

The Food and Drug Administration Should Approve Over-the-Counter Oral Contraception Without an Age Restriction

The Food and Drug Administration (FDA) is currently reviewing the first-ever application to make an oral contraceptive product available over the counter (OTC) in the United States. That application is for a progestin-only pill (POP or “mini-pill”) and was submitted in July 2022, and a decision is expected within 10 months, by May 2023.^{1 2} A second oral contraceptive pill, a combination oral contraceptive (COC), is currently in the pre-application review stage, with a final application anticipated in the near future.

The FDA has strict standards and processes for reviewing applications that are designed to ensure that its decisions are made based on the science and evidence, free from political interference. It is critical for the FDA staff to follow these standards and for FDA leadership and the policymakers that oversee the agency to reject any politically motivated demands for an age restriction. Such a restriction would be medically inappropriate, would be harmful for both minors and adults, would be a violation of minors’ legal and moral rights, and would repeat the mistakes of Plan B emergency contraception.

An Age Restriction Would Be Medically Inappropriate

Oral contraceptives have a 60+ year proven track record of safety and efficacy,³ and they are sold without a prescription in dozens of other countries.⁴ Medical experts have said that consumers can assess the minimal health risks on their own, without provider assistance, and that these risks are outweighed by the benefits of eliminating the unnecessary barrier of a prescription.⁵ In fact, the progestin-only pill (POP) that is currently being considered for OTC status is the same type of

¹ The New York Times, [F.D.A. to Weigh Over-the-Counter Sale of Contraceptive Pills](#), July 11, 2022

² CAI, [The Food and Drug Administration’s 10-Month Clock to Weigh Over-the-Counter Status for Oral Contraception](#)

³ Planned Parenthood, [How safe is the birth control pill?](#)

⁴ Free the Pill, [Where on Earth?](#), 2022

⁵ ACOG, [Over-the-Counter Access to Hormonal Contraception](#), 2019

medication class that is contained in Plan B (progestin emergency contraception), which has been available OTC without an age restriction for nearly a decade.

OTC access to oral contraceptives would meet a demonstrated demand for a highly reliable and effective method that can be accessed readily, without the expense, delays, and time off from work, school, or other responsibilities that come with a visit to a health care provider to obtain a prescription. Improved access to safe and effective oral contraceptives would help reduce people's risk of an unplanned pregnancy, along with the considerable health risks of pregnancy and delivery.⁶

Importantly, the highly respected medical professionals at the American Medical Association (AMA)⁷ and the American College of Obstetricians and Gynecologists (ACOG)⁸ support OTC status for oral contraceptives for all ages.⁹ Similarly, the American Academy of Pediatrics (AAP) encourages "FDA review of oral contraceptives for over-the-counter use, and approval for all age groups as supported by the data."¹⁰ In the words of AMA board member David Aizuss, "Providing patients with OTC access to the birth control pill is an easy call from a public health perspective as the health risks of pregnancy vastly outweigh those of oral contraceptive use."¹¹

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According to an assessment of the scientific literature published in the Journal of Adolescent Health, oral contraceptives are safe and effective for adolescents, and contraindications are rarer for adolescents than for adults.¹² That report notes that adolescents are less likely than adults to face the most serious contraindications of any oral contraceptives, and the POP formula, currently at the final approval stage for OTC status, has almost none of these contraindications. The report also found scant evidence to suggest that adolescents are unable to assess these minimal risks, to make informed decisions about oral contraceptives, or to use oral contraceptives consistently and correctly.

