# IUD's: Intrauterine Danger?

## Intrauterine devices may eventually fall under Government regulation, but in the meantime, women face a continuing medical uncertainty

by Deedee Pendleton

It began like many medical disasters do . . . misdiagnosed. A college woman, suspecting she might have a uterine infection, came to the student health clinic for a check-up. Tests were negative. Two weeks later she was back in the clinic, complaining of severe cramps. Again she was sent home. Three weeks later, in the emergency room of the university medical center, she was told her chances of becoming sterile were two to one, that one of her Fallopian tubes was infected and that unless her Dalkon Shield was removed, her chances of ever bearing children would be drastically reduced.

The Dalkon Shield is the second IUD to have been linked in any numbers to dangerous side effects. Last year the Food and Drug Administration seized 9,000 IUD's known as Majzlin Springs, after accumulating enough evidence to verify reports (which began in 1968) of their being almost impossible to remove.

Because the FDA is authorized to test and approve drugs, but not devices, the manufacturing and marketing of such medical items as glass eyes, pacemakers and heart valves has functioned for years without Government scrutiny, except when their use is so strongly protested as dangerous by physicians that the Government is forced to investigate. A bill to amend the FDA's authority to regulate medical devices, introduced into Congress March 26, would, in essence, require companies to report defects in their products and register them with the FDA. Even if the bill passes, it may take months to activate.

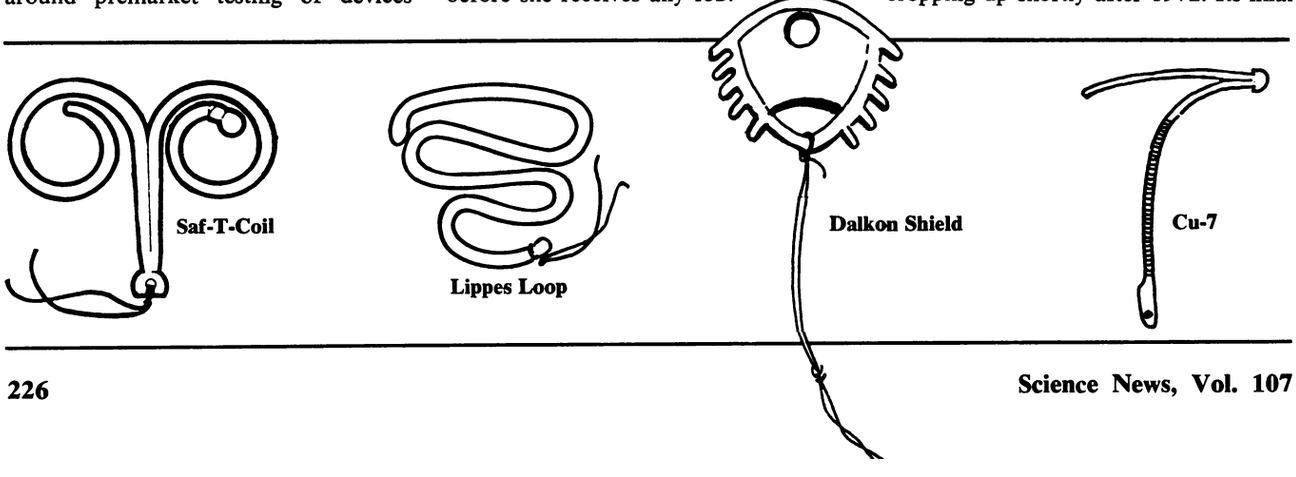
The problem, basically, centers around premarket testing of devices such as the IUD before they are issued to patients. "A tremendous amount of false advertising about IUD's' supposed safety has been distributed to women and physicians, but very limited premarket studying has been done," Kathleen Jennison, coordinator for the California Coalition for the Medical Rights of Women, says. It is presumed by most women that manufacturers properly test their products before marketing them, but in her view patients consenting to use new medical devices are, in fact, agreeing to participate in experiments with unregulated products, relying on their physicians' judgments rather than on scientific research. In testimony before the California State Board of Health, Jennison said, "The coalition decries the fact that women have been used as guinea pigs for untested and unregulated intrauterine devices . . . . It is crucial to insure that regulatory agencies charged with protecting the public health actually comply with their legal obligations."

