YOUTH LAW NEWS

VOL. XXIII NO. 1 JANUARY-FEBRUARY 2002

CALIFORNIA TO ALLOW MORNING AFTER CONTRACEPTION WITHOUT A PRESCRIPTION

By Rebecca Gudeman

As of January 1, 2002, with the passage of a new state law[1], California became only the second state in the nation (behind Washington) to allow women to purchase emergency contraception pills (ECP)[2] at a pharmacy without a prescription.[3] Making ECP available through a pharmacist can increase not only their use, but also their effectiveness. While there is great potential for pharmacist-available ECP to play an important role in lowering unplanned pregnancy rates, there is also a real possibility that those with the greatest need may be left out in the cold.

Early evidence from Washington State indicates that non-prescription, pharmacist-available ECP could reduce unplanned pregnancies by as much as 60 percent.[4] Results also indicate, however, that pharmacist-available ECP does not guarantee increased access for certain populations of women, and in particular, for teens. In order to ensure teens fully benefit from California's new legislation and to make progress towards reducing the almost 40,000 unplanned pregnancies to California teens each year,[5] it is important for youth advocates to be aware of the special obstacles teens will face when accessing non-prescription pharmacy available ECPs.

Emergency Contraception - Valuable yet Unavailable

Its after-the-fact nature is what makes emergency contraception so powerful compared to all other forms of contraception. Though not an abortive[6], it can be taken up to 72 hours after intercourse. It can be a backup for failed traditional contraception, a safety net for spur of the moment forgetfulness, and a comfort to victims of forced acts.

While ECPs have been around as long as birth control pills, few in the public were aware that they existed. In fact, even physicians knew little of their existence. A critical barrier fell in 1997 when the FDA officially approved birth control pills for off-label use as emergency contraception.[7]

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[1] *S. B. 1169, 2[d] sess., 2001-2002.*

[2] *Also known as morning after contraception and post-coital contraception, emergency contraception (ECP) is NOT the abortion pill, RU-486. ECPs are high doses of regular birth control pills taken within 72 hours of unprotected sex. If a woman is already pregnant when the pills are taken, the pills will have no effect. They will neither cause an abortion nor harm the fetus. For a discussion, see American Medical Women's Association.* Position Statement on Emergency Contraception. *AMWA (1996).*

[3] *Under S.B. 1169, California pharmacists will be able to dispense emergency contraception if they have a signed protocol with a prescriber and have completed an accredited training program or one approved by the State Board of Pharmacy. This training must "include, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation." S.B 1169 also states that pharmacists must provide every ECP recipient "a standardized fact sheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical follow-up, and other appropriate information." S. B. 1169, 2[d] sess., 2001-2002 (Cal. 2001)(amending Cal. Business and Professions Code §4052(a)(8)).*

[4] *Kristin D. Marciante, Jacqueline S. Gardner, David L. Veenstra, Sean D. Sullivan, Modeling the Cost and Outcomes of Pharmacist-Prescribed Emergency Contraception,* American Journal Of Public Health *91(9): 1443-1445 (Sept 2001)(Pregnancy rate for women accessing pharmacy available ECP is 1.8 percent compared to 4.9 percent for control group.)*

[5] *See Alan Guttmacher Institute,* Teen Pregnancy Statistics *at www.agi-usa.org/pubs/teen_preg_stats.html.*

[6] *See American Medical Women's Association. Infra at note 1; See also* Brownfield v. Daniel Freeman *Marina Hospital, 208 Cal.App.3d 405 (2nd Dist. 1989)(holding that California's statute exempting conscientious objectors from providing abortions did not exempt a hospital from providing emergency contraception service because morning after contraception does not constitute abortion).*

[7] *Bonnie Scott Jones,* Emergency Contraceptive Pills: What Does the Law Say About Prescribing, Dispensing, Repackaging, and Advertising?, *JAWMA 53(5): 233-237. (suppl 2. 1998).*

Shortly thereafter, two drug manufacturers began to develop dedicated emergency contraception products and quickly received FDA approval for their use. The two dedicated EC products on the market today are Preven and Plan B.[8]

Still, ECP use remains limited. The main reason for this limited use is the time delay inherent in receiving prescription medication.[9] Given the prescription process, it is virtually impossible to ensure that a woman receives ECP in time to make it effective. The regimen of pills should be taken within 24 hours (at the latest within 72 hours) of intercourse to be effective.[10] The U.S. prescription system, however, requires the lengthy process of doctor's appointment, visit, prescription, and pharmacy stop. After-hours or weekend access is virtually impossible. This system also requires a woman to have a regular healthcare provider and a means of payment.

