(Even the maximum assumed fatality of 2 per 100,000 was well below the 3 per 100,000 demonstrated for the pill from clotting diseases. The pill also has been shown to cause nonfatal but disabling clotting in some women, psychic depression, skin blotching and hair loss.)

Aside from fatalities, 369 women were reported to have suffered critical inflammatory infections in connection with IUDs.

The committee pointed out that among the fatal and critical IUD cases were an undetermined number of needless victims—women who had been fitted with unsterile or improper devices and insertion techniques.

An additional 177 women were reported to have suffered perforation of the uterus. One fact stood out: A high proportion of the 177 victims had been fitted with one of the "closed" IUD designs.

Even more striking were cases of perforation that were followed by intestinal obstruction. This is a highly dangerous condition which almost always requires surgical removal of the IUD.

Of the 15 such cases reported, 13 had been fitted with a "closed" IUD. In the remaining two cases the design was not ascertained.

In sum, the committee attributed a significant proportion of all deaths and critical illnesses in IUD users to two factors:

First, the use of "closed" designs, and second, the use of nonsterile packaging for most IUDs then being sold, the lack of disposable tools with which physicians insert the devices, and inadequate insertion instructions in the labeling.

The committee warned that "the safety of the material used, the quality control and its manufacture, and the labeling and packaging of intrauterine devices are at present the sole concern of each manufacturer."

Obviously, the problem is even more urgent today. Not only are more women using IUDs, but new designs are being developed including two that unlike early ones can be used in women who have not been pregnant.

Last September Virginia Knauer, the President's consumer affairs adviser, said that defective medical devices were needlessly killing, injuring and exploiting people.

She cited poorly designed artifical kidney machines; "5,000 to 10,000" diathermy machines used to give 20 million heat treatments yearly "that are worthless for any known medical purpose," and 40,000 ineffective emergency respirators.

President Nixon, in his October consumer message to Congress, said "certain minimum standards should be set" for medical devices, with the government being given "additional authority to require pre-marketing clearance in certain cases."

Dr. Theodore Cooper, director of the National Heart and Lung Institute, heads a panel studying legislative reform at Mr. Nixon's request. It is seeking a proposal which will protect the public without denying it the benefits of new technology and is scheduled to report by the end of this month.

Hopeful as this may sound, Presidents Kennedy and Johnson sent six messages to Capitol Hill urging lawmakers to require manufacturers of medical devices to demonstrate before marketing that devices to be implanted in the body are safe, effective and reliable. All were unsuccessful.

Members of Congress have introduced a series of bills aimed at that objective. But all such proposals have had less steam behind them than a $500-million-a-year industry.

[From The Evening Star, March 8, 1970]

MEDICAL REPORT—'PILL' WARNING TO SET A PRECEDENT

(By Judith Randal, Star Staff Writer)

Within the next two or three weeks a notice will appear in the Federal Register that will set a precedent.

Its publication will serve notice to pharmaceutical manufacturers that the Food and Drug Administration intends to insist that the 8.5 million American women who take "the pill' have access to authoritative information about what the side effects may be.

No longer will it be good enough—as it is for the thousands of other prescription drugs on the market—merely to inform the physician what transient