# Beating the birth control drum

Is there a need to develop new contraceptive methods or even to organize yet another meeting to debate the question? A recently released Institute of Medicine (IOM) report concludes that a second contraceptive revolution is long overdue, with few new contraceptive choices available since the introduction of oral contraceptives and intrauterine devices in the early 1960s. Daunting statistics faced the nineteen IOM committee members. As many as 228 million women (17 percent of the world's reproductive-age females) who would like to use contraception are faced with unavailability or methods that are ineffective. The global situation is mirrored by statistics from the United States. "More than 50 percent (3.5 million) of all US pregnancies are unintended and, of these, half end in abortion," says Polly Harrison, the senior director of the IOM study. "This is not just a teenage problem but is broad-based, transcending age, race and socioeconomic status."

The IOM report is not alone in advocating development of new contraceptive methods. Both the 1994 International Conference on Population and Development in Cairo and the 1995 World Conference on Women in Beijing drew similar conclusions. Allan Rosenfield, committee chair and dean of the School of Public Health at New York's Columbia University, notes that "although there are good contraceptive methods available, all of them have problems." This sentiment is echoed by Willard Cates, director of Medical Affairs at Durham's Family Health International, who says "we definitely need an increase in the number of contraceptive choices to meet the demand of a wide variety of lifestyles."

The past six years have seen remarkable progress in the scientific understanding of reproductive biology, providing a wealth of possibilities for developing new contraceptives. Richard Douglas of Genzyme Corporation in Cambridge, Massachusetts (one of the committee's industrial representatives, although Genzyme *per se* is not involved in contraceptive research), says "scientifically, the opportunities for developing innovative new contraceptives are very good." The IOM convened this investigation partly to address the many scientific advances made since their previous contraceptive development study in 1990. The biological events leading to conception provide a plethora of potential targets. The IOM committee recommends that methods that target the unique steps in gametogenesis should have priority over hormonal methods that act systemically. In addition, novel approaches such as immunocontraceptives (reversible vaccines that target specific immunogens of the sperm/egg or reproductive hormones) should continue to receive support.

While science surges forward, a number of societal, political and regulatory issues act as disincentives to industry's involvement in contraceptive development, despite the huge worldwide market. The controversy surrounding sexuality and contraception continues to hamper progress, as evidenced by the checkered history of the abortifacient RU 486 (see box). The IOM report suggests that, particularly with respect to postimplantation methods, small companies may have to unite with nonprofit organizations to ensure that such controversial products reach the marketplace. Says Rebecca Cook, professor of law at the University of Toronto, "The short patent life, product liability and burdensome regulatory process all contribute to industry's unwillingness to develop new contraceptives." Harrison adds that "the unpredictability of damage awards is disconcerting for industry." The IOM report reiterates the recommendation of the 1990 study for Congress to enact reasonable caps on punitive damage awards. However, a reform bill addressing this issue, although it passed both the House and the Senate, was recently vetoed by President Clinton. As is the case with vaccines, Cook points out, contraceptives are given to healthy individuals, so safety requirements are more stringent than, for example, with chemotherapeutics. Among other disincentives, Harrison notes, is the fact that "contraceptives are erratically covered by health-care providers." Yet she argues preventing unwanted pregnancies by providing comprehensive contraceptive coverage beforehand translates into "cost reduction in the long term for both the public sector and third-party payers."

According to Harrison the "woman-centered agenda" advocated by the IOM committee will help develop new contraceptives for women that are safe, effective and discreet. Such an agenda also encourages development of male contraceptives so that both partners can share the responsibility. However, as Malcolm Potts, a population expert at the University of California at Berkeley, points out (see p. 722), given severely limited resources, efforts should focus primarily on methods that control female fertility and also protect against sexually transmitted diseases (STDs). The IOM committee advises the collaboration of groups developing anti-infectives with those working on new contraceptives in an effort to produce a dual prophylactic. Notes Cook, "Regulations should be combined and streamlined to expedite approval of anti-infective contraceptive methods." The IOM report and myriad other studies reiterate the need for new contraceptive development. Now it is up to government and industry to combine forces to meet this need and bring to the marketplace an array of new, safe, efficacious contraceptive methods that preferably also protect against STDs — a move that will surely improve women's health worldwide while proving cost-effective in the long-term.

ORLA SMITH

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The abortifacient RU 486 has met with fierce opposition both in the United States and elsewhere and is currently only approved for use in France, Britain and Sweden. The Population Council, a nonprofit New York organization, to whom Roussel-Uclaf (the French drug company that developed RU 486) donated all US patent rights, filed for Food and Drug Administration (FDA) approval in March, based on French clinical studies supported by data from US clinical trials involving 2100 women at 17 locations. "Clinical studies show that the drug is safe and effective" says Sandra Waldman, director of public information at the Population Council who notes that the preferred US name for RU 486 is mifepristone. If FDA approval is granted, manufacture and marketing of mifepristone is planned for the beginning of next year. However, because of the controversial nature of the drug, the Population Council declined to give details.