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# Access to levonorgestrel emergency contraception: science versus federal politics

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Past US FDA decisions about emergency contraception (EC) have been subject to undue political influence, and last year's barring of over-the-counter access to Plan B One-Step® for those under the age of 17 years is no exception. The US Department of Health and Human Services cited insufficient data on EC use for females aged 11–12 years. These youngest adolescents, however, rarely need EC: data from California (USA) show that in 2009, fewer than one in 10,000 females under the age of 13 years received EC. Maintaining barriers to safe and effective EC is not medically necessary and conflicts with national goals to decrease teenage and unintended pregnancies.

Levonorgestrel emergency contraception (EC) is a safe and widely used product; however, it has encountered regulatory and political opposition in the USA. The latest move to oppose greater access to EC came in December 2011, when a recommendation by the US FDA to approve marketing Plan B One-Step® EC as a nonprescription product without age restriction was over-ruled by the Department of Health and Human Services (HHS). The rationale for this decision was that the label comprehension and actual use studies submitted to the FDA did not include data on all ages for which the drug would be approved and available over-the-counter, including the youngest girls of reproductive age who reach menarche by 11 years of age. EC use is exceedingly rare in 11–12-year olds – so rare, in fact, that collecting data regarding them is unreasonable and represents an insurmountable requirement. Meanwhile, by continuing to restrict access to EC for sexually active teens aged 16 years and under, we limit access to women of all reproductive ages and compromise our national goals of reducing teenage and unintended pregnancy.

Since the inception of levonorgestrel EC products, FDA decisions regarding them have been subject to political intervention. Approval of behind-the-counter access for levonorgestrel EC for women aged 18 years and over was delayed for nearly 3 years, from 2003 to 2006 [1]. Barriers to approval came from within the agency, and the Government Accountability Office found that multiple aspects of the FDA's decision process were unusual compared with other products the FDA reviewed during this time [101]. Despite scientific

evidence in support of a lower age restriction, a federal district court order was necessary to obtain approval for behind-the-counter access for 17-year olds in 2009 [102].

During the most recent FDA review of the Plan B One-Step supplemental new drug application to market the product as a nonprescription drug without any age restriction, the FDA's Center for Drug Evaluation and Research reviewed data from rigorous studies on actual use and label comprehension. These studies demonstrated that adolescents aged 12–17 years could read and comprehend the package labeling, and correctly self-select and use the product without provider guidance [2,3]. The FDA's Division Director Summary Review of Regulatory Actions, which represents the position of the FDA, recommended approval of the application [103]. Hours before the decision was to be announced on 7 December 2011, the Secretary of US HHS overruled the FDA's decision – an unprecedented use of this HHS authority over the FDA.

In a memorandum to the FDA Commissioner Margaret Hamburg, HHS cited insufficient data for 11–12-year olds as the reason for the decision: “The label comprehension and actual use studies submitted to the FDA do not include data on all ages for which the drug would be approved and available over-the-counter. Yet it is commonly understood that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age” [103]. By contrast, Commissioner Hamburg agreed with Center for Drug Evaluation and Research's determination that “the product was

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safe and effective in adolescent females, [and] that adolescent females understood the product was not for routine use ... Additionally, the data supported a finding that adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider” [104].

If implemented, the FDA recommendation would have made it possible to market this one type of emergency contraception on store shelves next to condoms. As it is, behind-the-counter restrictions remain in place: consumers aged 17 years and over must present proof of age and request EC from a pharmacist, while those under the age of 17 years must seek a prescription for EC from a licensed healthcare provider. Plan B One-Step is being held to a different standard than other medications transitioning to over-the-counter status – a standard that is not merited by the product’s safety record or by scientific evidence, as we describe below. By contrast, there is no age limit on the sale of pain medications, cough suppressants and stimulants, which are on the shelves of pharmacies and sold without age limits. These medications have never been tested for correct use among adolescents and have the potential to cause serious harm or death if used improperly. No other product transitioning from prescription to over-the-counter status has been required to present use data for 11- or 12-year olds.

#### **Scientific evidence on adolescents & EC**

Nearly 50 years of research and use of levonorgestrel have shown that it is safe – according to the CDC, there are no medical contraindications to its use as EC [4]. EC has been studied in adolescents as young as age 12 years, providing a wealth of comparative information on pharmacokinetics, safety, tolerability, reading comprehension of instructions, proper use and sexual behaviors. For adolescents, levonorgestrel EC is safe, well-tolerated and has transient side effects similar to those experienced by adults [5,6]. The sexual behavior of teenagers, sexually transmitted infections, and risk taking do not change when they have easier access EC or advance provision, nor does their use of condoms or other contraception [7].