Pharmacy Access to Emergency Contraception

Advocates have offered many strategies to circumvent this time barrier. One such approach is to encourage physicians to provide preventive prescriptions to all patients at their regular check-ups. Another plan (offered by a few Planned Parenthood clinics) is to provide a 24-hour emergency contraception prescription hotline. The newest strategy, giving *pharmacists* the ability to prescribe ECP, takes access one step further. Supported by both the American Medical Association and the American College of Obstetricians and Gynecologists, so-called 'pharmacy access' does not just circumvent the prescription process, it eliminates physician prescriptions altogether. Pharmacy access programs allow pharmacists to dispense emergency contraception to women without the need for a doctor's visit, prescription or an appointment.

Modeled after Washington's program, California's legislation allows pharmacists to prescribe ECP when they have a collaborative protocol agreement with a supervising prescriber. The law mandates that pharmacists who choose to participate undergo special training and that they provide a fact sheet and referral information to their ECP clients.[11]

There is no doubt that pharmacy access to ECPs will increase their use and make ECP more widely available. In Washington State, which implemented the program in 1997, more than 12,000 women took advantage of pharmacy-generated ECP prescriptions in the first two years. Prescriptions also were timely. Pharmacy records show that 70 percent of Washington clients received ECP within one day of unprotected intercourse, and more than 40 percent came to the pharmacy during evening, weekend, or holiday hours.[12]

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[8] *Plan B is manufactured by Women's Capital Corporations and Preven by Gynétics.*

[9] *Of course, other issues have contributed to underutilization of emergency contraception, including a continued lack of awareness about the product and confusion with RU-486, the "abortion" pill, but the ultimate barrier remains time-delayed access.*

[10] If the regimen is begun within 24 hours, the risk of pregnancy is reduced by up to 94 percent. While ECPs can be taken up to 72 hours after intercourse and still be effective, with each 12 hour delay, the effectiveness of the method declines. If the regimen is begun between 48 and 72 hours after intercourse, the percentage of prevented pregnancies goes down to only 31 to 58 percent depending on the product. (Progestin only pills have a higher pregnancy prevention rate than combination pills). *See* Ammie Feijoo, *Emergency Contraceptive Pills – A fact sheet,* TRANSITIONS, 12(4):11 (June 2001) at www.advocatesforyouth.org (citing Abma JC et al. *Fertility, Family Planning, and Women's Health: New Data from the 1995 National Survey of Family Growth*. [Vital & Health Statistics, Series 23, no.19]).

[11] S.B. 1169 i*nfra* at note 2.

[12] *See* Jane Hutchings, Jennifer L. Winkler, Timothy S. Fuller, Jacquelin S. Gardner, Elisa S. Wells, Don Downing, Rod Shafer, *When the Morning After is Sunday: Pharmacists Prescribing of Emergency Contraceptive Pills*, JAMWA 53(5): 230-232, (suppl. 2. 1998). *See also* Don Downing, *Pharmacist Prescribing of Emergency Contraception: The Washington State Experience*, in EMERGENCY CONTRACEPTION: THE PHARMACISTS ROLE, American Pharmaceutical Association, 2000.)

Teens Will Not be Able to Fully Benefit From S.B. 1169

Though an important program, most California adolescents likely will be unable to avail themselves of non-prescription, pharmacy-available ECP. Results from Washington demonstrate that even though women's access to ECP increased statewide, adolescents underutilized the program. While 25 percent of unintended pregnancies in Washington are to women under the age of 19,[13] only 13 percent of Washington pharmacy access clients were under 18 years old.[14] Stated another way, an adult woman at risk for unplanned pregnancy was twice as likely to use the program as a teen at risk for unplanned pregnancy.[15] Because we know that teens are willing to use contraception,[16] it is fair to hypothesize that additional barriers rather than lack of interest contributed to the low teen utilization rate.

[13] Using data on 1996 Washington pregnancies to all women from the Washington Department of Health and on Washington teen pregnancies from the Alan Guttmacher Institute, I calculated the percent of unwanted pregnancies to teens by using the national estimate cited previously that 50 percent of pregnancies to all women are unwanted and 80 percent of pregnancies to teens 15-19 are unwanted. Because I cannot say whether each of my sources used the same methodology to measure unplanned pregnancy rates, my numbers are only an approximation and not scientific. Nevertheless, because I used conservative national unplanned pregnancy rates, my calculation if anything under- rather than overstates the percent of unwanted pregnancies to Washington teens compared to adults.

[14] Downing, *supra*, note 11.

