APPENDIX XI

UNITED STATES SENATE,
Washington, D.C., March 10, 1970.

Mr. BENJAMIN GORDON,
Select Committee on Small Business,
Senate Office Building, Washington, D.C.

DEAR Mr. Gordon: Enclosed are several newspaper articles concerning oral contraceptives and the recent hearings of the Monopoly Subcommittee.

I would appreciate them being included in the record of the Subcommittee hearings.

Sincerely yours,

BOB DOLE,
U.S. Senate.

[From The Washington Post, March 5, 1970]

HEALTH—IUD HAZARDS

(By Morton Mintz)

Sen. Gaylord Nelson's hearings on the Pill, which ended yesterday, have awakened women to known and possible hazards they never heard about from their doctors. Thousands have decided to be fitted with an intrauterine device (IUD).

Some of these women are going to be injured needessly, because certain IUD designs are unduly hazardous, because of improper insertion by doctors and because of inadequate precautions to assure sterile packaging and insertion.

The origin of the problem is that the Food, Drug and Cosmetic Act puts drugs and medical devices in different categories.

Since 1938, when the original law was passed, a manufacturer wishing to market a medicine has carried the burden of truth. That is, it has been up to him to demonstrate to the Food and Drug Administration—before marketing can begin—that the product is safe (and also, since 1961, effective) in the uses for which it is recommended.

But the maker of a medical device has not been required to get premarketing clearance. He is generally free to market what he will.

Once a device is on sale, the FDA, if it sees a need to act, must be prepared to assume the burden of proof; that is, to try to demonstrate in court that a device falls short of the claims of safety and efficacy made for it by the manufacturer.

If the FDA should prevail, it will—probably after lengthy proceedings—get an injunction against further manufacture of the questioned device.

As a practical matter, however, this cumbersome procedure has severely limited the FDA's potential for protecting the public.

In January, 1968, the Advisory Committee on Obstetrics and Gynecology, a consultant group to the FDA, briefly stirred hope for legislative reform.

At that time, when an estimated one million women in the United States, Canada and Puerto Rico had been fitted with IUDs, the committee issued a comprehensive report on the devices.

IUDs come in two basic shapes. By far the more popular is the "open" shape, of which the best known example is the Lippes Loop. The other is the "closed" shape, of which the better known designs are the "bow," the "Incon Ring" and the "Butterfly."

The committee said that in a survey of Fellows of the American College of Obstetricians and Gynecologists 10 deaths were reported among IUD users. A clear cause-effect relation was shown in four of the 10 cases, but not in the others. In addition, the committee estimated that 10 deaths (for a total of 20) had not been reported.