is an accurate figure. I would add if I were chief of the service in a major teaching hospital and if I could not get my residents and internes to do better than that, I think that maybe I would look at myself, not my staff.

I think we can do better than that. I think maybe some do better than this, but I think the situation is generally poor throughout the country.

Senator MCINTYRE. Mr. Chairman, you asked the question back there, or called for the figures on the number of reports that FDA