COMPARISON OF THE AVAILABILITY OF CONTRACEPTIVE METHODS IN SELECTED EUROPEAN COUNTRIES AND THE UNITED STATES

ELOF D.B. JOHANSSON*

I.
INTRODUCTION

The decision about whether or not to develop most pharmaceutical products is largely based upon market and scientific research, but contraceptive products are different. Development decisions about contraceptive products are heavily influenced by political and religious beliefs in addition to market and scientific research. The influence of politics and religion with regard to contraceptives manifests itself at all levels of the development process—from generating ideas, to applying for agency approval, to actual marketing efforts—and hampers the development of new contraceptive products. The influence of politics and religion on contraceptive development is apparent in both Europe and the United States.

One issue that makes contraceptive development more difficult in the United States than in Europe is the American tort liability system. In the contraceptive field, history shows that even potential, unverified, imaginary problems with a contraceptive product can discourage a company from proceeding with development of that product. The legal dangers associated with producing contraceptives in the United States are well-known to pharmaceutical companies, and it is perhaps for this reason that an organization like the Population Council, rather than pharmaceutical companies, has been responsible for developing and testing important new contraceptive products in the United States like Norplant and the Copper (Cu) T 380A IUD.[1]

Of course, there are several non-pharmaceutical contraceptive methods that warrant consideration. The most common non-pharmaceutical contraceptive methods are sterilization and abortion. In comparing the total contraceptive "packages" available in Europe and the United States, it is important to also consider these methods.

---

* M.D., Ph.D., Center for Biomedical Research, The Population Council.

1. Population Council, *General Information About the Council* (last modified Jan. 29, 1998) <http://www.popcouncil.org/general.html>. ("The Population Council, a nonprofit, nongovernmental research organization established in 1952, seeks to improve the well-being and reproductive health of future and current generations around the world .... The Council analyzes population issues and trends; conducts research in the social and reproductive sciences; and develops new contraceptives ....").

II.

DRUGS: ORAL CONTRACEPTIVES, PROGESTIN-ONLY PILLS, INJECTABLES (I.E., DEPO PROVERA), IMPLANTS (NORPLANT)

European women use oral contraceptives at a higher rate than in the United States (41 percent of European women using contraception rely on oral contraceptives versus 28 percent of women in the United States). However, the market value of oral contraceptives is slightly higher in the United States than in Europe ($1.16 billion in the United States compared to $1.05 billion in Europe), despite the larger population of European users. This discrepancy is due to considerably higher prices in the United States than in Europe.

During the 1980s, many pharmaceutical companies focused their development efforts on the progestin component of the combined birth control pill. Less effort has been focused on estrogen (all companies use ethynylestradiol as an estrogen). The prime movers in the area of progestin development have been Schering AG and Organon. Wyeth-Ayerst has a joint development agreement with Schering AG on progestins related to levonorgestrel. Recent reports of a correlation between the so-called "third generation" of progestins, desogestrel, norgestimate and gestodene,[2] and the incidence of deep vein thrombosis, have complicated the situation.[3] Fear of increased regulation may reduce development efforts within European companies.

Another contraceptive drug whose availability might be affected by liability issues is Depo Provera. In the United States, Depo Provera is the only approved injectable contraceptive. Approval for Depo Provera came about eight years earlier in Europe but,[4] as in the United States, approval was opposed by activist groups claiming side effects not seen in clinical studies, and arguing that the product could be forced upon women without their consent.[5] Many European countries also have the norethindrone-based injectable contraceptive manufactured by Schering AG.[6]

---

2. M.A. Lewis, L.A.J. Heinemann, K.D. MacRae, R. Bruppacher, & W.O. Spitzer, *The Increased Risk of Thromboembolism and the Use of Third Generation Progestagens: Role of Bias in Observational Research*, 54 CONTRACEPTION 5 (1996).