Some IUD's, such as the Lippes Loop, through years of use have proven relatively safe, and have consequently won the endorsement of many gynecologists. But others, such as the short-lived Lem (manufactured by the G. D. Searle Co.) was on and off the market in less than a year, at the expense of countless "test" patients.

One solution many feminist activists advocate, and one the FDA is enacting, is the publication of warning information, in much the same way that women are warned about possible side effects of the pill, and the requiring of a consent form to be signed by a patient before she receives any IUD.

Antibiotics have effectively counteracted what could have been fatal infections in many IUD-related septic abortions, Russel J. Thomsen, a Walla Walla (Wash.) obstetrician-gynecologist, says. According to the FDA, in a review of all reported deaths purportedly attributable to intrauterine devices there have been 17 in association with the Lippes Loop, 14 with the Dalkon Shield, four with the Saf-T-Coil and four with all other devices. Of the 14 septic deaths with which the Dalkon Shield has been associated, 13 were related to complicated pregnancies. The reported morbidity in pregnancy was 219 infected abortions with the Dalkon Shield, 50 with the Lippes Loop, 14 with the Saf-T-Coil and six cases with all other IUD's since these IUD's were introduced in 1965. One problem in interpreting such figures is that no one knows how many women have used each type of IUD. The Lippes Loop, for example, has been in use several years longer than has the Dalkon Shield and may therefore have had greater total use. The Dalkon Shield, however, experienced a burst of popularity with doctors prescribing IUD's to childless women, because of its reported low expulsion rate, just after its introduction in 1970, and in 1973, the Dalkon Shield accounted for 39 percent of all IUD users.

IUD's are often invented by private physicians, then marketed by manufacturers under a pharmaceutical company name. It usually takes between two and four years for the adverse effects of a product to begin circulating; in the case of the Dalkon Shield, difficulties began cropping up shortly after 1972. Its final



failure, its multifilament tail, was only one in a series of difficulties with the device. Its shape made it the largest, and in some cases, the most difficult to insert; the shield did not show up on X-rays and sometimes its tail came off once the device was inserted. Early in 1974 it became apparent that the ramifications of its many differences from other IUD's were serious: The shield's unique multifilament tail, Howard J. Tatum, an IUD-inventor himself, and several colleagues reported (JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 231:711) can convey bacteria, and if a woman becomes pregnant while wearing a Dalkon Shield her chances of infection and consequent septic abortions are very high. Last year Dalkon-related infected abortions accounted for 88 percent of all those occurring in IUD wearers. (About two percent of women wearing IUD's can be expected to develop pelvic inflammatory disease during the first year of use, the International Planned Parenthood Federation says.) Although the FDA had the authority to ban the Dalkon Shield, there was insufficient evidence to take the company to court, since the Dalkon Shield has not been proven unquestionably more dangerous than other IUD's presently on the market. Instead, the FDA consented to what some doctors say amounts to an overwhelming pile of paperwork. If a new Dalkon Shield is redistributed, the A. H. Robins Co. of Richmond, Va., has agreed to require physicians to register each patient at the time of insertion and to keep detailed records of their experience with the shield, redesigned with a single, monofilament tail much like those used with other IUD's. The FDA would then receive data on patient experience from the Robins Co. and manufacturers of other IUD's voluntarily participating in the registry every six months.

In commenting on the proposed registry system, one bioengineer already employed by the FDA to test questionable devices says the question is based on the amount of money Americans are willing to pour down the bureaucratic tube for investigations into new products, and possible enforcement of regulations of them. FDA's role in the past has been one of policing drugs that proved unsafe or were being sold illegally.

Robins and other manufacturers participating in the registry would be financing it themselves, and Federal regulations governing the experimentation on humans with drugs do not cover women using IUD's in studies conducted and paid for by private companies. A woman's chief recourse, should she suffer damage directly linked to her contraceptive device, is in the courtroom. The Robins Co. faces 186 such cases presently.

