Public Health Policy Forum

Editorial: Over-the-Counter Oral Contraceptives—An Immodest Proposal?

David A. Grimes, MD

On public health grounds, oral contraceptives could be made available in vending machines and cigarettes by prescription only. Trussell and his coauthors ably argue the former point in this Public Health Policy Forum.[1] Our society's approach to these two agents, both widely used by young women, is paradoxical. Cigarettes, which are readily available even to children, kill over a thousand persons each day. In contrast, oral contraceptives prevent unwanted pregnancy and improve women's health.[2] Nevertheless, the medical profession poses numerous obstacles to this method of contraception, including a physical examination,[3] a prescription, often a pharmacist, and an impenetrable package insert.[4] Trussell et al. suggest that these medical requirements neither serve nor protect women; they are merely impediments.

As is usually the case in medicine, the intensity of feelings on this issue is inversely related to the amount of information available. Little is known about how dropping or relaxing the current medical requirements for oral contraceptives might affect either contraception or preventive services for women. Several of the arguments merit consideration.

Are Oral Contraceptives Too Dangerous to Be Made Available over the Counter?

As elaborated by Trussell and colleagues, this point of view is no longer scientifically tenable. More is known today about the safety of oral contraceptives than has been known about any other drug in the history of medicine. Thirty years of intense epidemiologic study have confirmed that oral contraceptives are very safe.[5] Cardiovascular disease appears to be unrelated to low-dose pills with appropriate screening.[6] More than 20 large case–control studies have shown no net effect of oral contraceptive use on the risk of breast cancer. In contrast, the health benefits offered by oral contraceptives, including protection against endometrial and ovarian cancer, are so compelling that some would argue that most women should take oral contraceptives as prophylaxis for at least a year, regardless of their need for contraception.

US vital statistics provide some insight into the relative safety of medicines. Although the numbers of women exposed are unknown, none were reported to have died in 1988 from ovarian hormones and synthetic substitutes.[7] In contrast, five died from antidiabetic agents and one from adrenal cortical steroids. Six died from penicillin. Four died accidentally from analgesics, antipyretics, and antirheumatics; 202 women committed suicide with analgesics, antipyretics, and antirheumatics in 1988. Aspirin, which is widely available over the counter (and in vending machines), appears to be more lethal than oral contraceptives.

Some skeptics note that heavy smokers may not read pill labeling advising against oral contraceptive use by such women. Do smokers not read or not heed? Heavy smokers already choose daily to ignore a strong, clear warning on each package of cigarettes. If the combination of smoking and oral contraception is unhealthy, which of the two should be discouraged or prohibited?

David A. Grimes is with the Department of Obstetrics, Gynecology and Reproductive Sciences, San Francisco General Hospital, University of California, San Francisco.

Requests for reprints should be sent to David A. Grimes, MD, Department of Obstetrics, Gynecology and Reproductive Sciences, Ward 6D, San Francisco General Hospital, San Francisco, CA 94110.

Editor's Note. See related article by Thijs and Knipschild (p 1113) in this issue.

Do Oral Contraceptives Provide an Inducement for Preventive Services?

Oral contraception, family planning clinics, and screening tests are closely linked. Women who use oral contraceptives are much more likely than other women to receive screening for sexually transmitted diseases, cervical neoplasia, breast disease, and hypertension.[8,9] This is especially true for those who receive care from a family planning clinic. However, screening for infection appears to be unrelated to the apparent risk of disease.[9] This suggests that decisions about screening are inappropriately based on choice of contraception rather than on the basis of risk.

The provision of oral contraceptives should not be contingent on unrelated screening services. Preventive health care services are important in their own right for women of reproductive age.[10] Must preventive services necessarily be "bundled" with other services, like software packages installed in a new computer? To use a pill prescription as a lure for cervical cancer screening resembles a bait-and-switch tactic, especially when an abnormal test would not preclude the use of pills.

Would dropping the need for an annual prescription refill undermine women's health? The levonorgestrel subdermal implants and copper T380A intrauterine device generated similar fears of sabotaging preventive health services for women. Because these contraceptive methods are effective for up to 5 and 8 years, respectively, some physicians worried that women would drop out of health care for lengthy intervals. This does not appear to have happened. Similarly, the advent of over-the-counter antifungal medications for vaginal candidiasis has apparently not hurt women's health. The availability of oral contraceptives without prescription would neither prevent nor discourage women from continuing to see physicians; it would, however, make visits related to oral contraception voluntary rather than mandatory.

