

January 6, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to urge the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) to move swiftly to expand access to oral contraceptives by making them available over the counter without a prescription. We were pleased to see progress on an application to the FDA to make available a progestin-only pill without a prescription, but urge FDA and HHS to ensure a variety of oral contraceptive options are available to women, including both progestin-only and combination oral contraceptives. At a time when unrestricted access to reproductive health services is under threat in many areas of our country, easy access to affordable contraceptive options has become a more critical women's health issue.

Access to oral contraceptives without a physician's prescription is a safe and necessary step that we must take to ensure that women are able to effectively limit unintended pregnancies and manage their reproductive choices, as those choices are being limited in many states. Oral contraceptives have been used safely by millions of women in the United States and around the world since the 1960s, building a significant evidence base demonstrating their safety and efficacy and preventing unintended pregnancy. While contraindications do exist, there are a number of studies demonstrating that women are able to successfully self-identify contraindications and select appropriate contraceptive methods using standardized checklists. Additionally, over 100 countries globally have already made oral contraceptives available without a prescription. Years of safe use have demonstrated that while there is some risk with using oral contraceptives, pregnancy poses greater short-term health risks, and the significant benefits of oral contraceptives outweigh the long-term risks for the vast majority of women. While we support efforts to appropriately review applications for making oral contraceptives available without prescriptions, we strongly encourage HHS and FDA to do so as quickly as possible while maintaining appropriate standards of review. We also encourage HHS and FDA to ensure that regulatory standards are consistent and clearly communicated to applicants for both progestin-only and combined oral contraceptive options and that additional regulatory hurdles are limited for both.

The AMA is well aware that there are significant barriers to access to oral contraceptives that currently prevent women from having ready access to affordable options. While the AMA strongly encourages all women to receive the recommended breast and pelvic exams, cancer screenings, and sexually transmitted infection screenings, these exams and screenings are not necessary prior to initiation or refill of an oral contraceptive prescription. For uninsured or underinsured women or those without a regular physician, policies requiring access to a physician and in-person office visits are significantly cost-prohibitive to

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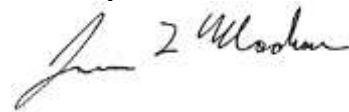
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accessing oral contraceptives, particularly when factoring in the cost of time off from work, childcare, and traveling long distances. The accelerating closure of reproductive health clinics in many states is rapidly reducing access to physician care, often overlapping with states that have declined to expand Medicaid or offer Medicaid's family planning program. Access is particularly constrained for Black, Indigenous, and People of Color, and those living in high-poverty and rural communities.

In addition to the burdens to access created by in-person screening and examination policies, the cost of the prescription can represent an additional increased burden to many women. While the Affordable Care Act mandates coverage without co-insurance for oral contraceptives, many plans severely limit the options that are available without cost sharing. For those women who are uninsured or underinsured, a typical oral contraceptive prescription can cost \$30-\$40 per month, representing a prohibitive financial burden to many. Additionally, moves to make oral contraceptives available over the counter may throw coverage policies for these drug products in doubt, even for women with adequate insurance coverage. As we look to move towards making oral contraceptives more widely available without prescriptions, it is critical that HHS take action to ensure the financial burdens of accessing oral contraceptives are not prohibitive. This could include consideration of federal funding for the manufacture of oral contraceptive products to assist in lowering list prices, other federal programs to assist uninsured or underinsured women acquire oral contraceptives, updates to Indian Health Service, Medicaid family planning, and Federally Qualified Health Center pharmacy policies, or coverage mandates for over the counter oral contraceptives, although this list should not be considered exhaustive of all possibilities to provide this essential financial assistance.

The AMA remains firmly committed to ensuring women have access to the entire spectrum of reproductive health care services, including easy and affordable access to oral contraceptives. We strongly encourage HHS and FDA to move as swiftly as possible to eliminate burdensome prescription requirements for these drug products, including for both progestin-only and combined oral contraceptive options. We also encourage further action be taken to ensure that any over the counter oral contraceptive options are affordable and that cost does not serve as a barrier to access. As access to women's health care services is increasingly limited in several states, this issue is of critical importance. We look forward to continuing to work with you to support women's right to access essential health care services. If you have any questions or would like to further discuss, please contact Shannon Curtis, Assistant Director of Federal Affairs at Shannon.Curtis@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD