

May 7, 2025

Secretary Howard Lutnick, Department of Commerce
Washington, DC

Re: XRIN 0694-XC120, Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Submitted electronically at regulations.gov

The Contraceptive Access Initiative (CAI) is pleased to submit these comments in response to the Department of Commerce's section 232 investigation of imports of pharmaceuticals and pharmaceutical ingredients.¹ CAI is a project of the nonprofit Hopewell Foundation that supports affordable over-the-counter (OTC) access to the combined hormonal contraceptive pill and the progestin-only pill (mini-pill) without restrictions and affordable to all.² We write to express our concerns over the potential impact of pharmaceutical tariffs on the availability, accessibility, and affordability of contraceptive drugs and devices generally and of OTC oral contraceptives in particular.

Importance of Contraception

Contraceptives are among the most commonly used pharmaceuticals in the United States, with 47 million women aged 15-49 using one or methods in 2018³ and more than 99% of women having used one or more methods in their lifetime, if they had ever had sex.⁴ Birth control is so widely used because it enables people to exercise their reproductive autonomy — to avoid unplanned pregnancies and to time and space wanted pregnancies.

Pregnancy prevention in turn has numerous health benefits for women and their children.⁵ It protects women against the inherent risks of pregnancy, including maternal mortality, and is especially beneficial for women with medical conditions that can be complicated by a pregnancy, such as diabetes or hypertension.⁶ Sufficient pregnancy spacing is linked to better birth

¹ Federal Register. "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients." (2025).

<https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of>

² Contraceptive Access Initiative, (CAI). <https://thepillotc.org/about>

³ Guttmacher Institute. "Contraceptive Use in the United States by Method." (2021).

<https://www.guttmacher.org/fact-sheet/contraceptive-method-use-united-states>

⁴ Guttmacher Institute. "Contraceptive Use in the United States by Demographics." (2021).

<https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>

⁵ National Women's Law Center. "The Affordable Care Act's Contraceptive Coverage Requirement: Importance and Impact." (2024).

<https://nwlc.org/resource/the-affordable-care-acts-contraceptive-coverage-requirement-importance-and-impact/>

⁶ Women's Preventive Services Initiative. "Contraception: Women's Preventive Services Initiative Update." (2021).

<https://www.womenspreventivehealth.org/wp-content/uploads/WPSI-Contraception-Evidence-Update-2021.pdf>

outcomes for infants, and it allows women to prepare in advance for pregnancy, such as by quitting smoking and taking folic acid. Pregnancy planning via contraception also has social and economic benefits for women and families, helping people to achieve their goals and to improve their financial outlook.⁷

In the process of helping individuals and families protect their health and well-being, contraception also has benefits for private and government payers. Unplanned pregnancies, preterm and low-birth-weight births, maternal morbidity and mortality, and chronic conditions that can be exacerbated by an unplanned pregnancy are not only individual health concerns, but also expensive for payers. For example, federal and state expenditures on births, abortions, and miscarriages resulting from unintended pregnancies totaled \$21 billion in 2010 alone.⁸

To fully reap the numerous benefits of contraception, patients and consumers must have a choice among a wide range of potential methods and products. Research has demonstrated that women use contraception most consistently and effectively when they can identify and use an option that best fits their needs.⁹ Their criteria might include the effectiveness of the method, its potential side effects and contraindications, its non-contraceptive health benefits, and how easy it is to use, among other considerations. Cost pressures leading to the use of a contraceptive option that does not meet their needs may result in gaps in contraceptive use and other mistakes that can lead to an unintended pregnancy.

The advent of highly effective OTC contraceptives has the potential to help even more women and families achieve their reproductive health goals. OTC options reduce both medically unnecessary barriers and major logistical and financial barriers that are often attached to prescription options, including finding a regular health care provider, taking time off from work or other responsibilities, the insurance cost-sharing or other out-of-pocket costs for an office visit, and expenses for travel and child care.

⁷ Guttmacher Institute. "The Social and Economic Benefits of Women's Ability To Determine Whether and When to Have Children." (2013).
<https://www.guttmacher.org/report/social-and-economic-benefits-womens-ability-determine-whether-and-when-have-children>

⁸ Guttmacher Institute "Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy Care: National and State Estimates for 2010." (2015).
<https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>

⁹ Guttmacher Institute. "Why Family Planning Policy and Practice Must Guarantee a True Choice of Contraceptive Methods." (2017).
<https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods>

Potential Impact of Tariffs

Like numerous other pharmaceutical products, many prescription and OTC contraceptive products are manufactured overseas and/or use pharmaceutical ingredients manufactured overseas. For example, according to its product label, Opill, the first and so far only OTC oral contraceptive approved for sale in the United States, contains a drug substance from Germany and is manufactured as a drug product in Ireland.¹⁰

New tariffs on pharmaceuticals could have the immediate direct effect of raising costs for companies that manufacture their products overseas and/or import ingredients to manufacture their products in the United States, resulting in reduced profit margins for manufacturers and/or increased prices for purchasers, including insurance companies, government health care payers, and individual customers. Either possibility could have a significant impact on Americans' access to a range of affordable and effective contraceptives.

While tariffs could incentivize pharmaceutical companies to shift some of their manufacturing capacity to the United States in the long run, it could result in disruptions to the market for contraceptive drugs and devices in the short run. Alternatively, some companies may decide it makes financial sense to withdraw some or all of their products from the U.S. market or decide against introducing new products to the United States, thereby reducing the number of contraceptive options for consumers.

If drug companies continue to serve the U.S. market but set higher prices for their products, insurance companies, pharmacy benefit managers, and government health care payers may then restrict their coverage and formularies and to steer consumers away from options that are suddenly more expensive. That would leave consumers with fewer contraceptive options, higher copays, and/or additional red tape to navigate in order to access the contraceptive option that best meets their needs. Unlike many other pharmaceutical products, contraceptives are used by tens of millions of people on an ongoing basis for years at a time, meaning that these disruptions would be widely felt as a significant new cost for individuals and families.

These types of disruptions could be particularly problematic for access to OTC contraceptives. Under current law, private insurance, Medicaid, and other types of health coverage are generally not required to cover contraceptives that are purchased over-the-counter. This means that many or most people who rely on OTC contraceptives are paying for them out of pocket, without insurance coverage, and would therefore experience any price increases directly. Moreover, OTC oral contraceptives are a new product in the U.S. market — approved in 2023 and first sold in 2024 — and demand for them is still developing. Higher prices and/or supply shortages as the result of tariffs could result in long-term damage to U.S. consumers' interest in the currently approved OTC oral contraceptive and to future options in the drug development pipeline. That would undermine the potentially revolutionary benefits of OTC access to highly effective contraception.

¹⁰ Food and Drug Administration. "Opill Daily Oral Contraceptive" labeling. (2024). https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/017031Orig1s042,%20s043lbl.pdf

We appreciate the opportunity to provide comments on this important issue and its potential impact on access to and affordability of contraceptives. If you have any questions about our comments, please contact Dana Singiser of the Contraceptive Access Initiative at dana@kspartnersdc.com.

Sincerely,

Dana Singiser
Co-founder, Contraceptive Access Initiative