No. 20-1374

# In The
# Supreme Court of the United States

CVS PHARMACY, INC., et al.,

*Petitioners,*

v.

JOHN DOE, ONE, et al., on behalf of themselves and all others similarly situated,

*Respondents.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit**

## BRIEF OF AMICI CURIAE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL, ET AL. IN SUPPORT OF RESPONDENTS

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## INTEREST OF AMICI CURIAE[1]

Amici are the Center for Health Law and Policy Innovation of Harvard Law School; ADAP Educational Initiative Columbus, OH; AIDS Action Baltimore; AIDS Alabama; AIDS Foundation Chicago (AFC); AIDS Law Project of Pennsylvania; American Academy of HIV Medicine; American Medical Association; APLA Health; Equitas Health; Fenway Health; HIV Medicine Association; Human Rights Campaign; International Association of Providers of AIDS Care; Legacy Health; North Carolina AIDS Action Network; Prism Health North Texas; San Francisco AIDS Foundation; SisterLove, Inc.; The AIDS Institute; Treatment Action Group; Whitman-Walker Health; Whitman-Walker Institute; and Vivent Health.

The Center for Health Law and Policy Innovation of Harvard Law School advocates for legal, regulatory, and policy reform to improve the health of underserved populations, with a focus on the needs of low-income people living with HIV and other chronic illnesses and disabilities. All Amici promote access to health care and services for people living with HIV. Amici engage in a broad range of activities, including public education, policy advocacy, community-building, research, health care, and law. Amici include health care systems

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[1] Amici submit this brief pursuant to Supreme Court Rule 37.3(a). Both parties have provided written consent to the filing of this amicus curiae brief. In compliance with Supreme Court Rule 37.6, Amici state that no counsel for a party authored this brief in whole or in part and that no person or entity other than Amici, its members, and its counsel contributed monetarily to the preparation or submission of this brief.

dedicated to serving people living with or affected by HIV and professional associations that support practitioners who engage in HIV prevention, care, and research. Amici also include organizations that provide services such as housing, mental health treatment, preventive care, and sexual health and substance use services.

Amici each have an extensive history advocating for people living with HIV, and, as such, are uniquely positioned to provide insight on the importance of private, timely, and safe access to HIV prescription drugs and pharmacy services, and the harm that mail-order mandates can have on people living with HIV.

## SUMMARY OF ARGUMENT

People living with HIV have historically faced many barriers when accessing prescription drugs, resulting in a range of harmful impacts. Affordable, predictable, and effective access to prescription drugs is essential for the health and well-being of people living with HIV. Mail-order requirements in health insurance programs are not appropriate for people living with HIV. Mail-order programs can present significant privacy, timeliness, and safety concerns and can undermine the ability for people living with HIV to use the health insurance benefits necessary to maintain healthy lives. The Court should uphold the judgment of the Ninth Circuit Court of Appeals.

## ARGUMENT

An estimated 1.2 million people in the United States live with HIV. HHS, *U.S. Statistics* (last updated June 2, 2021), https://perma.cc/PHS5-RCXY. Over the last quarter century, advances in science, health care delivery systems, and community advocacy have transformed HIV prognoses. With steady access to antiretroviral therapy (a structured regimen of HIV prescription drugs) and certain health indicators, people living with HIV can have a longer life expectancy than those a decade earlier.[2] Antiretroviral therapy is thus considered the core component of modern HIV treatment.

People living with HIV need certainty that they can receive their medications in a private, timely, and safe manner. Policies—such as those at issue in this case—requiring mail delivery or restricting pharmacy pick-up in order to qualify for in-network pricing unduly limit access to necessary care; the out-of-network cost of these medications is so high that it creates a *de facto* mandate for people living with HIV to receive their drugs through the mail.[3] While some people may

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[2] Julia L. Marcus, Harvard Medical School, Oral Abstract at the Conference on Retroviruses and Opportunistic Infections: Increased Overall Life Expectancy But Not Comorbidity-Free Years for People Living with HIV (March 11, 2020), https://perma.cc/J98A-4R3S. Antiretroviral therapy typically involves the oral ingestion of one or more pills on a daily basis and is recommended as a long-term treatment for HIV.