#### **Data on the youngest adolescents’ use of EC**

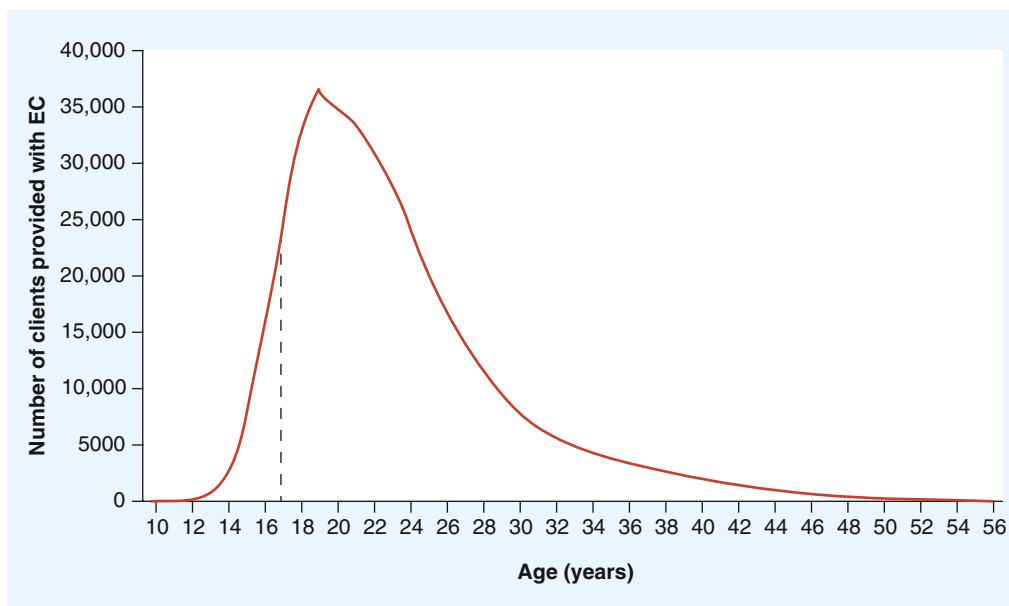
There are no national data on the use of EC among women under the age of 15 years, who are excluded from the national survey definitions of women of reproductive age (15–44 years). This article examined data from the California Medicaid family planning expansion program

to reveal the age distribution of EC users. The program offers free and confidential reproductive healthcare and contraceptive methods to over 1.8 million low-income, uninsured or underinsured California (USA) residents annually. Nearly all adolescents are eligible based on their own income. Since 2006, program providers have supplied EC to clients at no cost. While the more than 2200 program providers do not encompass all adolescent reproductive healthcare visits in California, the program is an important source of care for young women at high risk of unintended pregnancy. Although these data are limited to California, the state is populous and diverse, with more than one in eight US adolescents aged 11–19 years as residents. Furthermore, there is no evidence that California teenagers experience menarche or first sex at ages different from the national average; fewer than 10% of 11-year olds have reached menarche [8] and only seven in 1000 have had sex [105].

The data demonstrate that few females under the age of 13 years seek family planning care at program providers. In 2009, fewer than one in 2500 female program clients were under the age of 13 years. By contrast, nearly one in six female clients were aged 13–19 years. Fewer than one in 10,000 California females under the age of 13 years received EC from a program provider, compared with one in 70 California females aged 13–19 years. **FIGURE 1** shows the steep age curve for EC provision in the program, with the first significant provision occurring in females aged 15 years and up. As these data are from a family planning program, adolescent clients are more likely to be sexually active than those not seeking program services. Therefore, even this rare use of EC among the program’s youngest clients may be an overestimate of overall EC use by this age group.

#### **Implications of these data on EC use**

These findings concur with other evidence on adolescent development and health services utilization, which indicate that females under the age of 13 years use EC exceedingly rarely [8,9]. Given that so few of the youngest adolescents need EC, the HHS contention that there are insufficient data on how 11-year olds use EC is of little practical relevance. There will never be sufficient data on EC use among females under the age of 13 years as it is very rare that they use it. However, keeping EC prescription-only for females under the age of 17 years keeps it out of reach for a much larger population of 15–16-year olds, despite evidence that these teenagers are



**Figure 1. California Medicaid family planning expansion program female clients provided with emergency contraception by age (2009).** Dotted line shows the age after which women may obtain over-the-counter EC from a pharmacy with proof of age. EC: Emergency contraception.

able to safely and effectively use EC to prevent pregnancy, and that they represent a population at high risk of unintended pregnancy.

