Mifepristone Rollout Begins; FDA Okays New Contraceptive Shot

On September 28, 2000, four years after first declaring it safe, effective and “approvable,” the Food and Drug Administration (FDA) gave final permission for the abortion drug mifepristone to be marketed in the United States as an alternative to surgical abortion. Initial rollout of the drug, under the trade name Mifeprex, began in November. Mifepristone was approved for use in conjunction with the drug misoprostol (which stimulates uterine contractions and is already marketed in the United States) for termination of very early pregnancy—through 49 days’ gestation. U.S. clinical trials demonstrated the combination regimen to be 92% effective in terminating pregnancy during that time period. Whether the availability of mifepristone will increase the total number of abortions in the United States, as antiabortion advocates maintain, is highly questionable; many prochoice advocates predict, however, that the drug will increase the proportion of early abortions, because it can be used before the point in pregnancy when surgical abortions are generally performed.

Mifepristone will not be available to women directly in pharmacies by prescription; instead, it is being made available to physicians. The FDA’s terms of approval require that a woman make three visits to a physician, first to receive the mifepristone, then two days later for a dose of misoprostol and once again, on day 14, for follow-up. (Already, however, protocols of the National Abortion Federation and Planned Parenthood Federation of America permit additional means of administering the drug that vary from the current FDA labeling. These protocols, based on more recent studies than those considered by the FDA, include options for fewer physicians’ visits and a lower dose of mifepristone.)

Additional restrictions that according to unconfirmed reports were actively being considered by the FDA last summer were not included as part of the final approval. The apparent decision to drop these restrictions sparked an outcry from antiabortion members of Congress, notably Rep. Tom A. Coburn (R-OK), who had previously attempted without success to deny FDA funds for the testing and approval of mifepristone. In October, Coburn and Sen. Tim Hutchinson (R-AR) introduced the RU-486 Patient Health and Safety Protection Act, which would “reinstate” several of the reported restrictions, including that only physicians “legally empowered” and trained to perform surgical abortions, and those with admitting privileges at a nearby hospital, be allowed to prescribe mifepristone. Although Coburn is retiring from Congress, the legislation he drafted is likely to be reintroduced next year.

Not to be lost in the publicity surrounding mifepristone, the FDA also approved the first once-a-month contraceptive injection, marketed under the name Lunelle. Unlike the three-month injectable contraceptive, depot medroxyprogesterone acetate (or Depo-Provera), Lunelle combines progestin and estrogen, allowing women to maintain normal estrogen levels. It offers a more regular bleeding pattern and a return to fertility within 60–90 days, or about twice as fast as that achieved by Depo-Provera. Lunelle is 99% effective when injected monthly and is already in use in several other countries. Research into a technique that would allow women to self-inject is reportedly under way.

Saudi Arabia’s Obaid To Head United Nations Population Fund

Effective January 1, Thoraya Obaid of Saudi Arabia will become executive director of the United Nations Population Fund (UNFPA), succeeding Nafis Sadik, who is retiring after leading the world’s largest international source of population assistance since 1987. The first woman to receive a Saudi government scholarship to study at a university in the United States, Obaid has held various posts within the United Nations since the mid-1970s, in which her focus has been on programs to promote gender equality. She became director of UNFPA’s Division for Arab States and Europe in 1998.

Obaid is the first Saudi national to be appointed to head a United Nations agency. The Saudi government is reported to have campaigned vigorously on her behalf despite the fact that in Saudi Arabia, women still cannot drive, need written permission from their male relatives to travel, cannot socialize with men and must be covered from head to toe in public. Saudi Crown Prince Abdullah recently called for women to have a greater role in society, however, and during the five-year review of the platform from the 1995 Beijing women’s conference in June, the Saudi government announced its intention to ratify the Convention on the Elimination of Discrimination Against Women.

Sadik, a Pakistani obstetrician-gynecologist, was the first woman to head a United Nations agency. She played a major role in forging the landmark “Cairo consensus,” which put individual women’s health and empowerment at the center of population stabilization and development efforts and was ratified at the United Nations International Conference on Population and Development in 1994.