[3] For example, as noted in Respondents' amended complaint, "JOHN DOE ONE called CVS Caremark and spoke to a CVS Caremark representative, who informed him that he must obtain

be able to use, or even prefer, mail-order pharmacy programs, these programs present major obstacles that compromise privacy, timeliness, and safety, and should not be mandated for people who rely on HIV drugs.

## I. Timely access to affordable prescription drugs is critical for the health and wellness of people living with HIV.

### A. Antiretroviral therapy reduces morbidity and mortality among people living with HIV and can prevent or reduce transmission.

All people living with HIV are recommended to take antiretroviral therapy to lower the amount of plasma HIV-1 RNA in their bodies. HHS, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV*, https://perma.cc/KY55-YLYR (*National HIV Guidelines*). When the amount of plasma HIV-1 RNA, also known as "viral load," is kept below certain limits regularly, positive health outcomes typically result, including a stronger immune system, a lower risk of serious AIDS-related and non-AIDS-related health events, and increased life expectancy.[4]

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his prescriptions under the Program or pay full-price for his medications. A month's supply of his HIV/AIDS Medication costs more than $2,000." Pl.'s Am. Compl. at 8, *Doe v. CVS*, 348 F. Supp. 3d 967, No. 18-cv-01031-EMC (N.D. Cal. 2018).

[4] *National HIV Guidelines* at E-1. Initiation of antiretroviral therapy can also improve immune function for patients with acute, AIDS-associated opportunistic infections and studies have shown that immediate initiation of antiretroviral therapy

Timely, regular antiretroviral treatment can help many people living with HIV achieve undetectable viral loads (when the amount of HIV in the blood is too low to be detected by lab tests).[5] When a person maintains an undetectable viral load, they have "effectively no risk of sexually transmitting HIV to HIV-negative partners." Centers for Disease Control and Prevention (CDC), *HIV Treatment as Prevention*, https://perma.cc/PQ3F-24BH; *see generally* Prevention Access Campaign, https://perma.cc/JR2Z-E9FU. Undetectable viral loads also reduce the risk of HIV transmission through pregnancy, labor, and delivery to 1% or less, making timely initiation of antiretroviral therapy particularly important for people who are pregnant.[6] Maintaining regular access to antiretroviral treatment thus has beneficial implications for both individuals and public health more broadly.

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significantly lowers the risk of serious AIDS-related events such as tuberculosis, Kaposi's sarcoma, and malignant lymphomas. *National HIV Guidelines* at E-3; INSIGHT START Study Group, Jens D. Lundgren et al., *Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection*, 373 N. Engl. J. Med. 795 (Aug. 27, 2015).

[5] *Undetectable Viral Load*, HHS, HIV/AIDS Glossary, https://perma.cc/9U24-V5K9.

[6] CDC, *HIV Treatment as Prevention*, https://perma.cc/PQ3F-24BH. Because antiretroviral therapy significantly reduces the risk of HIV transmission from mother to infant, Amicus American Medical Association (AMA) recommends HIV testing as part of routine perinatal care and education for pregnant people living with HIV. *Maternal HIV Screening and Treatment to Reduce the Risk of Perinatal HIV Transmission H-20.918*, AMA PolicyFinder (2020), https://perma.cc/QTV9-MC6C?type=image.

### B. Federal and provider guidelines, along with public health strategies to end the HIV epidemic, support rapid initiation of antiretroviral therapy.

Because antiretroviral therapy can have a positive impact on health outcomes for people living with HIV, guidelines developed by HHS' Office of AIDS Research Advisory Council (National HIV Guidelines) recommend that people initiate antiretroviral therapy "as soon as possible after HIV diagnosis." *National HIV Guidelines* at E-2. Designed to guide practitioners on the treatment of people living with HIV, National HIV Guidelines have even been modified to remove outdated recommendations that delayed treatment, such as an older instruction to withhold the initiation of drug therapy until a person's CD4 count fell below a certain threshold.[7] Studies outside of the

