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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.

in *Griswold v Connecticut* in 1965, 5 years after oral contraceptives were first marketed, *Eisenstadt v Baird* in 1972, and *Carey v Population Services International* in 1977.[2] By the late 1970s, the medicalization of oral contraceptives was deeply entrenched.

Health Concerns

Whenever it is proposed that oral contraceptives be made available over the counter without prescription, two health concerns are commonly raised: safety and efficacy. First, women's health might be imperiled because some women who have conditions that preclude the use of oral contraceptives or who later develop medical contraindications would use these contraceptives, and because some women would cease to have regular gynecological exams. Second, efficacy during typical use might decline and the risk of unintended pregnancy would consequently rise because women would be more likely to use oral contraceptives imperfectly without clinical counseling. We argue that while both of these concerns are understandable, the health benefits of increasing the availability of this highly effective method of contraception by distributing it over the counter outweigh the possible health costs.

Safety

Oral contraceptives are among the most thoroughly evaluated drugs, and research has identified several health benefits as well as potential risks of their use. In addition to protecting women from unintended pregnancy and its attendant health risks, oral contraceptives protect against ovarian and endometrial cancers, pelvic inflammatory disease, ectopic pregnancy, iron deficiency anemia, primary dysmenorrhea, functional ovarian cysts, and benign breast disease.[3] Use of oral contraceptives may also prevent *leiomyomata uteri,* osteoporosis, toxic shock syndrome, and rheumatoid arthritis.[3]

Most studies show no overall effect on the development of breast cancer, although this disease clearly is the most important potential risk that has been identified and remains to be clarified.[3] Unfortunately, even if oral contraceptives increase the risk of breast cancer, routine clinician screening would not mitigate this risk. Periodic clinician exams to detect breast lumps are recommended for all adult women, regardless of whether they use or have used oral contraceptives. Earlier work linking high-dose oral contraceptives and cardiovascular disease is probably not relevant to the low-dose formulations currently used; recent studies have shown no link between the use of oral contraceptives and myocardial infarction or stroke.[3] Some epidemiological studies tie the use of oral contraceptives to an increased risk for cervical neoplasia; others find no significant association. Establishing a causal relationship is difficult because women who use oral contraceptives are more likely to have regular Papanicolaou tests and, consequently, are more likely to be diagnosed. Moreover, many studies have failed to control for confounding effects such as smoking and sexual behavior.[3] Even if a causal relation does exist, however, the increased mortality risk associated with cervical neoplasia would be offset by the reduced mortality from diseases for which oral contraceptives provide protection (listed above).[4] And, fortunately, routine Papanicolaou tests can detect early treatable stages of cervical neoplasia.

Health concerns about their over-the-counter distribution do not, therefore, stem from evidence that oral contraceptives are generally unsafe. Instead, there are three worries. First, more women with contraindications might use oral contraceptives since clinicians would no longer control access. Second, if women can obtain oral contraceptives without prescription, some might not receive regular exams and Papanicolaou tests. Third, oral contraceptives do not protect against sexually transmitted diseases, including the human immunodeficiency virus (HIV).

Screening for contraindications to oral contraceptives. Screening for contraindications to the use of oral contraceptives is based primarily on review of medical history. The only physical examination steps pertinent to contraindications of oral contraceptives, as they are listed in the product labeling for physicians, are measurement of blood pressure and breast exam. Papanicolaou test screening is also commonly provided, although most clinicians are willing to prescribe oral contraceptives at the time of the patient's initial visit—before Papanicolaou test results are known.

The patient herself provides her medical history, whether through clinician interview or written questionnaire. Similarly, a woman could perform a breast self-exam with appropriate instruction prior to using oral contraceptives. Blood pressure screening is commonly available at pharmacies and supermarkets. Thus, the only remaining issue is Papanicolaou test screening. We argue that the health benefit of such screening, while of undisputed importance, does not justify withholding the health benefit that would accrue from reduced obstacles to use of oral contraceptives.