The fact that both the pill and pregnancy are more dangerous than any IUD clouds the issue further. Women presently wearing IUD's must decide between the relative risks of an IUD infection or the consequences of pregnancy or possible pill-related blood clotting. A typical rationalization voiced by one Government researcher is that when the number of deaths from IUD's is compared with the number of fatalities that could have occurred among the approximately 8.8 million women who have received an IUD since 1966, the inherent risks and fatalities from Dalkon Shields seem almost insignificant. Data indicate that between one and 10 deaths per million users per year are IUD related; with oral contraceptives the rate is 22 to 45 per million users per year. Probably the safest contraceptive device available, from recorded complication figures, although not the most effective, is the diaphragm, which, when used with cream, has a failure rate of three pregnancies per 100 woman-years of use. (One hundred woman-years equals 100 women protected by a contraceptive for one year, or one woman protected for 100 years.) Failure rate with the pill is 0.1 pregnancies per 100 woman-years.

About a dozen new IUD's were patented last year; three are currently on the market: Lippes Loop, Saf-T-Coil and Cu-7, the latter the first to be classified as a drug because it leaches minute amounts of copper into the wearer's uterus. Ideally, the perfectly designed shield would solve the basic IUD problems—perforation, expulsion, bleeding and unplanned pregnancy. Copper-containing devices appear to cause less bleeding than inert IUD's and to be better suited for childless women because of their smaller size and ease of insertion. Latest in a long line of these bioactive devices is one designed by Howard Tatum, the researcher who helped confirm that the Dalkon Shield's tail was dangerous. Tatum's Copper TCu-220C has copper sleeves, segmented for flexibility, instead of copper wire winding, which, Tatum says, should last up to 75 years before it is leached away.

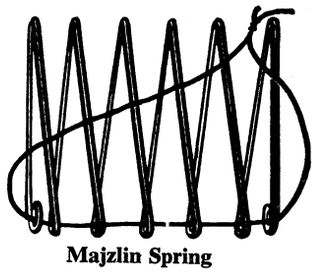
Designing a shield whose shape prevents expulsion, yet that can be removed when necessary, prompted the production of the Majzlin Spring, the M and the Dalkon Shield, all eventually withdrawn from the market for one reason or another. A new device, called the Ypsilon, to be marketed by Syntex Corp., is being tested at New York Hospital and at the Cornell Medical Center. The Y shape has a frame of stainless steel wire but is completely covered by silicone and adjusts to the uterine lumen (cavity). A silicone web between the two arms of the Y prevents too much spread. How the device actually prevents pregnancy is still conjecture, though, as is the case with most IUD's.

A device designed by the Battelle Population Study Program in Seattle, called the membrane, looks something like an arrowhead and is squeezed into a funnel-shaped inserter, then unfolds once in the endometrical cavity.

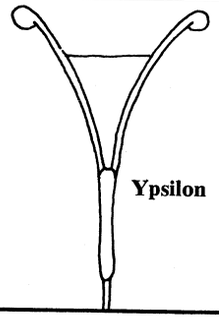
The Alza, a flexible plastic T with a hollow vertical stem, uses progesterone, released daily (65 micrograms) for a year into the uterus to tranquilize the endometrical surfaces and prevent sperm implantation. Research with this device, done primarily on women outside the United States, indicates the IUD eases the problem of heavy menstrual flow and severe cramping normally associated with insertion.

Marketing of the new Dalkon Shield cannot begin until late in the year, if at all, since the FDA must approve new labeling, brochures for doctors and patients and plans to register patients for the FDA studies.

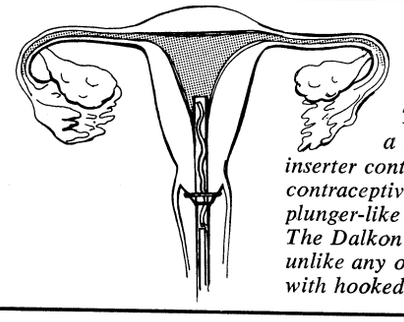
In the meantime, advocates on both sides of the fence are forced to wait for further testing and for Federal action on device-regulation legislation. □



Majzlin Spring



Ypsilon



*Thinner than a straw, an* IUD *inserter contains the collapsed contraceptive, which is pushed plunger-like just past the cervix. The Dalkon Shield inserter, unlike any other, is a solid rod with hooked end.*

Planned Parenthood