[15] The ratio of unwanted pregnancies of teens to adults is .25/.75. The ratio of teen to adult pharmacy access utilization is .13/.87. (.87)(.25)/(.13)(.75)=2.32. I am using the number of actual unplanned pregnancies to substitute for the number of women or teens at risk for unplanned pregnancy. Because teens are more likely to have an unplanned pregnancy than an adult, the relative ratio of teens to adults at risk for unplanned pregnancy may be even higher. This would suggest an even greater lack of utilization.

[16] *See* Sherry A. Everett, Charles W. Warren, John S. Santelli, Laura Kann, Janet L. Collins, Lloyd K. Kolbe, *Use of Birth Control Pills, Condoms, and Withdrawal among U.S. High School Students,* JOURNAL OF ADOLESCENT HEALTH, 27(2): 112-118 (August 2000)(More than 75 percent of sexually active 9-12 graders use contraception.)

Barriers to Access: Cost and Confusion about Minor Access Rights

Cost will be the most critical barrier to pharmacist-prescribed ECP for California adolescents. The cost of ECP includes the cost of medication (approximately $30) as well as the cost of the physician's or pharmacist's consult. Depending on the length of the consult, this counseling fee can range from $15 to $60.

The great majority of teens have no insurance coverage of their own (68 percent of California teens in need of family planning have none),[17] and thus will have to pay out of pocket the entire cost for pharmacy-available ECP. Facing out-of-pocket costs from $30 to $90, many teens simply will be unable to afford pharmacy-accessed ECP.

Even those teens with insurance coverage will not have full access to the program, however, for two reasons. First, most teens with insurance are covered by a parent's insurance policy. Many teens will be unwilling to make use of a family policy to cover confidential family planning services.

Second, even when teenagers are willing to use their family insurance for pharmacy-accessed ECP, they still will face prohibitive additional costs in many instances. Most insurance covers the full cost of physician prescribed ECP – the physician consult and the medication; No insurance covers the full cost of pharmacy prescribed ECP in California. While it may cover the cost of the medication, no insurance plan covers the cost of the pharmacist consult. And there is no way to avoid this pharmacist consult. As required by S.B. 1169, pharmacists must evaluate the appropriateness of the prescription prior to dispensing ECPs to a customer. For this reason, in Washington State, many insured women were asked to pay additional out-of-pocket fees of up to $60 when they wanted pharmacist prescribed ECP.

[17] *See* Alan Guttmacher Institute, *Contraception Counts: California* (1999) at http://www.agi-usa.org/pubs/state_facts99/california99.pdf

Ironically, almost every uninsured teenager seeking ECP could qualify for California's Family PACT insurance program or California's Medicaid for minors program, Medi-Cal Minor Consent, both of which offer confidential coverage for family planning services and cover some if not the full cost of the ECP product and service.[18] Unfortunately, pharmacists cannot enroll clients in either program at the pharmacy. Thus, unless a teen is already enrolled in FamilyPACT prior to her contraceptive emergency, -- in effect, requiring her to predict the unpredictable, -- these insurance programs won't increase timely access to ECP.

A second and very distinct barrier to teen access will be confusion on the part of pharmacists about a minor's right to access and consent to confidential ECP use. While minors in California have the right to access family planning services without their parents' knowledge or the need for parental consent, [19] many providers are either unaware of this right or do not consider ECPs within the scope of "family planning." Because misunderstandings of this sort have limited teen access to family planning services in *health* clinics in the past, there is every reason to believe the issue also will also arise in pharmacies.

Facilitating Teen Access to Pharmacy Access

Even with these barriers, pharmacy access can be an option for California teens, and advocates can facilitate teen access in several ways. (1) For pharmacy access to be viable in the long term, advocates must push for changes in how pharmacy services are reimbursed by insurance. (2) Advocates also should push for a change in the public insurance enrollment system so that uninsured eligible young women can enroll in state-sponsored insurance programs at pharmacies. (3) In the meantime, advocates should encourage sexually active adolescents to enroll in the Medi-Cal program and use this coverage for pharmacist-prescribed ECPs. (4) Finally, advocates must continue to educate adolescents and the public about minors' rights.