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[7] *National HIV Guidelines* at A-2, E-4–E-5. The National HIV Guidelines are often referred to as a resource by practitioner organizations and associations, including Amicus American Academy of HIV Medicine, and mirror other guidance and protocols issued by these groups. *See*, *e.g.*, American Academy of HIV Medicine, *HIV Treatment Guidelines*, https://perma.cc/MND5-6VC2; Melanie Thompson et al., *Primary Care Guidance for Persons With Human Immunodeficiency Virus: 2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America*, Clinical Infectious Diseases 1, 3 (2020) ("With few exceptions . . . , there is no reason to delay initiation of [antiretroviral therapy] among newly diagnosed or [treatment-naïve] populations who desire therapy. Ideally, patients should be initiated on ART on the day of diagnosis or as soon thereafter as feasible."); International Advisory Panel on HIV Care Continuum Optimization, *IAPAC Guidelines for Optimizing the HIV Care Continuum for Adults and Adolescents*, J. Int'l Ass'n Providers AIDS Care 1, 9 (2015) ("Recommendation 18: The immediate

United States also "suggest that same-day initiation of [antiretroviral therapy] . . . could potentially improve clinical outcomes" compared with initiation of treatment weeks after diagnosis. *Id.* at E-3.

While providers may opt to delay antiretroviral therapy in certain situations (e.g., when a patient needs immediate treatment for another condition), providers will generally weigh the benefits of treating other conditions against the impact of delaying antiretroviral therapy (e.g., their patient experiencing a "worsened immunocompromised state").[8] In fact, the National HIV Guidelines state that the presence of many opportunistic infections and other conditions should *not* delay or impact the initiation of antiretroviral therapy.[9] The improved immune response that results from antiretroviral therapy can be critical for addressing opportunistic infections, including when no effective treatment exists. *National HIV Guidelines* at E-3.

The link between undetectable viral loads and decreased transmission has made early access to

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offer of ART after HIV diagnosis, irrespective of CD4 count or clinical stage, is recommended.").

[8] CDC, *AIDS and Opportunistic Infections*, https://perma.cc/NRU5-XAJL; HHS, *Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV* K-5, https://perma.cc/U3TD-2CB3.

[9] *See*, *e.g.*, *National HIV Guidelines* at D-3 (mucocutaneous candidiasis), *F-4* (coccidioidomycosis), G-10 (bacterial pneumonia), N-3 (orolabial and genital herpes simplex virus), *Mycobacterium avium* complex disease (HPV-related oral, anal, or genital disease), U-3 (Mycobacterium avium Complex Disease), Y-5 (syphilis).

antiretroviral therapy a key pillar of efforts to end the HIV epidemic. Chief among such campaigns are the federal government's initiative, Ending the HIV Epidemic in the United States, and the World Health Organization's (WHO) Consolidated HIV Strategic Guidelines. CDC, *Ending the HIV Epidemic in the United States (E.H.E.)*, https://perma.cc/7GQ2-KALN (stating the CDC "[c]ollaborates with partners and providers so people who receive a positive HIV test result are quickly linked to care and receive treatment as soon as possible after diagnosis"); WHO, *Consolidated HIV Strategic Information Guidelines* 96, https://perma.cc/E62Q-9WLF ("In the era of 'Treat All', all people diagnosed as living with HIV should be rapidly initiated on treatment to optimize treatment outcomes and prevent new infections."). Prominent medical associations and advocacy coalitions have also opposed policies that unduly delay patient access to medication. Amicus American Medical Association (AMA), for example, supports access to needed medications and opposes "pharmacy practices that interfere with patient access to medications by refusing or discouraging legitimate requests to transfer prescriptions to a new pharmacy" including the "transfer of prescriptions from mail-order to local retail pharmacies." AMA, *Access to Medication H-120.920*, https://perma.cc/4HFT-3YU3?type=image. *See also* American Academy of HIV Medicine, Public Policy Platform 12, https://perma.cc/YZ6W-HJW6 ("We [] oppose forced participation in mail-order pharmacies for HIV-infected patients. Mail order pharmacies can . . . create problems for patients in terms of access to medications,

patient adherence, and patient privacy[.]"); AIDS United & ACT NOW: END AIDS, *Ending the HIV Epidemic in the United States: A Roadmap for Federal Action* (2018).

### C. Drug resistance can develop when access to antiretroviral therapy is interrupted, making timely and consistent access to antiretroviral therapy essential.

