U.S. Lags on Birth Control Development

An NAS panel calls for changes in FDA regulation and product liability laws to get new contraceptives on the market

WOMEN IN FINLAND, Sweden, and ten other countries are being protected against pregnancy for up to 5 years by a contraceptive implanted under the skin of the upper arm. The West Germans are marketing in 40 countries an injectable contraceptive that protects for 2 months. China and Mexico both manufacture their own 1-month injectable. The French have RU 486, the abortion pill.

And U.S. couples are stuck with the old standbys: the Pill, condom, IUD, diaphragm, and surgical sterilization. Indeed, in the three decades since the Pill and IUD came on the market, no fundamentally new form of birth control has been introduced in the United States, according to a report on contraceptive development by a joint committee of the National Research Council and the Institute of Medicine.

Without a drastic change in federal policy, the United States will continue to miss out on the plethora of new contraceptive technologies now being developed, says the committee. These include contraceptive vaccines, a once-a-month pill to induce menstruation, reversible male and female sterilization, a hormone-releasing patch worn like a Band-Aid, and male contraceptives. The likelihood of any of these getting on the U.S. market before the year 2000 is negligible, says the committee.

"It's bleak, bleak," says Luigi Mastroianni, director of the division of human reproduction at the University of Pennsylvania and chairman of the joint committee. All but one major U.S. pharmaceutical company have fled the field of contraceptive research, driven out by lawsuits and an inhospitable regulatory climate. That leaves the bulk of the effort to small companies and foundations. But foundation support is dwindling as well, and the federal government has not picked up the slack. Support for training in reproductive biology is eroding. The upshot, says Mastroianni, is that "the United States is in a second-class position on contraceptive development."

The consequences of this stagnation are enormous, says the committee, which blames contraceptive failure for about 2 million unwanted pregnancies a year in the United States and for about half of the 1.5 million abortions. New, easier-to-use contraceptives would go far toward reducing that abortion rate, the committee says, which is one of the highest in the industrialized world. Another telling indictment of the status quo is that surgical sterilization, both male and female, is the most popular form of contraception in the United States.

The committee points to myriad factors that conspire to keep new contraceptives off the market. Some of it is simply economics. The ideal contraceptive, if there is such a thing, might be a vaccine, or a long-acting injection, or perhaps a "once-a-month" pill—none of which is likely to be a huge moneymaker. Without the large market that comes from frequent repeat use, there are few incentives to develop these contraceptives. And there are some powerful disincentives: the growing number of product liability suits—and some multimillion dollar awards; the peculiarities of contraceptive regulation; and the powerful anti-abortion movement, which has made pharmaceutical manufacturers leery of consumer boycotts and the federal government reluctant to invest in contraceptive research.

CONTRACEPTIVE USE IN THE UNITED STATES

Method	Estimated % use	% Accidental pregnancy in the 1st year of use
MALE STERILIZATION	14	.15
FEMALE STERILIZATION	19	.4
COMBINED (ESTROGEN AND PROGESTIN) ORAL CONTRACEPTIVE PILL	32	3
CONDOM	17	12
DIAPHRAGM	4-6	2-23
NATURAL FERTILITY CONTROL (FORMS OF PERIODIC ABSTINENCE)	4	20
INTRAUTERINE DEVICE	3	6
CONTRACEPTIVE SPONGE	3	18
VAGINAL CONTRACEPTIVES (FOAMS, JELLIES)	2	21

SOURCE: Developing New Contraceptives: Obstacles and Opportunities, Washington, D.C.: National Academy Press, 1990

Some of the blame must also be laid on the Food and Drug Administration, which has set a tougher approval standard for contraceptives than for almost any other drug, says the committee. The reason for the extra caution is that contraceptives, unlike other drugs, are used by predominantly healthy women for a long time. The committee argues that FDA should rethink how it balances benefit and risk in evaluating contraceptives—specifically, to give more weight to the benefits of contraceptive effectiveness and convenience and to factor in the risks of unwanted pregnancy.

"We are not saying FDA should unleash on the market a high-risk product but that the agency needs to be more careful that it has fully considered the benefits of contraceptives, which are unique," says committee member Richard Cooper, who was formerly chief counsel of FDA and is now with the Washington firm of Williams and Connolly. Philip Corfman, head of FDA's panel on reproductive drugs, says he welcomes the committee's recommendations and has invited the group to brief the agency.

But simplifying the regulatory maze will not be much help unless would-be contraceptive manufacturers' biggest problem—the threat of litigation—can be solved. Manufacturers have good reason to be concerned about lawsuits, the committee says. In 1986 a judge awarded more than $5 million to a woman who alleged that a spermicidal jelly had caused birth defects in her child, despite extensive scientific evidence to the contrary. Legal skittishness over the Dalkon Shield litigation prompted three manufacturers to withdraw their FDA-approved IUDs from the U.S. market in the mid-1980s, even though the agency had not raised any questions about their safety.

To address the litigation problem, the committee proposes a new federal product liability law that would give contraceptive manufacturers a partial defense if they met all FDA requirements in designing, testing, and manufacturing a drug or device and if they provided proper warnings.

"Does it make legal sense? Yes. Do I think it will happen any day now? No," says Peter Huber, a product liability expert and senior fellow at the Manhattan Institute, a New York think tank. Congress did recently pass a law to protect manufacturers of childhood vaccines, "but vaccines are a lot less poisonous, politically, than contraceptives," says Huber. "A special clause for contraceptives would seem very difficult to get through." And without one, warns the committee, U.S. couples may be stuck awhile longer with the contraceptives of three decades ago. ■ LESLIE ROBERTS