United States Senate

September 15, 2022

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

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

The Honorable Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Attorney General Garland, Secretary Becerra, and Administrator Milgram,

I write to urge the Biden administration, as it develops policies to advance LGBTQ equality, to consider rescheduling testosterone from a Schedule III to a Schedule V controlled substance, or descheduling testosterone entirely, in order to make it more accessible to transgender people, including transgender men and transmasculine nonbinary people. Testosterone's Schedule III status adds barriers to medically necessary, gender-affirming care while leaving transgender people vulnerable to harassment, discrimination, and surveillance.

Gender-affirming care encompasses a wide range of medical and non-medical services for transgender, genderqueer, and non-binary people, including changing one's hair or clothing, hormone therapy, and gender-affirming surgery.[1] For example, masculinizing hormone therapy for transgender people includes taking testosterone, which can suppress menstruation, decrease estrogen production, deepen voices, and stimulate facial and hair growth.[2] Moreover, gender-affirming hormone therapy is safe, effective, medically necessary, and critical to the health and well-being of transgender people. Leading professional medical organizations have endorsed

[1] Office of Population Affairs, *Gender- Affirming Care and Young People*, U.S. Department of Health and Human Services (Mar. 2022), https://opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf.

[2] *Masculinizing Hormone Therapy*, Mayo Clinic (July 21, 2021), https://www.mayoclinic.org/tests-procedures/masculinizing-hormone-therapy/about/pac-20385099; *Masculinizing Hormone Therapy*, Cleveland Clinic (Feb. 3, 2022), https://my.clevelandclinic.org/health/treatments/22322-masculinizing-hormone-therapy.

gender-affirming hormone therapy, including the Endocrine Society,[3] the American Medical Association,[4] and the American Association of Family Physicians.[5]

Testosterone's status as a Schedule III substance limits access to this important care for transgender people. The Controlled Substances Act of 1970 (CSA) classifies drugs, substances, and chemicals by their accepted medical use and dependency potential, imposing varying criminal penalties for illicit production, possession, or distribution of scheduled substances.[6] Testosterone is currently a Schedule III substance, a class defined as having "a potential for abuse less than substances in Schedule I or II and abuse may lead to moderate or low physical dependence or high psychological dependence."[7]

Congress added testosterone to the CSA through the Anabolic Steroids Control Act of 1990 in response to concerns about the use of testosterone and other steroids by amateur and professional athletes. At the time, the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and the National Institute on Drug Abuse provided testimony to Congress objecting to the measure on the grounds that testosterone did not have the abuse potential to necessitate additional controls on the drug under the CSA.[8] The American Medical Association also opposed the measure, arguing that testosterone and other steroids did not meet the standards for physical or psychological dependence under the CSA. Congressional efforts to address the non-medical use of testosterone by athletes thirty years ago has inadvertently created barriers to medically necessary gender-affirming care today.

Testosterone's Schedule III status means the hormone is subject to restrictions on the length, quantity, and method of prescription. Prescriptions for Schedule III and Schedule IV substances cannot be filled or refilled six months after the prescription was issued, or be refilled more than five times.[9] On top of these requirements, states and private health insurers may impose further restrictions, such as 30-day limitations on controlled substances or limitations on mail delivery of

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[3] *Advocacy to Protect Access to Gender Affirming Care*, Endocrine Society (June 7, 2022), https://www.endocrine.org/advocacy/accomplishments-and-champions/access-to-gender-affirming-care.
[4] *Advocating for the LGBTQ Community*, American Medical Association, https://www.ama-assn.org/delivering-care/population-care/advocating-lgbtq-community.
[5] *Care for the Transgender and Gender Nonbinary Patient*, American Academy of Family Physicians (2022), https://www.aafp.org/about/policies/all/transgender-nonbinary.html.
[6] Joanna Lampe, *The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress*, Congressional Research Service (Feb. 5, 2021), https://www.everycrsreport.com/files/2021-02-05_R45948_947eb3c52b068a17dc7c223301e9d048aef26164.pdf.
[7] *Controlled Substance Schedules*, U.S. Dep't of Justice, Drug Enforcement Administration, Diversion Control Division (Apr. 29, 2022), https://www.deadiversion.usdoj.gov/schedules/.
[8] Rick Collins, *Changing the Game: The Congressional Response to Sports Doping via the Anabolic Steroid Control Act*, 40 NEW ENG. L. REV. 753 (2005), https://heinonline.org/HOL/P?h=hein.journals/newlr40&i=771.
[9] 21 CFR § 1306.22.