Notably, adolescents already have OTC access to a wide range of drugs and medical devices, because the FDA has determined that the benefits of these drugs and devices outweigh their risks. Adolescents can purchase a variety of contraceptive products without a prescription, including condoms, spermicides, and (since 2013) Plan B emergency contraception. They can also purchase an array of

⁶ Contraception, [Pregnancy: not a disease but still a health risk](#), 2013

⁷ AMA, [AMA urges FDA to make oral contraceptive available over-the-counter](#), 2022

⁸ ACOG, [Over-the-Counter Access to Hormonal Contraception](#), 2019

⁹ Contraceptive Access Initiative, [Medical Experts](#)

¹⁰ AAP, [Equitable Access to Sexual and Reproductive Health Care for All Youth](#), 2022

¹¹ AMA, [AMA urges FDA to make oral contraceptive available over-the-counter](#), June 15, 2022

¹² Journal of Adolescent Health, [Over-the-Counter Access to Oral Contraceptives for Adolescents](#), 2017

other drugs, including some that have the potential to be misused (by adolescents or adults) to get high or even to attempt suicide¹³ — risks that do not exist for contraception.

There are only a few examples of age restrictions on OTC products, and those have been reserved for products related to addiction and substance abuse — again, factors that are not at issue for contraception. Specifically, the FDA has limited OTC access for nicotine replacement products to people 18 and older,¹⁴ and many states have imposed age restrictions on dextromethorphan, a cough medication that can be used in excessive doses to get high.¹⁵

An Age Restriction Would Create Harmful Barriers for Minors and for Adults

Instituting a medically unsupported age restriction on OTC oral contraceptives would create a harmful barrier to access for minors and many adults, undermining the purpose and benefits of OTC status.

Minors subject to an age restriction might instead rely on other options for pregnancy prevention that may be less effective for them or that depend on their partners' cooperation, such as condoms or withdrawal ("pulling out"). Other minors might seek out prescription contraceptive options and face the associated hurdles, expenses, and delays, such as finding a health care provider, scheduling a visit, traveling to a clinic, missing school or work, and potential breaches in confidentiality. Some minors might rely on a parent or guardian to purchase an OTC oral contraceptive — most minors do involve their parents in reproductive health decisions¹⁶ — but that might not be an option for minors who fear physical or emotional abuse or who live on their own.

For some minors, the end consequence of these practical barriers would be an unplanned pregnancy, with all of its health risks and its other potentially life-changing consequences — even more so now that abortion is no longer an option in many states. Pregnancy, childbirth, and parenting have enormous financial, educational, social, and emotional implications for adolescents (as they do for adults).

In fact, we know that the unnecessary prescription barrier to the pill has resulted in unplanned pregnancies for young people. In a 2022 survey of 243 young people, 55% of them could not get on

¹³ Vox, [Young people are poisoning themselves at alarming rates with over-the-counter drugs](#), Oct. 7, 2019

¹⁴ FDA, [Want to Quit Smoking? FDA-Approved and FDA-Cleared Cessation Products Can Help](#)

¹⁵ Consumer Healthcare Products Association, [Ohio Becomes 21st State to Adopt Age-18 Sales Law for Cough Medicine](#), July 1, 2021

¹⁶ Guttmacher Institute, [Ensuring Adolescents' Ability to Obtain Confidential Family Planning Services in Title X](#), 2018

daily oral contraceptives when they wanted due to barriers caused by the prescription-only system. Of those youth, 58% had a pregnancy scare, 20% got pregnant, and 16% had an abortion.¹⁷

Researchers have found that denying minors access to confidential contraceptive care can lead them to forgo needed care, but it does not lead them to stop having sex.¹⁸ Additionally, the research affirms that improvements to contraceptive access (such as condom availability in schools or increased access to emergency contraception) do not increase sexual activity.^{19 20} For all of these reasons, major medical authorities support confidential contraceptive care for minors,^{21 22} and (as noted above) groups such as ACOG and the AMA support OTC access for all ages.²³

An age restriction for an OTC oral contraceptive would also have spillover consequences for adults. Implementing an age restriction would effectively relegate the drug to a “back of the counter” status where a pharmacy employee would need to check the customer’s proof of identity and age. That would limit where and when an OTC oral contraceptive can be sold. It would also pose barriers for the millions of adults in the United States without government-issued identification, including many immigrants, low-income people, and people of color.²⁴

An Age Restriction Would Violate Minors’ Rights

An age restriction for OTC oral contraceptives would run contrary to long-standing legal precedents in the United States and violate minors’ legal and moral rights. Minors’ right to use contraception was established nationwide in a 1977 decision by the US Supreme Court.²⁵ That case, *Carey v. Population Services International*, continued the Court’s line of reasoning in its earlier cases establishing the constitutional right to contraception, and specifically struck down a ban on the distribution of OTC contraceptives (such as condoms) to minors younger than 16.

