How do you propose to address these issues?

Dr. HERTZ. I think, as you well know, from a legal standpoint, problems of this type are handled case by case. It is the tradition of our courts to establish precedence case by case and then to return to precedence or to break the precedence as indicated. I don't see any other substitute for that in this instance. I think this is a well-established legal basis. I think that the conditions of life and of clinical activity are so varied and so heterogeneous and conditioned by so many qualifying factors that it would be virtually impossible to reach any kind of a universal evaluation of the technical status of an individual patient-doctor relationship, and even more complicated of the legal status of the individual constituent in a public health agency who is attending a public clinic to the physicians in charge. I think that is an even more complex consideration.

So, that I think all we can do to assist on this aspect is to as explicitly and as definitively define the risks involved, make them as widely known as possible, and to evaluate them as objectively as they can be evaluated, and to not deviate from what is known or what is not known by presumption and inference.

Mr. DUFFY. When you say to make the risks involved as widely known as possible, we would require this as a matter of law, and this would indicate to me the foregone conclusion that these risks have been proven to the substantial agreement of a preponderance of the responsible medical community.

Are you aware of tests which would demonstrate that all of the risks that are now speculatively associated with the pill are amply documented?

Dr. HERTZ. I think there are only two features——

Mr. GORDON. I just want to interrupt for just one moment. A Dear Doctor letter was sent out by the Food and Drug Administration on June 28, 1968.

Dr. HERTZ. Is this pertinent to the same question?

Mr. GORDON. Pardon me?

Dr. HERTZ. Is this pertinent to the same question?

Mr. GORDON. Yes; for Mr. Duffy's information. There is a definite association between the use of oral contraceptives and the incidence of thromboembolic disorders.

In addition the labeling states that——

Mr. DUFFY. I hope that Mr. Gordon does not feel that I am interrupting him but for Mr. Gordon's information I think we have already established that there are sufficient studies which prove that to everyone's satisfaction and that Dr. Hertz and I were discussing the remaining items on the package insert.

Dr. HERTZ. Yes.

Mr. DUFFY. It is clear then, Doctor, that we were discussing the other items that were not so proved.

Dr. HERTZ. That is right.

Mr. DUFFY. And my question to you was, Were you aware of studies which were generally accepted within the medical community which would document to, let's say, a legal standard that such risks actually are associated with the pill?

Dr. HERTZ. The only two features about the pill which I think are substantiated to the extent that you describe for legal purposes is, one,