Evidence that women can screen themselves accurately is provided by a Mexican study that compared 13 health indicators, primarily related to circulatory disease, among three groups of current users of oral contraceptives: women who had never been examined by a clinician for contraindications but who obtained oral contraceptives from a community-based distribution program (after completing a screening checklist) or directly from a pharmacy without prescription, and women who had been examined by a clinician for contraindications. Educational levels were low; only 19% had advanced beyond elementary school. Yet health profiles of women in the three groups were similar. Women screened themselves for contraindications to oral contraceptives just as accurately as clinicians screened them.[5]

General health screening. The broadest defense of prescription status is that it ensures regular health examinations, which in turn detect problems unrelated to the use of oral contraceptives. Underlying this defense is the opinion, usually unstated, that coercion based on the "carrot" of a prescription for oral contraceptives is appropriate. We believe that it is not. Men face no comparable coercion. Should men be required to obtain an annual prescription for condoms to promote the early detection of testicular and prostate cancer? And regardless of the importance of routine exams to women, there are two additional, unexamined premises to consider. First, the "carrot" policy assumes that it would be worse for a woman's health to miss out on routine care than it would be to miss out on taking oral contraceptives. Second, it assumes that policymakers, rather than women themselves, should make the decision.

Protection against sexually transmitted diseases. Viral sexually transmitted diseases cause much of the physical and emotional misery directly related to sexual intimacy in the United States, but concern that oral contraceptives do not protect against such diseases has no bearing on their prescription status. The concern regarding sexually transmitted diseases applies to all hormonal contraceptives, to periodic abstinence, to withdrawal, to intrauterine devices, to male and female sterilization, and—with respect to HIV

infection—perhaps also to spermicides, the cervical cap, the sponge, and the diaphragm.[6] The appropriate public health response is education rather than restriction of one or more contraceptive options. Those who are at risk of acquiring or transmitting sexually transmitted diseases need explicit education to help them recognize and reduce risk. For example, condoms and information on assessment of risk for sexually transmitted diseases could be packaged with all contraceptives sold, and recipients could be urged to use the condoms or give them to someone who might need them.

Summary. In the case of many medications, need can be determined only by a skilled professional. The disease to be cured or managed must be diagnosed, and an appropriate therapy must be selected and sometimes professionally administered. In contrast, a woman herself determines her need for oral contraceptives; she assesses her own risk of pregnancy and sexually transmitted diseases and the costs and benefits of both pregnancy and alternative contraceptives. Professional services are not required for correct administration, overdose is not life threatening, and oral contraceptives are not addictive. Even selection of an appropriate initial product and dose does not require professional expertise.

The vast majority of oral contraceptives now prescribed are low-dose products containing either 30 μg or 35 μg of the synthetic estrogen ethinyl estradiol.[7] Although the 30 products in this group contain seven different progestins, all provide similar biologic activity. Thus, family planning experts no longer recommend that an initial choice be based on selecting an ideal product.[8,9] Most clinicians routinely prescribe one standard initial product, often the cheapest or most easily available. Few women would experience problems with any of the low-dose oral contraceptives currently marketed. Professional expertise is required if problems such as breakthrough bleeding or acne develop, but package labeling can advise women to consult a clinician if problems arise.

Carefully designed package labeling could provide sufficient information for women to decide for themselves whether it would be safe to use oral contraceptives. Many commonly used over-the-counter products, such as aspirin, antihistamines, decongestants, vaginal yeast medications, and tampons, provide a precedent. Labels would include a clear explanation of the contraindications of oral contraceptives, instructions for breast exam and blood pressure determination, and the reasons for and steps needed to verify a normal Papanicolaou test result. Labeling should also describe danger signs for possible adverse reactions and advise that (1) those who have any doubts about whether they should use oral contraceptives should first consult a clinician, (2) annual exams and Papanicolaou tests are especially important safeguards for sexually active women, and (3) oral contraceptives do not reduce the risk of sexually transmitted diseases. Much of this information is already included in package labeling mandated for oral contraceptives, but it should be made more user friendly.

We conclude that prescription status for oral contraceptives is not justified by compelling health risks or by a necessity for professional expertise in their use. Furthermore, we believe that restricting access to oral contraceptives so that women will be forced to have regular checkups, or because some women might choose to use oral contraceptives instead of other methods that protect against sexually transmitted diseases, is unacceptably paternalistic.