3. *Id.* Women using oral contraceptives have an increased risk of developing venuous thromboembolism (VTE), a blood clotting disorder. Drug manufacturers have created a series of drug combinations in an effort to reduce this risk. Recent studies suggest, however, that the latest contraceptives or "third generation" drugs, may slightly increase, rather than decrease, the risk of VTE. While some researchers believe these tests may be biased, many countries responded to the third generation studies with increased regulation.

4. Anne Szarewski & John Guillebaud, *Contraception: Current State of the Art*, 302 BRIT. MED. J. 6787 (1991).

5. *New Era for Injectables: Injectable Contraceptives*, JOHNS HOPKINS POPULATION REPORTS, Aug. 1995. Controversy over injectables and their impact on minority and poor women continues today. *See, e.g.*, DOROTHY ROBERTS, KILLING THE BLACK BODY (1997).

6. Malcolm Potts & John M. Paxman, *Depo Provera: Ethical Issues in Its Testing and Distribution*, 1 J. MED. ETHICS 9 (1984).

There is no big difference between the United States and Europe in the progestin-only contraceptive market. Most European countries have progestin-only pills containing norethindrone, lynesterol, or norgestrel.[7] In the United States, there are two progestins containing norethindrone.

Norplant, a contraceptive drug delivery device that is implanted under a woman's skin, is available in Scandinavia, the United Kingdom, and the United States.

III.
INTRAUTERINE DEVICES

Most intrauterine devices are based on the development of the Copper T concept by the Population Council. The Cu T 380A appears to have reached such a high level of efficacy and safety that further improvements of these features are unlikely.[8] Improvements may still be possible, however, with regard to insertion and the incidence of expulsion.

IUDs operate under different market conditions from contraceptive drugs. For example, IUDs are usually regulated by separate government entities from those that regulate drugs. In addition, in many countries (i.e. Italy, Germany and Austria), IUDs may be sold directly to patients by doctors via the pharmacy distribution channel

IV.
INTRAUTERINE DRUG DELIVERY

Progestasert was the first intrauterine device to deliver progesterone. Progestasert is a unique method of contraception because it reduces a woman's menstrual flow. Unfortunately, the amount of progesterone needed to be effective is too high for the delivery system. Progestasert has been withdrawn from all European markets, except France, due to poor efficacy and a high incidence of extrauterine pregnancy. Progestasert is still available in the United States.

The Population Council has developed a highly improved system of intrauterine drug delivery based on a levonorgestrel and silastic rod delivery system. This system (Mirena in Europe, Levonova in Scandinavia)[9] has

7. M.F. McCann & L.S. Potter, *Progestin-Only Oral Contraception: A Comprehensive Review*, 50 CONTRACEPTION (Supp. 1) (1996).

8. Hallie Levin, *The Most Effective Contraception Methods You've Never Tried*, COSMOPOLITAN, Sept. 1, 1997, at 204. The Copper T 380A is commonly known as ParaGuard. Two out of every 100 women will become pregnant within the first year of use. Possible side effects include: cramps, backache, spotting, and heavy menstruation.

9. *See Drug Delivery System, Intrauterine Levonorgestrel Leiras, Pharmacia & Upjohn Registered, Netherlands, Germany*, R & D FOCUS DRUG NEWS, Jan. 13, 1997, *available in* 1997 WL 8506424 (citing Mirena as available in Netherlands and Germany, developed by the Population Council).

a very low rate of contraceptive failure,[10] as low a rate of extrauterine pregnancies as oral contraceptives. It also leads to a significant reduction of menstrual blood loss.[11]

Mirena recently has been approved in most central European countries, and it has been on the Scandinavian market since the early 1990s.[12] However, the current status of Norplant liability makes it unlikely that Mirena will be available in the United States in the next few years.[13]

There is a real difference in the availability of different types of intrauterine devices in Europe and the United States. In the United States, only the classic Lippes Loop and the Cu T 380A are available. Most major companies withdrew their IUDs from the United States market after the Dalkon Shield trials ended in 1988.[14] Thus, while IUDs are popular in many countries, they are hardly used at all in the United States.[15] Presently, the Paragard T 380A and Progestasert are the only intrauterine devices available in the United States.[16] In Europe, on the other hand, a great variety of copper IUDs, inert IUDs, as well as the levonorgestrel-releasing systems, are available.[17]

V.
BARRIER METHODS

There is no big difference between Europe and the United States in the availability of condoms, sponges, diaphragms, and spermicidal agents.

