United States Senate
Washington D.C. 20510

July 18, 2023

VIA ELECTRONIC TRANSMISSION

Mandy Cohen, M.D., M.P.H.
Director
U.S. Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, G.A. 30333

Dear Dr. Cohen:

I am writing to you with serious concern about the Centers for Disease Control and Prevention's (CDC) guidance for biological men who identify as women (transgender individual) who wish to breastfeed. CDC's Pledge to the American People commits that the basis of all public health decisions will be made on the highest quality scientific data that is derived openly and objectively. This guidance, however, seems driven by political considerations rather than science, and the Agency has provided no explanation of the reasoning and data behind these recommendations.

In at least two pages of CDC's "Infant and Young Child Feeding in Emergencies Toolkit" the Agency gives guidance related to transgender individuals breastfeeding. Specifically, CDC states that "Transgender and nonbinary-gendered individuals may give birth and breastfeed or feed at the chest (chestfeed)."[1] CDC also responds to the question of "Can transgender parents who have had breast surgery breastfeed or chestfeed their infants?" with the one-word answer "Yes."[2] CDC further explains that these transgender parents may need help with "Medication to induce lactation," among other concerns.[3] What is explicitly left out is the acknowledgement of limited research on the ability of transgender individuals to breastfeed infants. CDC also does not provide

[1] *Health Equity Considerations*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nutrition/emergencies-infant-feeding/health-equity.html (last updated Sept. 13, 2022).
[2] *Breast Surgery*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/maternal-or-infant-illnesses/breast-surgery.html (last updated Apr. 4, 2023).
[3] *Id.*

any information about any unique health and safety risks posed to the transgender individual or the infant.

The only reference to any of the serious risks involved appears at the bottom of both of these pages, in a section titled, "Learn More," where CDC links to a clinical protocol published by the Academy of Breastfeeding Medicine (ABM) regarding lactation care for transgender patients.[4] The protocol, which was published in 2020, noted that there was only one official case report of a transgender individual successfully inducing lactation, but cautions that "Significant research gaps exist in this field," and that "there is no published research on the frequency of success" with inducing lactation.[5] It further emphasizes that "investigation is needed into milk production in parents who have undergone gender-affirming surgeries and those who have induced lactation."[6]

While this lack of transparency is troubling, perhaps the most concerning aspect of the CDC guidance is where the Agency states that health care providers should help transgender individuals obtain "Medication to induce lactation."[7] As you know, there are currently no medications approved by the U.S. Food and Drug Administration (FDA) to increase the supply of breast milk. The two drugs most commonly used off-label for this purpose, metoclopramide and domperidone, are both intended for other conditions and come with significant risks and side effects.

Metoclopramide is a drug that is approved by the FDA to treat symptomatic gastroesophageal reflux and diabetic gastroparesis. While it has been used by some women for lactation induction, it is not approved for this purpose, and FDA warns of serious risks when it is used in this way. The drug's label states that metoclopramide "can pass into your breast milk and may harm your baby."[8] The FDA-approved label further warns that taking metoclopramide could result in depression and tardive dyskinesia (which is noted in a boxed warning used for particularly serious risks), and says that the drug should not be used by anyone who suffers from depression or suicidal ideation. This is notable, especially because transgender individuals experience depression, suicidal ideation, and suicide attempts at rates higher than in the general population.[9]

Domperidone is approved in other countries to treat gastric problems, and is sometimes used in such countries to stimulate the production of breast milk, but it is not approved for *any* indication in the U.S.[10] In fact, FDA has explicitly warned against using domperidone to increase milk

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[4] Rita Lynne Ferri et al., *ABM Clinical Protocol #33: Lactation Care for Lesbian, Gay, Bisexual, Transgender, Queer, Questioning, Plus Patients*, 15 BREASTFEEDING MED. 284 (2020).
[5] *Id.* at 287, 290.
[6] *Id.* at 290.
[7] *Breast Surgery*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/maternal-or-infant-illnesses/breast-surgery.html (last updated Apr. 4, 2023).
[8] *REGLAN (metoclopramide) tablets*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017854s062lbl.pdf (last updated Aug. 2017).
[9] *See, e.g.*, Beth Hoffman, *An Overview of Depression among Transgender Women*, 2014 DEPRESSION RSCH. & TREATMENT 1 (2014).
[10] *How to Request Domperidone for Expanded Access Use*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/investigational-new-drug-ind-application/how-request-domperidone-expanded-access-use (last updated Feb. 2, 2021) ("Domperidone is not currently a legally marketed human drug and it is not approved for sale in the U.S.").

