

Do you feel additional funds are needed, and if so, in what specific areas?

Dr. EDWARDS. I think without any hesitation I would say that our research efforts in this whole general field have to be increased, both within the Food and Drug Administration and at the National Institute of Health.

Senator DOLE. You indicated on page 10 an increase of \$700,000 to in excess of \$3 million.

Dr. EDWARDS. When I say the 3 million, I am talking a ballpark figure and I am talking about total research. Again I do not mean that we are capable of taking this kind of increase all at once, but I think over a period of several years. I think this is the ballpark figure that we are talking about.

Senator DOLE. There are specific areas now with reference to oral contraceptives, where research could be done if you had the money, is that your opinion?

Dr. EDWARDS. I think additional research needs to be done in a number of these areas. This whole area of the carbohydrate metabolism, lipid metabolism, the possible effect or relationship between the oral contraceptive and carcinogenic effects have to be looked into in much greater depth than we have at this point in time. I am speaking only for the Food and Drug Administration, of course. Our research funds are extremely limited, and we have had to establish priorities. And as I can assure you, in establishing these priorities, the oral contraceptives have been up at the top of our list. So we have spent most of our funds on research in the oral contraceptives.

There are other areas, but I think these are certainly some of the main areas where additional research needs to be done.

Senator DOLE. Thank you.

Senator NELSON. May I pursue that subject a little further?

I guess every witness has commented on the question, including General Draper and Dr. Guttmacher, as well as various physicians and specialists who have appeared before the committee. They have all deplored the lack of adequate amounts of research. One of the points raised, I think by Dr. Corfman of NIH, although the record will correct me if it were not he, was that unfortunately there has been no dosage level research done in terms of trying to find out how low a dosage of progesterones and estrogens may be given and still be effective and what reduction in incidence of side effects might occur as a consequence of lower dosages or lower dosages in various combinations.

And you know, of course, that the first pills were 150 micrograms of estrogen and were effective, and 100 were effective, and 75 were effective. The British seem to think 50 are effective.

Would you consider it an important piece of research to establish some protocol for comprehensive investigation of this aspect of the oral contraceptive?

Dr. EDWARDS. Very definitely. I think this is an area in which far too little has been done. I am thinking in terms of the formulation of these products, the minimum amount that will provide the efficacy that we want.

I think some of this, however, has to also be done by the industry.