VI.
DO-IT-YOURSELF

Natural methods such as withdrawal and abstinence are, of course, available everywhere, but promotion of natural methods is most evident in countries with Catholic dominance.

---

10. *See Mirena: Significant Contraceptive Advance in UK*, COMMUNITY PHARMACY, June 1, 1995, at 6. (explaining that Mirena has a failure rate of just 0.2 percent in the first year.)

11. *See generally* Annie Stephenson, *Choices Choices: Women Can Find Many Choices as the Contraception is Concerned Mostly with 98-100% Liability*, BEAUTY COUNTER, Aug. 1, 1995, at 19 (noting that Mirena actually reduces menstrual flow).

12. *See Huhtamaki Optimism for 1991 Vindicated*, MARKETLETTER, April 20, 1992, *available in* 1992 WL 2792729 (citing approval of Mirena in Finland in 1990); *Huhtamaki Predicts Strong Growth for Pharmaceuticals*, PHARMACEUTICAL BUS. NEWS, Oct. 26, 1992, at 4. (noting approval in Finland and Sweden as well as expected approval in Norway and Denmark and other European countries).

13. *See* Sylvia Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. L. & SOC. CHANGE Part III.C.2 (1998).

14. Patricia Cohen, *The IUD: Birth Control Device that the U.S. Market Won't Bear*, WASH. POST, Aug. 6, 1996, at A1.

15. *Studies Show a Dramatic Rise in Sterilization*, N.Y. TIMES, Dec. 9, 1984, at 29 (citing National Center for Health Statistics report indicating that in 1982, only 4 percent of couples with partners 15 to 44 years old used IUDs).

16. Cohen, *supra* note 14, at A1.

17. Michelle Lynn Lakomy, *A Meaningful Choice: Two FDA Approved Drugs are Combined to Perform Medical Abortions*, 18 WOMEN'S RIGHTS L. REP. 49 (1996).

VII.
HOSPITAL METHODS

The largest market for a contraceptive method, in terms of monetary value, is sterilization, especially if hysterectomies are included in the definition of sterilization. It has not been possible for me to get a reliable figure for the market value of sterilization in the United States or in Europe, as prices vary greatly from hospital to hospital and no centralized statistics exist. Unfortunately, in most countries, sterilization procedures are not closely monitored and, therefore, figures as to the effectiveness of sterilization procedures varies. It is worth noting, however, that there is some evidence that suggests that sterilization may not be as effective as the most effective contraceptive systems, such as Depo Provera, the Cu T 380A IUD, the levonorgestrel intrauterine system, and Norplant.[18]

I believe that a high prevalence of sterilization (i.e., above 10 percent) indicates that there are an insufficient number of reversible contraceptives methods. In the United Kingdom, 25 percent of fertile women are either sterilized or live with sterilized men. Sterilization is even more common in the United States, where 42 percent of contraceptive users rely on sterilization. In the United States, there is also a high incidence of sterilization among women under the age of thirty, which is not true in Europe.

Induced abortions as a fall-back option when contraceptives fail are generally available throughout Europe, the one exception is Ireland. Induced abortions are also available in the United States.

VIII.
EMERGENCY CONTRACEPTION

Emergency contraception is an option in those markets where oral contraceptives, IUDs, and/or norgestrel tablets are available. However, in the United States and Italy manufacturers do not promote the use of these contraceptives in emergency situations. While doctors in the United States may prescribe combinations of approved oral contraceptives for "off-label use" as emergency contraceptives, no specially-labeled emergency contraceptive is available in the United States. In contrast, in the United Kingdom and Ireland a great deal of information is disseminated on the emergency use of contraceptives.[19]

18. H.B. Peterson, Z. Xia, J.M. Hughes, L.S. Wilcox, L.R. Tylor, & J. Trussel, *The Risk of Pregnancy After Tubal Sterilization: Findings from the U.S. Collaborative Review of Sterilization*, 174 AM. J. OBSTETRICS AND GYNECOLOGY 1161 (1996).