As the availability of life-saving antiretroviral therapy has increased over the past decade, so too has the prevalence of HIV drug resistance. WHO, *HIV Drug Resistance* (Nov. 18, 2020), https://perma.cc/YYF5-TLVD (*WHO Drug Resistance*). HIV drug resistance is caused by genetic mutations that "affect the ability of drugs to block the replication of the virus." *Id.* Resistance can be transmitted (through a strain of HIV that is already resistant to certain drugs) or acquired (through mutations that occur while someone is taking HIV drugs). Warren Tong, *Here's what you need to know about HIV drug resistance* (Dec. 4, 2017), https://perma.cc/E6W4-NQQ6. Acquired resistance is particularly a concern when treatment is not effective (e.g., when a drug is not absorbed well into the body) or consistent (e.g., when a person is not able to regularly follow their prescribed treatment regimen). *Id.*; *see also* Lance S. Rintamaki et al., *Social Stigma Concerns and HIV Medication Adherence*, 20 AIDS Patient Care & STDs 359, 359 (2006) ("[I]n order for [HIV] medications to work effectively, they must be adhered to with little or no deviation from prescribed regimens.").

When someone living with HIV starts to become resistant to a drug in their prescribed regimen, continuing to take that drug will exacerbate the problem. "If the resistant virus makes enough copies of itself, it may eventually become the dominant type of HIV in the body. Once this happens, the medication is ineffective, and the patient will become resistant to the specific medication." Stanford Health Care, *HIV Drug Resistance Testing*, https://perma.cc/MT8W-TV6P. The WHO has warned that "[i]f not prevented, HIV drug resistance can jeopardize the efficacy of antiretroviral drugs, resulting in increased numbers of HIV infections and HIV-associated morbidity and mortality." *WHO Drug Resistance*. Thus, it is essential for anyone who develops resistance to a drug in their prescribed antiretroviral regimen to switch to an appropriate alternative as soon as possible.

To help mitigate the risk of drug resistance, the standard recommendation for most adults who begin antiretroviral therapy is to perform drug resistance testing to determine which regimen is appropriate and to reduce the risk of drug-resistant strains of HIV. *National HIV Guidelines* at C-12–C-18. When too much time elapses between resistance testing and initiation of antiretroviral therapy, providers may need to re-test for resistance due to newly-acquired drug-resistant viral strains. *Id.* at C-15. In many cases, however, providers will opt to start treatment and conduct resistance testing concurrently. *Id.* at C-17 ("In Acute or Recent (Early) HIV Infection: . . . Treatment should not be delayed while awaiting results of resistance testing[.]")

("For pregnant persons, or if [antiretroviral therapy] will be initiated on the day of or soon after HIV diagnosis, treatment can be initiated prior to receiving resistance testing results."). In these situations, providers and patients need timely access to medications so that treatment regimens can be quickly modified upon receiving resistance testing results.

## II. Mandates requiring people living with HIV to obtain critical drugs only through mail-order pharmacy programs negatively impact access to necessary, life-saving medication.

### A. Privacy concerns impact adherence to HIV treatment regimens.

People living with HIV face stigmatization and discrimination due to their HIV diagnosis. *See*, *e.g.*, Susan Reif et al., *Perceptions and Impact of HIV Stigma among High Risk Populations in the US Deep South*, 4 J. HIV & AIDS 1, 3 (2018). They can face stigma, discrimination, and violence when their HIV diagnoses are disclosed to people who reveal their private medical information. *Id.* ("Public shaming on Facebook and other social media was also described, particularly instances when social media was used to disclose an individual's status without their consent, often by posting pictures of HIV medication bottles.") Furthermore, disclosure of HIV status could inherently disclose information about a person's sexual activity, sexual orientation, or drug use, which carries additional stigma and risk of discrimination and violence.

For this reason, many people living with HIV have significant concerns about the privacy of their diagnosis and the ability for mail-order pharmacy mandates to protect important medical information.[10]

Unfortunately, mail delivery services have been a source of privacy violations. In 2018, CVS Caremark was sued for sending mailers to 6,000 participants in Ohio's AIDS Drug Assistance Program. Marty Schladen, *State health department, CVS sued over HIV mailing*, The Columbus Dispatch, June 29, 2018, https://perma.cc/FHD9-H249. The mailers included a public notation of "PM 6402 HIV" above the participants' names and addresses, disclosing their HIV status (a pre-requisite for the prescription assistance program) to the general public. *Id.*; *see also Doe v. Caremark*, 348 F. Supp. 3d 724, 730 (S.D. Ohio 2018) ("A reasonable person seeing this envelope with the letter in it, or even seeing a mock-up of the letter with the code directly above the name . . . would conclude that the recipient was HIV-positive.").