prescriptions.[10] These limitations force transgender people to interact more frequently with medical providers and pharmacists, potentially resulting in exposure to unnecessary stigma and negative experiences. One-third to one-half of transgender people report verbal harassment, physical abuse, denial of care, and having to educate their provider about transgender people in order to receive appropriate care.[11] These negative experiences lead transgender people to avoid interacting with medical providers, and therefore limit their access to gender-affirming care, including testosterone.[12]

Limitations on which health providers are able to prescribe and administer testosterone exacerbate these negative experiences, reducing the number of trans-friendly providers available. Medical providers must register with the DEA before they can prescribe, dispense, or administer controlled substances, such as testosterone.[13] Physicians who do not prescribe or administer controlled substances do not have to register, and some choose not to register knowing they will not be prescribing common controlled substances, such as opioids. Another reason that medical providers may choose to forgo registering is the fee — almost $900 per physician for a three-year period.[14] This creates a financial barrier to doctors providing gender-affirming care, especially those in smaller clinics and those working in underserved communities.[15] Descheduling testosterone would remove the DEA-registration barrier for physicians and would allow more of them to prescribe testosterone.

Requirements for in-person consultations further limit access to controlled substances, including testosterone. Prior to the COVID-19 pandemic, prescriptions for controlled substances, including prescriptions through telemedicine, required an in-person medical evaluation.[16] The COVID-19 public health emergency showed that these requirements were not always necessary. With the declaration of the public health emergency on January 31, 2020 and the designation of

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[10] Skyler Rosellini & Abigail Coursolle, *Increasing Access to Testosterone to improve the lives of Transmasculine People*, National Health Law Program (Nov. 29, 2021), https://healthlaw.org/increasing-access-to-testosterone-to-improve-the-lives-of-transmasculine-people/.

[11] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf; Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities*, Center for American Progress (Aug. 18, 2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/.

[12] Jo Yurcaba, *Nearly half of trans people have been mistreated by medical providers, report finds*, NBC News (Aug. 19, 2021), https://www.nbcnews.com/nbc-out/out-health-and-wellness/nearly-half-trans-people-mistreated-medical-providers-report-finds-rcna1695.

[13] 21 CFR § 1301.13.

[14] Sophia Khawly, *What is a DEA License?*, Barton Associates, (July 29, 2021), https://www.bartonassociates.com/blog/what-is-a-dea-license.

[15] *DEA hikes registration fees for controlled substance prescriptions*, American Medical News (Apr. 9, 2012), https://amednews.com/article/20120409/business/304099974/6/.

[16] COVID-19 Information Page, U.S. Dep't of Justice, Drug Enforcement Administration, Diversion Control Division, https://www.deadiversion.usdoj.gov/coronavirus.html.

telemedicine allowance for Schedule II-to-V controlled substances on March 16, 2020, transgender people have been able to access testosterone through telemedicine for the past two years.[17] Early studies have already demonstrated the positive impact that this has had on their ability to access trans-friendly providers and testosterone prescriptions, especially for transgender people living in rural areas or far from a trans-friendly medical provider.[18] Rescheduling or descheduling testosterone would exempt testosterone from in-person visitation requirements when the public health emergency is eventually lifted, ensuring that this heightened access remains available for all transgender Americans.

