Mr. GORDON. Dr. Hellman, is it reasonable to assume that they are different in two countries like Great Britain and the United States, similarly situated as far as climate?

Dr. HELLMAN. Mr. Gordon, I think it is reasonable. There is a funny thing that has happened with thromboembolic disease that none of us understands. In about 1960, the incidence in Great Britain and the United States began to rise. It began to rise in both males and females. This is apparent in our own vital statistics reporting and that in Great Britain. This is idiopathic thromboembolic disease, no known cause. We have no explanation for this whatsoever except if I had to make a guess, I would say perhaps people do not walk so much as they used to and maybe the automobile is responsible.

Mr. GORDON. In both countries, though?

Dr. HELLMAN. In both countries. Now, the difference in the rise is not the same in both countries. I think any time you have different populations, you can expect a different incidence. I would not put too much emphasis on this point.

At the time that the British data were first available I happened to be in Great Britain and had the data firsthand. They were very cooperative with us. The Food and Drug Administration called a meeting of our committee and a meeting with representatives of the pharmaceutical industry. We placed this information before them and changed the labeling of the oral contraceptives, in spite of the fact that our own study was not available. In the labeling, we indicated what the British results were. We said at the time that we could not, in honesty, translate the British results to the United States.

Senator NELSON. When you say "labeling," you are referring to the package insert?

Dr. HELLMAN. Package insert. I guess "labeling" is a little slang for this, but that is what is used.

When we get to the other areas that the Committee considered, they considered utilization and efficacy, again we had a little better information than we had before. We had made some estimates of utilization, how many people were using the oral contraceptives, in the first report, and we made some projections for the future.

However, we found that we had underestimated the use. We had estimated in 1966 that by the year 1969 there would be about 6 million women using the oral contraceptives in the United States. Our figure in the second report is 8.5 million.

This piece of data is not quite as solid as I would like to have it be, because we have no way of really finding out how many people use what in the United States. So what we did was to take the sales and distribution figures from the pharmaceutical houses and by a formula that they use, and that I think is acceptable, get some idea of the usage. That is how this 8.5 million figure is arrived at. I do not think it is far wrong; but I wish it were a little better. The world usage figures again have the same limitations, but somewhere between 10 and 12 million women outside the United States use these compounds.

Senator NELSON. 10 or 12 million in addition to——

Dr. HELLMAN. About 18 million people in the world probably use these compounds now. Most of them, as you might imagine, are in the developed countries. The problem in the undeveloped countries with the oral contraceptives, as far as I personally know it, and I know