Efficacy and Access

The efficacy of oral contraceptives among *perfect* users will not be affected by prescription status. When combined estrogen–progestin pills are taken at the same time every day as directed and other instructions regarding concurrent drug use or diarrhea or vomiting are followed, only about one in a thousand women is expected to become pregnant each year. Progestin-only pills appear to be slightly less effective; perhaps five in a thousand women would become pregnant annually if these pills are used perfectly.[10]

Some fear that the likelihood of imperfect use might rise—and, consequently, that the efficacy of oral contraceptives during typical use would be diminished—if oral contraceptives are sold over the counter because users would receive no counseling by a clinician. Failure rates during *typical* use (which includes both perfect and imperfect use) of oral contraceptives vary widely from study to study.[9,11] The efficacy of oral contraceptives during typical use is overwhelmingly determined by the extent and type of imperfect use. Imperfect use includes missing pills and failing to use a backup method of contraception if pills are missed, if antibiotics (especially rifampin) or anticonvulsants are taken, or if vomiting or severe diarrhea occurs.

Missed-pill noncompliance. Little is known about the extent or type of missed-pill noncompliance among users of oral contraceptives[12,13] or about the risk of pregnancy involved. Possibilities include (1) failing to start a new package on time, (2) quitting in midcycle (because the user perceives no need or experiences side effects, especially breakthrough bleeding or amenorrhea[13,14]), (3) interrupting use for one or more cycles (because the user perceives no need to obtain or cannot obtain resupply or because she mistakenly believes she needs to give her body a rest[15]), (4) skipping pills occasionally by mistake, (5) taking pills (significantly) later than the correct time, and (6) taking triphasic pills out of sequence (perhaps in reverse order).

Available evidence suggests that missed-pill noncompliance is common, even though women must visit clinicians to obtain a prescription. In one Scottish study of 161 women, 27% reported missing a pill in the previous 3 months; of these three-fourths took no additional contraceptive precautions. More than a quarter indicated that they started a new package of pills at a time inconsistent with instructions.[16] In a second study of 216 adolescents attending a family planning clinic in South Africa, 31% had missed at least one pill in the previous 3 months. Only 25% reported that they would use a condom as a backup contraceptive after skipping a pill.[17] A third study of 76 adolescents in California found that those who returned for their 3-month follow-up visit missed 2.7 pills per month on average.[18] A fourth study of 612 women in a public health department family planning clinic in the United States found that only 42% always took a pill each day and only 17% always took a pill at the same time each day; 16% had pills left at the end of at least one package. Of those who missed pills, only 60% used backup contraception.[19] Another retrospective study of pill users in metropolitan health clinics in Michigan found that only 42% reported taking a pill every day. Only about 20% indicated that they always took their pills at around the same time each day. Six percent of women who missed a pill took no more pills from that package. Many women reported that they discontinued use if they ran out of supplies.[20] In 21-day pill packages, an additional type of noncompliance occurs when women fail to start a new package 1 week after finishing the last package. In an English study of 40 women using 21-day pill packages, 17% did not know that they were supposed to wait a

week before starting the next package. More than half did not know that efficacy would be reduced by missing pills.[21]

Other imperfect use. Most pregnancies that occur during "use" of oral contraceptives are probably due to missed-pill noncompliance, but two other factors that reduce efficacy are significant: drug interactions (particularly with anticonvulsants and antibiotics, especially rifampin) and diarrhea or vomiting[22] (including that associated with bulimia or other eating disorders). Package labeling warns women to use backup contraception under these circumstances, but many women do not heed these cautions. In an Australian study of 113 women who became pregnant while using pills, pregnancies classified as user failures were associated with one or more of the following four factors: missed pills (33%), diarrhea/vomiting (28%), concomitant use of other medications (predominantly antibiotics) (27%), and pills taken more than 6 hours late (27%). Among women with user failures, 92% did not use a backup method. Few realized that such a precaution was necessary.[23] In an English study, half of the respondents did not know that efficacy could be reduced by diarrhea/vomiting or by taking antibiotics.[21]