Placing testosterone on Schedule III has not only contributed to delayed medical care, but has played a role in the criminalization, discrimination, and harassment of transgender people. For example, transgender people may be surveilled and "outed" as a result of their testosterone prescription and use. Prescription Drug Monitoring Programs (PDMP) are state-level, electronic databases for tracking controlled substances; they give health providers and pharmacists a patient's prescription history.[19] Although PDMPs' primary objective is to identify and reduce diversions of prescription drugs such as opioids, other controlled substances, including testosterone, are also monitored on these databases.[20] Transgender people have expressed concern about being included in these databases, for fear of being outed to their health care providers, pharmacists, family members, and other people and agencies with access to these lists.[21]

States must enter prescriptions into the PDMPs, but they have flexibility to define covered substances and specify the information that physicians must provide about a prescription. Reclassifying testosterone as a Schedule V drug would remove it from a dozen states' PDMPs

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[17] *Id.*
[18] Chris Grasso et al., *Gender-Affirming Care Without Walls: Utilization of Telehealth Services by Transgender and Gender Diverse People at a Federally Qualified Health Center*, 7 Transgender Health 2 (Apr. 11, 2022), https://www.liebertpub.com/doi/full/10.1089/trgh.2020.0155; Li Lock et al., *Transgender Care and the COVID-19 Pandemic: Exploring the Initiation and Continuation of Transgender Care In-Person and Through Telehealth*, 7 Transgender Health 2 (Apr. 11, 2022), https://www.liebertpub.com/doi/10.1089/trgh.2020.0161.
[19] *Prescription Drug Monitoring Programs (PDMPs)*, Centers for Disease Control and Prevention (May 19, 2021), https://www.cdc.gov/drugoverdose/pdmp/index.html.
[20] Skailer R. Qvistgaard, *Testosterone and Transgender Men: The Discriminatory Impact of Testosterone's Schedule III Designation on Transgender Men Seeking Medical Care*, 13 J. Health & Biomedical L. 289, 306 (2018), https://cpb-us-e1.wpmucdn.com/sites.suffolk.edu/dist/e/1232/files/2016/12/TESTOSTERONE-AND-TRANSGENDER-MEN.pdf; Adryan Corcione, *How the Criminalization of Testosterone Attacks Gender Variant People*, Filter Magazine (Dec. 2, 2021), https://filtermag.org/testosterone-criminalization/; Sessi Kuwabara Blanchard, *DEA Wants to Surveil Patients. Trans Men Stopped Them Once Before*, Filter Magazine (Nov. 16, 2020), https://filtermag.org/dea-surveillance-trans-men/.
[21] Adryan Corcione, *How the Criminalization of Testosterone Attacks Gender Variant People*, Filter Magazine (Dec. 2, 2021), https://filtermag.org/testosterone-criminalization/.

that require reporting only of Class I through Class IV substances; [22] declassifying it altogether would take it outside the PDMP system. The Administration can therefore reduce the likelihood of criminalization, surveillance, and the forced outing of transgender people through rescheduling or descheduling testosterone.

Testosterone's inaccessibility and criminalization may also drive illicit use by the transgender community, which has health risks.[23]A 2020 study found that nearly 10 percent of transgender adults used nonprescription hormones.[24] Transgender people's use of nonprescription hormones such as testosterone presents health risks caused by using them without medical supervision or monitoring; taking the wrong dose or type of hormone therapy; and relying on unregulated medicines or components, including those of inferior quality.[25] And because testosterone is so tightly regulated, transgender Americans may turn to online pharmacies, including in countries such as India, Russia, and Pakistan, which lack the same safety standards as the FDA and U.S. government.[26] The current scheduling of testosterone as a Schedule III substance is driving patients to endanger their health and safety to get the care they need if they cannot find it close to home.

For all these reasons, I am asking if HHS, DOJ, or the DEA have explored, or will begin to explore, using their respective authority under the CSA to file and review a petition to reschedule testosterone from Schedule III to Schedule V.[27] Additionally, I call on the Attorney General to use the information provided by HHS on the safety of testosterone to consider adjusting testosterone's status on the CSA, or removing it altogether. The Attorney General has the authority to "add to such a schedule or transfer between such schedules any drug or other

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[22] *See, e.g.*, *Arizona Guidelines for Dispensing Controlled Substances*, Arizona Dep't of Health Services, (2013), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/dispensing-controlled-substances.pdf (requiring PDMP checks in Arizona for Schedule II and III substances); *Oregon PDMP v. DEA*, 998 F.Supp.2d 957, 960 (D.Or. 2014) (explaining that Oregon law requires reporting to its PDMP information on prescriptions for Schedule II, III, and IV substances).