#### Rationale for expanding access to EC

The scientific evidence and US national public health goals to reduce teenage and unintended pregnancies both support expanded access to EC [106]. Expanded EC access is particularly important for teenagers, who are at high risk of unintended pregnancy, have elevated rates of negative pregnancy outcomes [10], and face special challenges in accessing healthcare. The US teen pregnancy rate declined from 62 out of 1000 in 1991 to 34 out of 1000 in 2009 [11]; however, over four out of five of those pregnancies remain unintended [12,13]. One in five women aged 15–19 years report using no method of contraception during their first sexual experience [14]. Women under the age of 17 years who wish to prevent an unintended pregnancy after unprotected intercourse face the hurdle of procuring a prescription. The likely delay results in lower effectiveness, as levonorgestrel EC is more effective the sooner it is used [15]. Regardless of age, those wishing to obtain behind-the-counter EC must do so during pharmacist hours only, present the required form of identification, and may face pharmacist refusal to dispense the product.

Despite over 30 years of efforts to reduce the US teen pregnancy rate, it remains one of the

highest among developed nations – over two-times the rate of Canada (14 out of 1000), and three-times that of France and Germany (both ten out of 1000) [107]. EC is available without age restriction in all three countries – over-the-counter in Canada, and without prescription in France and Germany. While there are many reasons for lower teenage pregnancy rates in these countries, there is no evidence that removing medically unnecessary barriers to EC access has resulted in harm to adolescents [108].

Medical professional organizations such as the American Academy of Pediatricians and the American College of Obstetricians and Gynecologists have attempted to address EC access differences in the USA. These organizations have issued guidelines for routine counseling and advance provision of EC to adolescents [16] and recommended the removal of age restrictions on levonorgestrel EC [17]. However, experience has shown us that physician and pharmacist practice can only go so far in reducing barriers to EC access [18]; timely physician appointments can be difficult to obtain, pharmacists can decline to dispense the product, pharmacy hours can limit access, and not all women have an acceptable form of identification [19].

#### Conclusion

The FDA determined and the Commissioner agreed that evidence supports nonprescription access to EC for adolescents – the overwhelming

majority of whom are 13 years or older. Given the potential precedent for HHS to over-rule a carefully deliberated FDA recommendation, women's health advocates brought a lawsuit against the FDA and HHS in February 2012. Protracted legal challenges have become the normal route to secure regulation for levonorgestrel EC consistent with scientific evidence. While the legal challenges work their way through the courts, we miss thousands of opportunities to allow women prompt access to EC, including women under the age of 17 years. We may yet hold levonorgestrel EC to the same regulatory standards as other products transitioning to over-the-counter status, to the benefit of all those wishing to avoid an accidental pregnancy.

### Future perspective

Decisions about EC access in the USA have been subject to political intervention over the past 15 years; however, the general direction has been toward greater access and increased availability of these products. All medical literature supports greater access to levonorgestrel EC, so this trend

is likely to continue, albeit in an interrupted fashion. In 10 years, there will be more EC products – and the copper intrauterine device and ulipristal acetate will likely be more widely used for emergency contraception. In addition, widely used methods of contraception such as oral contraceptive pills will be considered for nonprescription marketing.

### Disclaimer

*All analysis, interpretations or conclusions reached are those of the authors, not the State of California nor Kaiser Permanente Northern California.*

### Financial & competing interests disclosure

*The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.*

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## Executive summary

### Background

- The US federal government has a history of political influence over US FDA decisions about emergency contraception (EC).
- A large body of evidence shows that levonorgestrel EC is safe for adults and adolescents, and that adolescents can use it correctly in simulated over-the-counter conditions.

### Data on adolescent use of EC

- Data from the California Medicaid family planning program show that females under the age of 13 years use EC and other family planning services exceedingly rarely.
- As it is so rare, scientists cannot collect sufficient data on EC use by those under the age of 13 years.

### EC access remains difficult for all

- Older, sexually active teenagers remain at high risk for unintended pregnancy.
- Availability of Plan B One-Step® over-the-counter may help address high rates of unintended pregnancy among teenagers, and would support US public health goals.

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