Summary. Two concerns must be weighed. On one hand, efficacy might decline if women are not forced to see a clinician in order to obtain oral contraceptives. On the other hand, prescription status could deter the use of this inherently effective contraceptive by raising important obstacles to access: a costly initial physician visit, often with an obligatory pelvic examination (a particularly daunting obstacle for some young women[24,25]), and additional periodic visits or telephone calls for prescription refills. The prescription status of oral contraceptives also discourages their use by implying that they are unsafe. A Gallup poll found that 84% of women did not know that oral contraceptives pose fewer risks than childbirth for women under 35 years of age.[26] Making oral contraceptives available over the counter would eliminate an important obstacle to use by signaling that these contraceptives are not dangerous. There is no compelling evidence that clinician control of oral contraceptives is essential for contraceptive efficacy. Instead, the evidence suggests that their improper use is widespread despite the current prescription requirement.

Making oral contraceptives available over the counter might actually raise obstacles for certain women. Some worry that insurance policies that cover prescription drugs might no longer pay for oral contraceptives. Others respond that such a decision would hardly be cost-effective. Some fear that manufacturers might discontinue deep price discounts to family planning clinics and, thus, that poor women who now obtain pills inexpensively might have to pay higher prices. Others reason that manufacturers would have even more incentive to create brand loyalty. While the allocation of costs for oral contraceptives would likely shift if they were available without prescription, the overall social cost of their use would almost certainly decline. Administrative costs associated with prescriptions and the costs associated with visiting a clinician to obtain oral contraceptives would disappear altogether.

A final and serious concern is that over-the-counter status for oral contraceptives could threaten the survival of family planning clinics. Millions of women using oral contraceptives receive primary health care from public or nonprofit family planning clinics such as those operated by Planned Parenthood.[27,28] Particularly for young or poor women, such contact with clinics may be the chief portal into the health care system. These clinics provide countless services in addition to dispensing oral contraceptives: they educate and counsel patients about a range of health issues; refer women for specialized health care; screen for and treat sexually transmitted diseases; offer HIV testing; screen for breast cancer, cervical cancer, diabetes, and anemia; and treat gynecological problems. Women will continue to need these services regardless of the prescription status of oral contraceptives. Since financial support for family planning clinics is substantially based on reimbursement associated with contraceptive distribution—especially the distribution of oral contraceptives—a change in the regulatory status of oral contraceptives could threaten the economic viability of clinics. We will need to think carefully about the best ways of preserving the essential services for women that only clinics can now provide; the private health care system could not currently accommodate the enormous numbers of women now served by clinics. The resolution of this important issue, however, hinges more on changing the reimbursement system to support and compensate clinics fully for the primary health services they provide than it does on the prescription status of oral contraceptives. As national health care reform proposals develop, the reimbursement system for family planning clinics will undoubtedly be altered regardless of any changes in rules regarding the distribution of oral contraceptives.

Creating New Options

There are several alternatives to providing oral contraceptives by prescription (with the current package design and labeling) and selling them over the counter. Possibilities, many of which could be adopted simultaneously, range from minor changes that remove some obstacles to major policy shifts that substantially increase availability. Options that allow pharmacies to sell oral contraceptives over the counter could also require that blood pressure screening be available on site.

New Packaging Options

Several packaging options are available. For example, all oral contraceptives could be packaged in an identical 28-day format (eliminating the 21-day package). Also, the most important rules for compliance and the chief danger signals could be stamped into the plastic packaging, along with a reminder to conduct breast self-exams while taking the placebo pills.

Labeling should be revised so that it is easily comprehensible and legible, and careful studies should be conducted to determine what women actually learn from it. (For a copy of a sample simplified package insert, contact the authors). Audiotapes or videocassettes might be helpful. Labeling should be made widely available in English, Spanish, and other prevalent languages, and it could advertise toll-free telephone access to a nurse able to answer questions about safety or efficacy.