[23] Gillian Branstetter, *Sketchy Pharmacies Are Selling Hormones to Transgender People*, The Atlantic (Aug. 31, 2016), https://www.theatlantic.com/health/archive/2016/08/diy-hormone-replacement-therapy/498044/.

[24] Daphna Stroumsa et al., *Insurance Coverage and Use of Hormones Among Transgender Respondents to a National Survey*, 18 The Annals of Family Medicine 6 (2020), https://www.annfammed.org/content/18/6/528.

[25] *Id.*

[26] Gillian Branstetter, *Sketchy Pharmacies Are Selling Hormones to Transgender People*, The Atlantic (Aug. 31, 2016), https://www.theatlantic.com/health/archive/2016/08/diy-hormone-replacement-therapy/498044/.

[27] John Hudak & Grace Wallack, *How to reschedule marijuana, and why it's unlikely anytime soon*, Brookings Institution (Feb. 13, 2015), https://www.brookings.edu/blog/fixgov/2015/02/13/how-to-reschedule-marijuana-and-why-its-unlikely-anytime-soon/.

substance" or "remove any drug or substance from the schedules if he finds that the drug or substance does not meet the requirements for inclusion in any schedule."[28]

Rescheduling or descheduling testosterone would further the goals and policies already announced by the White House and HHS. I applaud the Administration's ongoing efforts to support the transgender community's access to health, including strengthening Section 1557 non-discrimination rule-making[29] and working with states on expanding access to gender-affirming care. The June 15 Executive Order on Advancing LGBTQ Equality calls on HHS to "promote expanded access to comprehensive health care,"[30] and I believe that descheduling or rescheduling testosterone is an important and necessary step to expand access to gender-affirming, life-saving care.

In response to the issues raised in this letter, I respectfully request that DOJ and HHS respond in writing and with a staff-level briefing to the following questions by October 7, 2022.

1. What steps, if any, have the DOJ, HHS, or DEA taken to begin reconsideration of testosterone's Schedule III status?
    a. Has DOJ, HHS, or DEA met with any representatives of the transgender community about testosterone access issues related to its Schedule III status? If so, who and when? If not, why not?
    b. Has DOJ, HHS, or DEA met with any representatives of the medical community, about testosterone access issues related to its Schedule III status? If so, who and when? If not, why not?
2. What consideration has the Administration given to rescheduling or descheduling testosterone as part of its efforts to promote LGBTQ equality as reflected in the June 15 Executive Order?
    a. If the Administration has not already considered rescheduling or descheduling testosterone, will it now include testosterone access in future considerations and recommendations? If not, why not?
3. Has the DEA taken any steps to protect the health, safety, and privacy of transgender men whose prescriptions for testosterone are reported to a PDMP? If so, what steps has DEA taken? If not, why not?

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[28] 21 U.S.C. 811.
[29] Katie Keith, *HHS Proposes Revised ACA Anti-Discrimination Rule*, HealthAffairs (July 27, 2022), https://www.healthaffairs.org/content/forefront/hhs-proposes-revised-aca-anti-discrimination-rule#:~:text=Section%201557%20prohibits%20discrimination%20on,Obama%2Dera%20regulation%20from%202016.
[30] *Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals*, The White House (June 15, 2022), https://www.whitehouse.gov/briefing-room/presidential-actions/2022/06/15/executive-order-on-advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals/.

Thank you in advance for your consideration of this matter. If you have any questions, please contact Sedef Berk in Senator Markey's office at Sedef_Berk@markey.senate.gov.

Sincerely,

Edward J. Markey
United States Senator

Elizabeth Warren
United States Senator