This federal legal precedent establishing minors’ rights to contraception has been affirmatively written into statute in 23 states and the District of Columbia, which explicitly allow all minors to consent to

¹⁷ Advocates for Youth, [Behind the Counter: Findings from the 2022 Oral Contraceptives Access Survey, 2022](#)

¹⁸ Guttmacher Institute, [Ensuring Adolescents’ Ability to Obtain Confidential Family Planning Services in Title X](#), 2018

¹⁹ Journal of Adolescent Health, [Over-the-Counter Access to Oral Contraceptives for Adolescents](#), 2017

²⁰ Guttmacher Institute, [Promiscuity Propaganda: Access to Information and Services Does Not Lead to Increases in Sexual Activity](#), 2019

²¹ American Academy of Pediatrics, [Contraception for Adolescents](#), 2014

²² Society for Adolescent Health and Medicine, [The Use of Medication by Adolescents and Young Adults](#), 2017

²³ AMA, [AMA Urges FDA to Make Oral Contraceptive Available Over the Counter](#)

²⁴ Washington Post, [Getting a photo ID so you can vote is easy. Unless you’re poor, black, Latino or elderly](#), May 23, 2016

²⁵ US Supreme Court, [Carey v. Population Services International](#), 1977

contraceptive services. In 24 other states, the law explicitly allows minors to consent to contraceptive services in specific circumstances, such as when the minor is married.²⁶ However, even in states that have only limited protections in statute (or none at all), the Supreme Court precedent still holds. No state requires parental consent for contraception generally, although Texas and Utah require parental consent for state-funded contraceptive services.

Federal policy protects minors' right to confidential contraceptive care under the Title X family planning program, while also encouraging minors to involve their parents.^{27 28} Similarly, federal Medicaid law requires the program to cover family planning services for both minors and adults, and it has long been interpreted as protecting minors' confidentiality and barring parental consent for contraception.^{29 30}

Because of these strong court precedents and statutory protections, attempts to impose age restrictions on contraception have been rare in recent decades. The FDA's attempt to impose an age restriction on Plan B emergency contraception is the most prominent example, and it was ultimately overruled in federal court.^{31 32} Oklahoma's attempt to impose its own age restriction on emergency contraception was also struck down.³³

It is important to emphasize that minors' right to consent to confidential contraceptive care does not depend on the age of sexual consent under states' statutory rape laws. The law generally acknowledges that it would be wrong to deny needed contraceptive care to minors, even if some would prefer that they had no need for that care in the first place. Nevertheless, some policymakers — such as the Kansas attorney general in 2003 — have periodically tried to use the specter of statutory rape to undermine minors' right to reproductive health care, by arguing that health care providers should report to the authorities when any patient below the state's age of sexual consent asks for contraception or is treated for a sexually transmitted infection.³⁴ That attempt in Kansas was blocked in court. More recently, the Trump administration required Title X providers to screen for abuse in any

²⁶ Guttmacher Institute, [Minors' Access to Contraceptive Services](#), 2022

²⁷ Guttmacher Institute, [Ensuring Adolescents' Ability to Obtain Confidential Family Planning Services in Title X](#), 2018

²⁸ Kaiser Family Foundation, [Rebuilding Title X: New Regulations for the Federal Family Planning Program](#), 2021

²⁹ Manatt Health, [Enhancing Access to Family Planning Services in Medicaid: A Toolkit for States](#), 2019

³⁰ US Supreme Court, [Planned Parenthood Association of Utah v. Dandoy](#), 1986

³¹ Verywell Health, [The History of Emergency Contraception](#), 2021

³² AMA Journal of Ethics, [Inappropriate Obstructions to Access: The FDA's Handling of Plan B](#), 2014