Will Oral Contraceptive Users' Compliance Suffer without Physician Counseling?

This hypothesis assumes that physician counseling is both widespread and effective in improving patients' compliance. Little evidence supports either assumption. The demands of patient flow in physicians' offices often preclude lengthy discussions. In affiliates of the Planned Parenthood Federation of America, Inc, the nation's largest provider of contraception services, most counseling is done by midlevel clinicians and counselors, not by physicians.

Better written instructions for patients could reduce the need for counseling. The federally mandated patient package inserts are unattractive, inconsistent, confusing, and beyond the reading level of millions of users.[4] With current counseling and the sesquipedalian package insert, compliance with pill-taking is poor, yet oral contraception is still highly effective.[11]

Does the Economic Survival of Family Planning Clinics Depend on the Distribution of Pills?

As noted by Trussell et al., family planning clinics provide an array of preventive and curative services beyond family planning. For many poor women, these clinics may be the only health care provider. Without a steady stream of patients seeking oral contraceptives, clinics might be unable to pay their overhead. Some private physicians express the same concern. As noted by Trussell and his colleagues, this situation reflects a problem with reimbursement, not with oral contraceptives. For too long, our society has paid physicians (and others) for doing things to patients, not for keeping them well. We must shift our national health priorities toward primary prevention and reimburse accordingly.

Three pivotal questions remain unresolved. First, would the overall safety of oral contraceptives improve if they were made available without prescription? This seems unlikely.

Second, would compliance improve? Again, this seems improbable, although improved patient instructions might help. Third, would access to and use of oral contraceptives increase? This appears likely, yet the increase might be offset by lessened compliance.

In one region of Sweden, an experiment with making oral contraceptives available without prescription led to problems with poor compliance and high discontinuation rates (G. Samsoie, MD, PhD, conversation, 1993). In response, a compromise was developed in which midwives could prescribe oral contraceptives with flexibility concerning the timing of the pelvic examination. This program has been highly successful over the past decade. Nationally, about 80% of all patients using oral contraceptives are managed by midwives and rates of oral contraceptive use are very high.

A similar demonstration project in the United States was sponsored by the Family Planning Council of Southeastern Pennsylvania. The project allowed new adolescent patients to postpone a pelvic examination and blood tests for up to 6 months and still receive pills. The initial visit included a blood pressure determination, urinalysis, and urine pregnancy test. Fears that teenagers would not return for the pelvic exam and that sexually transmitted diseases would be missed proved unfounded. The director of the program noted that the option of delaying the pelvic exam gave the adolescents "a sense of importance . . . that they could make the decision" about the timing of medical services.[3] Older women may feel the same.

Fertility regulation and oral contraceptives in particular have traditionally been controlled by predominantly male physicians and not by consumers. Requiring a prescription for oral contraceptives, a measure ostensibly designed to protect women, may be counterproductive both medically and socially. Requiring a physician to determine whether a woman can take oral contraceptives may be analogous to requiring a hospital committee of physicians to judge whether a woman is a fit candidate for an induced abortion.

The hypothesis that the costs of "medicalization" of oral contraceptives outweigh the benefits[1] deserves to be tested in randomized controlled trials. Such an important policy change must be based on science, not opinion. The Swedish experience demonstrates the need for caution and perhaps compromise. However, until such trials have been performed, the distinction between protection and paternalism may remain fuzzy. □

References

1. Trussell J, Stewart F, Potts M, Guest F, Ellertson C. Should oral contraceptives be available without prescription? *Am J Public Health.* 1993;83:1094–1099.
2. Kost K, Forrest JD, Harlap S. Comparing the health risks and benefits of contraceptive choices. *Fam Plann Perspect.* 1991; 23:54–61.
3. Donovan P. Delaying pelvic exams to encourage contraceptive use. *Fam Plann Perspect.* 1992;24:136–144.
4. Klitsch M. How well do women comply

with oral contraceptive regimens? *Fam Plann Perspect.* 1991;23:134–138.
5. Grimes DA. The safety of oral contraceptives: epidemiologic insights from the first 30 years. *Am J Obstet Gynecol.* 1992;166: 1950–1954.
6. Hirvonen E, Heikkila JI. Cardiovascular death among women under 40 years of age using low-estrogen oral contraceptives and intrauterine devices in Finland from 1975 to 1984. *Am J Obstet Gynecol.* 1990;163:281–284.
7. *Vital Statistics of the United States, 1988.* Vol. 2, Part A. Hyattsville, Md: National Center for Health Statistics; 1991:216–222.
8. Wilcox LS, Mosher WD. Factors associated with obtaining health screening among women of reproductive age. *Public Health Rep.* 1993;108:76–86.
9. Mosher WD, Aral SO. Testing for sexually transmitted diseases among women of reproductive age: United States, 1988. *Fam Plann Perspect.* 1991;23:216–221.
10. US Preventive Services Task Force. *Guide to Clinical Preventive Services.* Baltimore, Md: Williams & Wilkins; 1989.
11. Letterie GS, Chow GE. Effect of "missed" pills on oral contraceptive effectiveness. *Obstet Gynecol.* 1992;79:979–982.

