James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

April 25, 2023

The Honorable Robert Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

On behalf of the physician and medical student members of the American Medical Association (AMA), thank you for this opportunity to provide comment in advance of the upcoming joint meeting of the Nonprescription Drugs and Obstetrics, Reproductive, and Urologic Drug Advisory Committees. The AMA is pleased to see the FDA moving forward with review of the supplemental new drug application (sNDA) for OPill, proposing to switch the drug from prescription to nonprescription status. In light of the current state of reproductive health, ready access to contraceptive options has become an issue of critical importance. The AMA therefore supports this application for nonprescription status and encourages the advisory committee members and FDA to move rapidly to make this and other oral contraceptive options available without prescription as soon as possible.

Access to oral contraceptives without a physician's prescription is a safe and necessary step that we must take to ensure that individuals are able to effectively limit unintended pregnancies and manage their reproductive choices, which is now particularly important as those choices are being limited in many states. Oral contraceptives have been used safely by millions of individuals in the United States and around the world since the 1960s, building a significant evidence base demonstrating their safety and efficacy at preventing unintended pregnancy. While contraindications do exist, a number of studies demonstrating that individuals are able to successfully self-identify contraindications and select appropriate contraceptive methods (both progestin-only and combined progestin/estrogen formulations) 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 risks, and the significant benefits of readily available oral contraceptives outweigh the long-term risks for the vast majority of individuals.

Nonprescription access to oral contraceptives is becoming increasingly important as reproductive health care options are under increasing threat by state actions to limit access to abortion services and now legal challenges to FDA's approval of medication abortion options. In many states, this could leave individuals with no options to safely terminate a pregnancy that is unintended and/or threatens the health of the pregnant individual, which may result in potentially severe social, economic, and health impacts to those faced with this situation. Increasing the number of unintended pregnancies stands to significantly exacerbate our severe maternal mortality crisis and deepen health care disparities. Medically underserved populations already face significant issues in accessing regular health care services, making access to prescription-only oral contraceptives challenging. Pregnant individuals in these communities could face

insurmountable obstacles in receiving pregnancy care should they be faced with an unintended pregnancy, especially in a state with limited reproductive health care choices, making access to affordable nonprescription contraception options an issue of critical importance.

The AMA urges FDA and its advisory committees to move swiftly towards approval of appropriate sNDAs seeking to move applicant oral contraceptives to nonprescription status. We also encourage FDA to ensure that regulatory standards are consistent and clearly communicated to applicants for both progestin-only and combined oral contraceptive options and that any additional regulatory hurdles are limited for both. At this critical juncture for reproductive health in the United States, over sixty years of safe and effective use of oral contraceptives have demonstrated that the benefits of widespread, nonprescription availability far outweigh the limited risk associated with their use.

We look forward to continuing to work with you towards ensuring safe access to these essential medications. Should you have any questions or wish to discuss further, please contact Shannon Curtis, Assistant Director of Federal Affairs at Shannon.Curtis@ama-assn.org.

Sincerely,

James L. Madara, MD