tion and 10 deaths with the intrauterine devices were reported, we thought, to perforation of the uterus at the time of insertion of the device, peritonitis, and intestinal obstruction.

Senator NELSON. May I interrupt a moment?

Dr. HELLMAN. Yes, sir.

Senator NELSON. Then death was not caused by the use of the intrauterine device, but by improper insertion by the physician?

Dr. HELLMAN. Well, I would not use the word "improper," Senator, because any obstetrician and gynecologist who puts something in the uterus realizes that the danger of penetration is quite real. This happens to all of us.

Senator NELSON. Just so the record is clear, it was not caused by the presence of the intrauterine device?

Dr. HELLMAN. That is correct, yes, sir.

In order to make an estimate of the frequency or prevalence or incidence of death, we had to estimate how many intrauterine devices were used in the United States. At that time the most sophisticated estimate we could come up with was about a million were in place in the United States.

We said, "Well, we have 10 deaths reported, let's say we made a 50-percent error and there were probably 20." So we came up with two deaths per 100,000 or 20 per million.

It is interesting, that although the Food and Drug Administration does have authority over devices as well as drugs procedures equivalent to those for drug approval do not exist for the approval and surveillance of devices. Therefore, direct action for the implementation of the recommendations in this report by the FDA was less feasible. Nevertheless, we made two specific recommendations.

One was that packaging of the intrauterine devices be improved. The way they were packaged before was that the device was separate and the inserter was separate and then they had to be sterilized and then the device placed in the inserter. All of this gave a chance for contamination. We recommended that packaging be sterile and that the device be in the inserter so there was little chance for contamination. I am very pleased to say that this recommendation was followed by a great many of the manufacturers.

The second recommendation we made is that the closed devices—a closed device is a ring that is hollow, and it collapses if you put it in the uterus and then it expands—be eliminated. It was these closed devices that caused the majority of the deaths, because when they perforated the uterus, they produced a hole through which a loop of bowel entered and then the bowel became obstructed. The closed devices are no longer used in this country.

Senator NELSON. There is continuing research. Has that been improved since your last report?

Dr. HELLMAN. There is a good deal of research on whether you can get a better intrauterine device, one that will not be extruded spontaneously and still do the job. There are almost as many devices as there are investigators, and I would have to answer you in candor, Senator, that I do not think there is much improvement in these devices at this time.

The third report of the Committee, which was issued, again against a deadline, the deadline being August 1969, I think is a scholarly re-