Should Oral Contraceptives Be Available without Prescription?

James Trussell, BPhil, PhD, Felicia Stewart, MD, Malcolm Potts, MB, BChir, PhD, Felicia Guest, MPH, and Charlotte Ellertson, MPA, MA

ABSTRACT

In this paper, it is argued that oral contraceptives should be available without prescription. Prescription status entails heavy costs, including the dollar, time, and psychological costs of visiting a physician to obtain a prescription, the financial and human costs of unintended pregnancies that result from the obstacle to access caused by medicalization of oral contraceptives, and administrative costs to the health care system.

After a review and evaluation of the reasons for strict medical control of oral contraceptives in the United States, safety concerns anticipated in response to the proposal discussed here are addressed. Also, concerns that prescription status is necessary for efficacious use are evaluated. It is concluded that neither safety nor efficacy considerations justify prescription status for oral contraceptives. Revised package design and patient labeling could allow women to screen themselves for contraindications, to educate themselves about danger signs, and to use oral contraceptives safely and successfully.

Several alternatives to providing oral contraceptives by prescription with current package design and labeling and selling them over the counter are suggested; the proposals discussed would make these safe and effective contraceptives easier to obtain and to use. (*Am J Public Health.* 1993;83:1094–1099)

Introduction

Empowering women to choose the number and timing of pregnancies is widely recognized as a primary goal of reproductive rights advocates. It follows that such advocates should endorse women's full and direct access to contraception. Indeed, if this goal is central, then only compelling health concerns could justify restrictions such as a prescription requirement.

In the United States, historical circumstances and health concerns once restricted all decisions regarding access to contraceptives to physicians. Eighty percent of American women now use oral contraceptives during their lives,[1] yet these contraceptives have been provided only by prescription for the last 30 years. Because there is now considerable evidence for the safety of current low-dose oral contraceptives, we believe that it is time to rethink this practice. While we recognize the difficulty of balancing patient autonomy and clinical guidance, we conclude that safety and compliance concerns are no longer sufficient to justify maintaining the current level of clinical control over a woman's contraceptive selection. A national dialogue on this issue is overdue. Our goal is not to promote the use of oral contraceptives but to remove obstacles for women who decide to use this method. In contrast, we strongly support efforts to promote use of barrier methods among those at risk of sexually transmitted diseases.

Historical Circumstances

The medicalized status of oral contraceptives derives in part from the history of family planning in this country. The influence of the 1873 Comstock Act, which made it a criminal offense to import, mail, or transport in interstate commerce any literature about birth control or any device designed to prevent conception or cause abortion, persisted for more than a century.[2] Birth control advocate Margaret Sanger challenged this legislation but succeeded in circumventing it only by making physicians the key to contraceptive distribution. In 1936, the Supreme Court, in *United States v One Package* (the package being three diaphragms imported from Japan), allowed the "importation, sale, or carriage by mail of things which might intelligently be employed by conscientious and competent *physicians* for the purpose of saving life or promoting the well-being of *their patients*" (emphasis added).[2] Major legal legacies of the Comstock Act lingered until the Supreme Court's decisions

James Trussell is with the Department of Economics, the Woodrow Wilson School of Public and International Affairs, and the Office of Population Research, Princeton University, Princeton, NJ. Felicia Stewart is with Planned Parenthood of Sacramento Valley and the Valley Center for Women's Health, Sacramento, Calif. Malcolm Potts is with the School of Public Health, University of California, Berkeley, Calif. Felicia Guest is with the Emory AIDS Training Network, Emory University School of Medicine, Atlanta, Ga. Charlotte Ellertson is a doctoral candidate at the Woodrow Wilson School of Public and International Affairs and the Office of Population Research, Princeton University, Princeton, NJ.

Requests for reprints should be sent to James Trussell, BPhil, PhD, Office of Population Research, Princeton University, 21 Prospect Ave, Princeton, NJ 08544.

This paper was accepted April 21, 1993.