

Panel Wants to Break R&D Barrier

Hundreds of millions of couples worldwide lack adequate contraception, despite the worldwide success of the pill and other modern contraceptives, and this situation leads to over 50 million abortions each year, according to a new report by the U.S. Institute of Medicine (IOM). Yet pharmaceutical companies have all but abandoned R&D programs in this area, forced out by towering political, economic, and cultural obstacles.

Staring at this bleak picture, a 17-member IOM panel recommends several ways for the U.S. government, industry, and organizations already involved in providing population services to break this impasse. They include: reforming U.S. product liability law, including contraceptives in health insurance coverage, and pooling contraceptive purchasing funds from international health agencies to create a large market. These several steps, taken together, might prod new research efforts, says Allan Rosenfield, the dean of the Columbia University School of Public Health in New York City, chair of the committee that produced the report. But both Rosenfield and outside observers acknowledge that most of these recommendations will face stiff opposition.

Even though dozens of new potential drug targets for contraceptives have been identified in recent years (see table), the number of major pharmaceutical companies involved in contraceptive research dropped from a dozen in the 1960s to just four by the mid-1980s. Company officials were worried about entering a market where safe, effective, and cheap alternatives (such as the pill) already exist, where there is a high potential for lawsuits should unforeseen side effects arise, and where the sale of such products could draw them into debates on abortion and appropriate sexual behavior (*Science*, 2 December 1994, p. 1489).

So Rosenfield and his colleagues recommend that Congress pass a product liability reform bill that would shield contraceptive manufacturers from some liability once their product had been approved by the Food and Drug Administration. "It would make a fantastic difference," says Nancy Alexander, who heads the contraceptive development branch at the National Institute of Child Health and Human Development's Center for Population Research. "There really is a reticence on the part of industry to develop new contraceptives," she says, particularly new drugs as opposed to barrier devices, because of the difficulty of gauging their long-term health effects. Yet hopes for such reform in the near future are dim, Alexander and Rosenfield

admit, noting that President Clinton vetoed a liability reform bill earlier this year.

The IOM panel also urges insurance companies to add contraceptives to their standard coverage as a way to boost access and demand. But here again, the recommendation is likely to encounter opposition, says Henry Gabelnick, director of the Contraceptive Research and Development Program in Arlington, Virginia. He notes that while covering contraceptives is likely to save insurance companies money in the long run by reducing costs associated with pregnancies, those companies typically balk at such suggestions for fear of being branded as supporting promiscuity.

Other recommendations are aimed at boosting economic incentives for new contraceptive research. One proposes a joint purchasing pool for international agencies that distribute contraceptives to developing countries—such as the U.S. Agency for International Development (AID)—in the hope that commitments to buy large volumes of contraceptives would induce companies to develop low-cost products. Yet Jeff Spieler, head of research at AID's Office of Population, says that it would be hard for agencies with annual budgets to make commitments extending for several years. Another avenue the report recommends may be less fraught with difficulties: cooperative ventures between private foundations, such as the Consortium for Industrial Collaboration in Contraceptive Research, whose grants to researchers are matched by drug companies.

SOME STRATEGIES FOR NEW CONTRACEPTIVES

Near-Term

- ♂ Stopping sperm production with injections of progestin-androgen combinations
- ♀ Inducing menses with a combination of antiprogesterins, antiestrogens, and inhibitors of enzymes involved in steroid synthesis

Medium-Term

- ♀ Preventing sperm passage by modifying mucous secretions from cervical epithelial cells

Long-Term

- ♂ Preventing sperm maturation by inhibiting epididymal function
- ♂ Preventing fertilization by causing sperm cells to prematurely release enzymes that otherwise break through the egg's protective coat
- ♀ Inhibiting ovulation using a combination of a nonpeptide gonadotropin-releasing hormone antagonist and hormones
- ♀ Preventing fertilization or the implantation of a fertilized egg in the uterine lining with various vaccines

SOURCE: "CONTRACEPTIVE RESEARCH AND DEVELOPMENT: LOOKING TO THE FUTURE" (INSTITUTE OF MEDICINE).

While these recommendations may face an uphill battle, Rosenfield says the report is important to show drug companies the massive need and potential market for new contraceptives and to underscore the need for continued public funding of research in the area. The recommendations, Gabelnick agrees, can "bring awareness to the public of the need for new contraceptives and that the private sector can't do it alone."

—Robert F. Service

MARINE POLLUTION

Science Intrudes on Brent Spar Saga

LONDON—This time last year, the environmental group Greenpeace scored a David-and-Goliath victory over the giant Shell Oil company. Greenpeace activists, playing to a worldwide television audience, boarded an oil storage buoy called the Brent Spar and temporarily halted Shell's plan to scuttle it in the deep Atlantic off the west coast of Scotland. Greenpeace claimed that the sunken rig—a 141-meter-long vertical steel tube that had served as a holding tank in the North Sea for 15 years—would pose a toxic threat. The publicity prompted a widespread consumer boycott of Shell products, particularly in Germany, as a result of which the company gave up and towed the Brent Spar to Erfjord in Norway.

Last week, a panel of scientists passed judgment on Greenpeace's claims—and both sides are claiming vindication.

The panel, chaired by oceanographer John Shepherd, director of the Southampton Oceanography Centre, concluded that Brent Spar, by itself, would have a very small impact on the marine environment. "Any adverse effects would be confined to the immediate vicinity of the wreckage," the report says—an area of only a few square kilometers—and sea-floor wildlife would recover after 2 to 10 years. The only real danger would come from exotic materials, such as polychlorinated biphenyls (PCBs), but as Shepherd told *Science*, "Brent Spar probably contains less of these than the average



Limited threat. Greenpeace made Brent Spar famous.

* "Contraceptive Research and Development: Looking to the Future," Institute of Medicine, 1996.