(1) Advocate For Public and Private Insurance to Cover Pharmacist Counseling

Pharmacy professional services must be covered by insurance plans as a separate reimbursable expense to assure the viability of pharmacy access programs. Currently, few, if any, insurance plans reimburse pharmacists' professional services. California's Medicaid structure, for example, makes no such provision. Some state Medicaid programs reimburse pharmacists for additional professional service charges when they can document the provision of 'pharmaceutical care'. Wisconsin has such a scheme, and Washington State now covers pharmacist-prescribed ECPs in this way. As pharmacist counseling becomes more complicated, it is appropriate to seek a change in the structure. Separate coverage of pharmacy professional services recognizes the more prominent role pharmacists are beginning to play in health care. Further, both California's Department of Health Services and insurance companies may be receptive to increase coverage for pharmacist counseling given the ultimate savings from reduced pregnancy coverage in the long term.[20]

[18] Almost every California teen is eligible for Medi-Cal Minor Consent coverage because only personal, not parental, income counts against a teen in determining eligibility.

[19] *See* CA. FAM. CODE §§ 6920, 6925.

[20] Alan Guttmacher Institute, *Contraception Counts: California* (1999) at http://www.agi-usa.org/pubs/state_facts99/california99.pdf (Studies document that "every one dollar spent for contraceptive services saves $3 in public funds that would have been needed to provide prenatal and newborn medical care alone.")

(2) Encourage the Department of Health Services to Allow Pharmacy Enrollment in Medi-Cal

California Advocates also must seek a change in the Medi-Cal enrollment system. Many uninsured teens will enter pharmacies seeking ECP. For pharmacist-prescribed ECP to be available to all, teens without insurance coverage must be able to enroll and receive immediate coverage at the pharmacy. Health clinics can enroll patients in some public insurance programs and can facilitate enrollment in Medi-Cal. Pharmacies should be given the same authority.

(3) Encourage Teens to Enroll in Medi-Cal 'Minor Consent' to cover ECP services

Until the reimbursement scheme is restructured as recommended in (1) above, even adolescents with private insurance coverage should be encouraged to use Medi-Cal to cover pharmacy-available ECP expenses. As discussed above, Medi-Cal currently does not reimburse pharmacists for counseling time when they dispense ECP. As demonstrated in Washington, pharmacists in California likely will pass the unreimbursed portion of the ECP bill on to the customer, asking the customer to make up the difference if their insurance plan falls short.

Teens should be encouraged to enroll in Medi-Cal for ECP services because pharmacists *cannot* pass unreimbursed costs on to Medi-Cal clients. According to federal and state law, pharmacists who accept Medicaid are obligated to accept the state's Medicaid reimbursement as payment in full for a service.[21] Thus, while pharmacists can charge private insurance clients for the fees their insurance company doesn't reimburse, they cannot similarly charge Medi-Cal or Medi-Cal Minor Consent clients additional out of pocket costs.

As noted above, in Washington State, some pharmacists did charge Medicaid clients a counseling fee. While acknowledging the federal mandate to not bill Medicaid clients for unreimbursed costs, the pharmacists argued that dispensing ECPs requires two services: dispensing the medication, and evaluating and counseling the client. They maintain that they did not violate the law by billing clients because they first billed Medicaid for one service, the dispensing, and accepted payment as payment in full for that service. Then they billed the client for a different service, the counseling. This argument has a fatal flaw in that pharmacy "dispensing" cannot be separated into two distinct services in this way. Federal Medicaid law mandates that pharmacists counsel customers when dispensing pills to them.[22] Thus, under Medicaid, reimbursement for dispensing ECP is reimbursement for both counseling and pill distribution. While counseling ECP clients may involve a more time-consuming interaction now, it still is a part of the standard dispensing service and Medi-Cal clients should not have to

[21] 42 C.F.R. § 447.15; *See also* CA. WELF. & INST. CODE § 14019.3(d)(payment received from the state in accordance with Medi-Cal fee structures shall constitute payment in full . . .") *and* CA. WELF. & INST. CODE § 24011(c)("Eligible individuals shall not be charged for any state-only family planning laboratory or pharmaceutical services" in FamilyPACT). *See also* 42 U.S.C. §§ 1396a(a)(14) and **1396o.**

[22] Incorporated into Medicaid law with the Omnibus Budget Reconciliation Act of 1990. *See* 42 C.F.R. § 456.705.

pay any additional out of pocket costs.

(4) Educate the Community about Emergency Contraception and Teens' Rights to Access Confidential Family Planning Care
Advocates must continue their efforts to educate the community. Advocates can facilitate teen access by educating professionals and adolescents about the existence and safety of ECPs, insurance issues, and minor consent and confidentiality rights in reproductive health.

Conclusion

Improved availability of emergency contraception could change the lives of tens of thousands of California teens. California's pharmacy access legislation is an important step. But pharmacy access legislation alone will not guarantee access for all teens. As implementation of California's new pharmacy access program gets underway, California minors will need help to assure they can reap the full benefit of non-prescription, pharmacy-available ECP.

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