19. Mark D. Somerson, *Emergency Contraception Unpublicized*, COLUMBUS DISPATCH, Oct. 9, 1997, at 9C.; *Pill Can Stop Pregnancy Next Day, Experts Say*, FORT WORTH STAR TELEGRAM, Oct. 9, 1997, at 13.

IX.
MEDICAL ABORTION

Medical abortion is available in only a few European countries. Mifepristone is approved in France, Sweden, and the United Kingdom, but its use varies depending on the attitude of local gynecologists.[20] Promotion of medical abortion has largely been left to family planning workers. The manufacturers of the products used for medical abortions (mifepristone and prostaglandin) do not actively promote the products.[21]

Medical abortion is not an option in the United States at present. But, Mifepristone is currently being evaluated by the United States Food and Drug Administration, pursuant to a new drug application filed by The Population Council.[22]

20. Four nations have approved the use of RU 486 (mifepristone): China, Sweden, Britain and France. Amy Porter, *International Reproductive Rights: The RU 486*, 18 B.C. INT'L & COMP. L. REV. 179, 180 (1995). In France, the use of RU 486 was approved in 1988, but the government of France has set restrictions on its use, including requiring four medical visits, with the first three occurring within the seven week gestation limit. France mandates a one week thinking or reflecting period And, only women who are less than six weeks pregnant are candidates for RU 486. *Id.* at 192. In Britain, there is a regimen of medical visits similar to France, and there is also a requirement of approval by two doctors; the government allows for the drug's use up until nine weeks of pregnancy. *Id.* at 196. *See* Claire Ahern, *Drug Approval in the United States and England: A Question of Medical Safety or Moral Persuasion?—The RU 486 Example*, 17 SUFFOLK TRANSNAT'L L. REV. 93, 105-6 (1994). The use of RU 486 in Sweden was approved in 1992. Porter, *supra*, at 197. In China, the government has developed and produced a generic version of RU 486. Porter, *supra*, at 198.

21. Roussel Uclaf has decided not to market and test RU 486 within the United States because of fears of a boycott by anti-abortion groups and liability concerns. Porter, *supra* note 20, at 105. *See* Tamar Lewin, *Settlement May Pave Way for French Abortion Pill*, ORANGE COUNTY REG., Nov. 13, 1997, at A24. On April 20, 1993, Roussel Uclaf agreed to license the drug to the Population Council for testing and future marketing purposes. Sandra Anderson Garcia, *Sociocultural and Legal Implications of Creating and Sustaining Life through Biomedical Technology*, 17 J.L. & MED. 469, 525, n. 20 (1996).

22. The Population Council has adopted a two track approach to the approval of the drug: preparing the New Drug Application and conducting the U.S. clinical trials. Population Council, *Mifepristone: Clinical Trials in the U.S.* (last modified June 1997) <www.popcouncil.org/rhpdev/usmife.html>. Clinical trials started in September 1994 and concluded a year later. Population Council, *supra*. The U.S. Food and Drug Administration (FDA) approved the use of RU 486 on September 18, 1996, but stated that the Population Council needed to provide additional information on labeling and manufacturing, which has been given to the FDA. David E. Rovella, *Abortion Pill Triggers Change in Legal Tactics: A Leading Anti-Abortionist Concedes that Trying to Ban Such Operations Is Futile*, NAT'L L.J., October 7, 1996 at A11; Population Council, *supra*. In November 1997, The Population Council settled lawsuits with the Giant Group and with Joseph D. Pike, the businessman handling the RU 486 project, which eliminated some road blocks to finding investors for RU 486. Lewin, *supra* note 21, at A24.