³³ Rewire, [Judge Permanently Blocks Oklahoma Law Restricting Emergency Contraception](#), Jan. 24 2014

³⁴ Guttmacher Institute, [Politicizing Statutory Rape Reporting Requirements: A Mounting Campaign?](#), 2005

minor who presented with a sexually transmitted infection or a pregnancy;³⁵ that regulation has since been rescinded.³⁶

Major medical groups have pushed back on this extreme interpretation of the requirement to report suspected sexual abuse.³⁷ Specifically, a 2004 position paper from the American Academy of Family Physicians, AAP, ACOG, and the Society for Adolescent Medicine made it clear that consensual underage sex is not synonymous with sexual abuse, and that most adolescents having sex need medical care, rather than being reported to the authorities and having their privacy violated. Demands to treat all underage sex as abuse — including similar potential objections to minors' access to OTC contraception — would only result in denying adolescents needed health care.

Finally, although parents do in general have well-established rights to make health care decisions on behalf of their minor children, these rights do not outweigh minors' own rights to contraceptive care or the potential harm to minors from being unable to access needed care. And in fact, policymakers and courts have established stronger legal rights for minors when it comes to contraception and many other sensitive services (such as STI testing and treatment, and substance abuse treatment) than they have for most forms of medical care. Because of those stronger rights, an age restriction would be less — not more — appropriate for contraception than it is for other OTC drugs.

The FDA Should Repel Any Political Interference

The FDA's review of applications for OTC oral contraceptives comes more than a decade after politicians interfered with the agency's decision-making on whether Plan B, an emergency contraceptive, should be available OTC. Plan B emergency contraception was a strong candidate for OTC status: safe, effective, with few contraindications. Yet political appointees under two federal administrations, led by Republican and Democratic presidents, repeatedly departed from the FDA's usual procedures to delay the drug's OTC approval, made highly unusual demands on the drug manufacturer, and imposed an age restriction that defied the science and the recommendations of the FDA's career staff and advisory committee.³⁸ This process damaged the FDA's reputation and set negative precedents for policymakers' interference with a process that is designed to be insulated from politics and to enable the career professionals at the FDA to make timely decisions based on science and evidence. It was only after repeated intervention by federal courts that the age restriction was lifted in 2013.

³⁵ Federal Register, [Compliance With Statutory Program Integrity Requirements](#), 2019

³⁶ Federal Register, [Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services](#), 2021

³⁷ Journal of Adolescent Health, [Protecting adolescents: Ensuring access to care and reporting sexual activity and abuse](#), 2004

³⁸ AMA Journal of Ethics, [Inappropriate Obstructions to Access: The FDA's Handling of Plan B](#), 2014

The history of Plan B also highlighted the practical harms of an inappropriate age restriction — barriers to needed care for both adolescents and adults that muted the potential benefits of OTC access. In fact, a study published in 2022 found that use of emergency contraception and the purchase of emergency contraception at drug stores has increased substantially among sexually experienced adolescents and young adults in the years after the elimination of the FDA’s age restriction.³⁹ At the same time, nearly a decade of OTC sales of emergency contraception without an age restriction have provided real-world assurance that a hormonal contraceptive can be made safely available for people of all ages without a health care provider’s prescription or intervention.

Conclusion

Sound medical research demonstrates that an age restriction on OTC oral contraceptives is not necessary, would hinder access to needed health care for both adolescents and adults, would violate minors’ legal and moral rights to consent to contraceptive care, and would repeat the mistake made around Plan B in instituting a medically unsupported barrier to access, thereby damaging the FDA’s reputation at a time when public trust in the FDA is a concerning national issue. For all of these reasons, the FDA and the policymakers that oversee the agency should follow the evidence and reject politically motivated restrictions.

³⁹ Journal of Adolescent Health, [Trends in Emergency Contraceptive Use Among Adolescents and Young Adults, 2006-2017](#), 2021