production since 2004 because of safety concerns.[11] FDA's warning emphasizes that there have been several published reports and case studies of "cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an intravenous form of domperidone," and that in several countries where the oral form of domperidone is marketed, "labels for the product contain specific warnings against the use of domperidone by breastfeeding women and note that the drug is excreted in breast milk that could expose a breastfeeding infant to unknown risks."[12] The warning also states, "Because of the possibility of serious adverse effects, FDA recommends that breastfeeding women do not use domperidone to increase milk production."[13]

Shockingly, the only part of CDC's website that further explains its recommendation to help transgender individuals obtain "Medication to induce lactation" is, again, the ABM protocol linked at the bottom of the page. The protocol explains that domperidone "has the strongest evidence for successful lactation promotion" and that "the only published case report of a successful induced lactation is in a transgender woman who used this medication."[14] The case report that the protocol cites to says that the patient obtained domperidone from Canada and used it to induce lactation.[15] It is shocking that CDC would directly contradict FDA by recommending the use of an unapproved drug, without any context about the dangers of the product. A single case report about the use of a drug obtained from Canada is wholly insufficient to support recommending any drug, especially one whose distribution is illegal in the U.S.

The CDC should only issue guidance that is informed by sound data and that informs people of potential health risks. To issue breastfeeding guidance that does not highlight the clear risks posed to transgender women breastfeeding unnecessarily puts the parent and infant in jeopardy of potentially serious health complications. The CDC has already lost credibility amongst a wide swath of Americans due to the perception that the Agency's guidance is driven by politics, rather than science. Issuing breastfeeding guidance that does not highlight the unique health risks to adults and infants that accompany breastfeeding by transgender individuals only continues to harm the Agency's credibility. Moreover, the CDC should not be recommending drugs that are not approved in the U.S., and otherwise blatantly contradicting FDA, the agency that Congress has tasked with reviewing the safety and effectiveness of drugs. Even though some advocacy groups may want to deny the biological differences between men and women, the CDC has a responsibility to present all relevant scientific information, including information that may complicate or contradict this political narrative, or risk having their trust amongst the public sink to new lows.

Given these concerns, and the lack of information regarding the scientific basis for this guidance, I request you answer the following questions, on a question-by-question basis, **by August 1, 2023**.

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[11] *FDA Talk Paper: FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production*, U.S. FOOD & DRUG ADMIN. (June 7, 2004), https://www.fda.gov/drugs/information-drug-class/fda-talk-paper-fda-warns-against-women-using-unapproved-drug-domperidone-increase-milk-production.
[12] *Id.*
[13] *Id.*
[14] Ferri, *supra* note 4, at 288.
[15] Tamar Reisman & Zil Goldstein, *Case Report: Induced Lactation in a Transgender Woman*, 3.1 TRANSGENDER HEALTH 24 (2018).

1. Did the CDC use any peer-reviewed studies to inform its guidance on transgender individuals breastfeeding? If so, please provide these studies with your response. If not, why not?

2. What data did CDC rely on that compares the nutritional benefits of biological women's breast milk with the breast milk produced by a transgender individual?

3. What data did CDC rely on to evaluate the long-term effects or health risks to an infant from being breastfed by a transgender individual who has received hormonal therapy to transition genders?

4. Why does the CDC recommend that health care providers help transgender individual obtain a drug that is not approved for use in the U.S.?

5. What communications, if any, did the CDC have with FDA about the recommendations related to both metoclopramide and domperidone? How did the CDC consider FDA's warnings about the risks of both drugs when making its recommendations?

6. What data did CDC evaluate regarding whether the medications taken by transgender individuals to suppress testosterone production (androgen blockage) are excreted in the milk that is produced by transgender individuals? If so, does the CDC have any data on the potential harms this may cause to an infant who breastfeeds?

7. According to the data CDC reviewed in developing these recommendations, how many transgender individuals have been able to produce breast milk?

8. What data did CDC evaluate regarding the ability of transgender individuals to produce sufficient breast milk to exclusively breastfeed an infant for the CDC-recommended minimum of six months?

9. What is the review process for CDC to publish guidance that has little scientific backing on its website?

Thank you for your prompt attention to this matter.

Sincerely,

Roger Marshall, M.D.
Ranking Member
Subcommittee on Primary Health
and Retirement Security

Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions