

I saw, and in a commentary that he made in an interview about 2 weeks ago, emphasized this point. It was his opinion that the women were not, and had not been adequately informed, and that he thought that they should receive substantially the same type of information as had been given to the physician, and I think you brought this point out in your initial statement that the physicians have been given warnings which have not been transmitted, as least in written form to the women.

Now, the practicing physician very often does take the initiative to inform the women. But in a mass practice clinic situation I don't think the movies and brochures that have been used do this job adequately.

Senator NELSON. One of the drug companies has, I believe, suggested that there be a package insert. I don't know whether they are suggesting that it be the same package insert that goes to the physician with all its precautions, side effects, and indications or not. Would you think that would be valuable?

Dr. DAVIS. I think it would be a step in the right direction, yes, sir. I am not sure that we could use the same language, and I am not sure that we would have to deal in the same detail, and it seems to me that it should be the physician's responsibility to screen out (for example) the patient who has a history of high blood pressure during her last pregnancy if he attended her. It seems to me it is the clinic's responsibility to see that her blood pressure is taken. It seems to me that it is also the clinic's responsibility to see that she gets adequate Papanicolaou smears, breast examinations. It is the physician's responsibility and the clinic's responsibility to make sure that she has not had a problem with varicose veins or a history suggesting a tendency towards thromboembolism.

So that certain of these warnings, I think, are more relevant to the requirements established for a clinic to administer this type of medication, so that they maintain certain minimum standards. But certain of the other aspects of it, I think, definitely should be transmitted to the woman, including information about alternative means of handling her birth control problem.

A woman may be totally unaware that there are other mechanisms available unless positive steps are taken to inform her, and alternatives made available to her. She may not know what resources are open to her for other means of birth control and, therefore, becomes a chronic user and exposed to risk of long term use of these agents.

Senator NELSON. I noticed that Dr. Kistner states in his book that a user of the pill should have a physical examination, in his judgment, every 6 months and that, therefore, he did not give a prescription that would exceed that period so that the user would have to come back to him, at which time Pap smears and various appropriate examinations would be made.

My question is this: Do you have any guesses as to how many, what percentage of the women who are using the pill do, in fact, get an annual or semi-annual physical examination?

Dr. DAVIS. I really can't answer that in relation to the country as a whole. Certainly I can answer it with respect to the practices in the public health clinics in the State of Maryland operated by the State health department, and planned parenthood in Maryland, and our own practices in the hospitals and in private practice in Baltimore, and I would say that some type of examination at intervals of approximately 6 months is pretty standard, and generally practiced.