New Prescription Options

There are two alternatives to the current prescription requirements involved with oral contraceptives. First, the pelvic exam could be eliminated as a requirement for a prescription.[24] Otherwise, an initial exam could be required, but no further exams if the initial one is normal. Second, counseling could be required only for first-time users.

New Options for Refills

One refill option is portable prescriptions—perhaps in a wallet card—that could be provided to enable a woman to obtain a refill when not near her usual provider or pharmacy. Clinicians could provide wallet cards along with a woman's first sample package when they prescribe

oral contraceptives. Another option is an identification card that authorizes refills for several years. Finally, over-the-counter emergency purchase of a miniature package (e.g., 10 pills) could be allowed so that a woman would be able to continue her schedule while arranging to see her clinician for a refill.

New Over-the-Counter Options

Several over-the-counter options are possible. First, an over-the-counter system, managed by pharmacists, that uses a self-administered knowledge inventory could be organized to ensure that a woman understands contraindications and instructions for use before she is eligible to purchase oral contraceptives over the counter. Second, a toll-free telephone authorization process could be established, with a nurse available to administer a knowledge inventory and discuss the decision with a woman before authorizing a pharmacy to dispense oral contraceptives. Third, a fax or mail-in order form requiring answers to a self-administered questionnaire could be organized. Completion of this questionnaire would license a woman to purchase oral contraceptives over the counter or allow her to obtain them by mail order. Fourth, over-the-counter purchase of oral contraceptives could be allowed, but with the instruction that their purchase is not intended for first-time users (e.g., "If you have not previously used oral contraceptives, see your clinician before you start to take them"). Finally, over-the-counter purchase of oral contraceptives could be allowed with no restrictions.

Use of Oral Contraceptives for Unlabeled Purposes: Postcoital Contraception

Oral contraceptives are widely prescribed for unlabeled purposes. Examples include treatment of abnormal bleeding and prevention of dysmenorrhea, acne, and premenstrual syndrome. Potentially the most important unlabeled purpose is postcoital contraception. Oral contraceptives reduce the risk of pregnancy after unprotected sexual intercourse by at least 75%.[29] The treatment schedule is one dose as soon as possible (beginning no more than 72 hours after unprotected intercourse) and a second dose 12 hours after the first dose. Hormones that have been studied in clinical trials of postcoital hormonal contraception are found in the following brands of oral contraceptives: Nordette, Levlen, Lo/Ovral (four pills constitute one dose), Triphasil, Tri-Levlen (four yellow pills constitute one dose), and Ovral (two pills constitute one dose). Treatment can be obtained at family planning clinics, health maintenance organizations, college health services, and offices of private physicians.

The problem now is that few women or doctors even know about this option, in large part because these oral contraceptives are not approved by the Food and Drug Administration as postcoital contraceptives (no company has yet applied for such approval). While any physician may prescribe an approved drug for an unlabeled purpose, drugs may be advertised only for labeled uses. Thus, advertising cannot alert women and clinicians to the effectiveness of regular oral contraceptives as postcoital contraceptives. If postcoital hormonal treatment were widely available, the number of unintended pregnancies in the United States could fall by 1.7 million each year, and the number of abortions could be reduced by 800 000 annually.[30] If oral contraceptives are approved for sale over the counter, then clearly they would be far more available for postcoital contraception. Then as now, however, ignorance would limit widespread use.

Conclusion

In our view, the ostensible benefits of protecting women from the harmful health effects of hormonal contraception fall short of the costs of medicalization. Such costs include dollar, time, and psychological costs of visiting a physician to obtain a prescription, 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. Improved and simplified package inserts could enable women to judge for themselves whether oral contraceptives are medically contraindicated, and improved packaging and simplified instructions could enhance compliance. Even if oral contraceptives are not made available over the counter, several changes in the current prescription system could greatly increase availability and compliance. □

Acknowledgments

We are grateful to Sarah Abernathy, Elizabeth Armstrong, Philip Corfman, Erica Gollub, Kate Grant, David Grimes, Robert Hatcher, Michael Kafrissen, Deborah Kowal, Barbara Okun, Kristina Palmer, Lisa Rarick, Monica Selinger, Jeffrey Spieler, and Judith Tilton for comments on earlier drafts.

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