at that time on behalf of the Food and Drug Administration in an attempt to determine whether there had been any, serious complications, and they received reports of several instances of infection immediately following the insertion of the device.

On the basis of these reports the Food and Drug Administration committee recommended that sterile packaging of devices be carried out. They had previously been sterilized by simply soaking them in an antiseptic solution, and out of this survey they were able to pick up four insertion-related fatalities out of an estimated 2 million users. They thought that perhaps unsterile technique of insertion had introduced organisms and led to serious infection.

I think that you can safely state that the major hazards of the use of an intrauterine device are related to the technical act of insertion and that if you carry out technical precautions, it carries less risk than a smallpox vaccination which can under unusual circumstances lead to meningitis and death.

It is also said in relation to thromboembolic problems that the IUD is 15 times safer than you can reckon for the currently marketed high dose oral contraceptives.

Mr. DUFFY. Doctor, while we are on the subject of intrauterine devices in our preparation for these hearings we became aware of the report that indicated that you had recently patented such a device. Is there any truth or substance to that report?

Dr. DAVIS. I hold no recent patent on any intrauterine device. The Johns Hopkins University holds a patent on an intrauterine device that was developed in 1964 in a joint development venture together with the Ortho Research Foundation.

That particular device was a ring which was used for experimental purposes and has never been marketed, and I doubt ever will be marketed.

Mr. DUFFY. You say you have——

Dr. DAVIS. My name appears on a joint patent together with a Mr. Jones, and this patent is held jointly by the Johns Hopkins University for whom I am an employee, and by the Ortho Co. In the public interest this device was developed in 1964 and was the object of a patent application. This is not a marketed item and I doubt it ever will be.

Mr. DUFFY. Then you have no particular commercial interest in any of the intrauterine devices?

Dr. DAVIS. That is correct.

Mr. DUFFY. Thank you.

Senator NELSON. Thank you very much, Dr. Davis, for your very informative presentation to the committee. We appreciate your taking the time to come.

Dr. DAVIS. Thank you, sir.

Seantor NELSON. Our next witness is Dr. Marvin S. Legator, Chief, Cell Biology Branch, Divison of Pharmacology, Bureau of Science, Food and Drug Administration. Dr. Legator, the committee is pleased to welcome you here this morning. You may present your statement in any fashion that you desire.

Dr. LEGATOR. Thank you, Mr. Chairman.

Senator NELSON. It would be helpful if you would have that microphone close enough so that you are speaking directly into it.