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[10] These concerns can decrease adherence to treatment regimens and worsen health outcomes. *See* Tonia Poteat & Linda Wesp, *The HIV Care Provider's Role in Reducing Stigma*, HIV Specialist 6, 8 (June 2019), https://perma.cc/67C6-PCMJ (noting several studies found that "HIV-related stigma was associated with poorer mental health, including depression; lower quality of life, lower levels of social support; and poorer self-rated general health.").

### B. Mandated use of mail-order pharmacy programs can present processing and delivery issues that disrupt access to critical treatment and services for people living with HIV.

#### i. Mail-order pharmacy programs have delayed timeliness of treatment initiation for people living with chronic conditions.

Mail-order pharmacy programs can delay treatment initiation due to the need for programs to receive, process, approve, and mail the requested drugs. These delays have been reported by people with a variety of chronic conditions, frustrated by mail-order requirements foreclosing access through a nearby brick-and-mortar pharmacy. For example, Elvin Weir, battling a quick-spreading colorectal cancer, faced a two-week delay while his mail-order pharmacy mailed him chemotherapy pills. Marty Schladen & Catherine Candisky, '*Pharmacy benefit manager' system keeps meds from cancer patients*, The Columbus Dispatch, June 3, 2018, https://perma.cc/6QHY-P8K4. These chemotherapy pills were already available at a local cancer treatment facility's in-house pharmacy, but not accessible due to mail-order requirements.

### ii. Mail delivery systems have also delayed access to treatment for people living with chronic conditions.

Mandated mail-order pharmacies can also delay access to prescription drugs due to the mail delivery system used to transport the medication, such as the United States Postal Service (USPS). Recent delays in the USPS highlighted the broad impact that mail delivery systems can have in delaying access to medication. During the summer of 2020, when many packages were experiencing significant delays, senators reported constituents were rationing or skipping doses of prescription drugs in order to bridge the gap between their current supply of medication and incoming but delayed packages. *Examining the Finances and Operations of the United States Postal Service During COVID-19 and Upcoming Elections Before S. Comm. on Homeland Sec. & Governmental Aff.*, 116th Cong. (Aug. 21, 2020) (*USPS Hearing*). The impact of mail delays was particularly significant for veterans, many of whom obtain maintenance drugs through mail-order pharmacies. *Id*. Recent updates to USPS delivery expectations suggest that certain first-class deliveries may now take longer, particularly for mail that travels farther distances or that is delivered to certain areas.[11]

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[11] USPS, *Service Alerts*, https://perma.cc/582C-GCED; Jacob Bogage & Kevin Schaul, *DeJoy's USPS slowdown plan will delay the mail. What's it mean for your Zip code?*, The Washington Post, updated Sept. 30, 2021, https://perma.cc/M8PA-6KQD (explaining that 70% of first-class mail sent to Nevada, 60% to Florida,

The delays in the USPS are but one example of how mail delivery systems can impact the accessibility of prescription drugs. Once a package is mailed out from the specialty pharmacy, people reliant on these medications are vulnerable to general postal delivery issues. For example, Zach Matheny, who relied on mail-order delivery for blood thinning medication, never received a delivery of his prescription and was unable to track where his medications were in the USPS system. Paige Pfleger, *Postal Service Slowdowns Cause Dangerous Delays in Medication Delivery*, NPR, Aug. 25, 2020, https://perma.cc/ER99XHBS. Matheny was unable to order another refill from his insurance company and instead bought single pills out-of-pocket and skipped doses to bridge the gap until his next month's prescription drug supply was available. Similar tactics are not always feasible for people living with HIV due to the high list price of antiretroviral therapy and the danger of drug resistance, explained *infra*.

#### iii. Delays in accessing medications are particularly harmful for people living with HIV.

For people living with HIV, timely treatment initiation is of the utmost importance. Once initiated, treatment must be "continued indefinitely without interruption." *National HIV Guidelines* at E-2. In particular, for pregnant people with HIV and people with

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58% to Washington, 57% to Montana, and 55% to Arizona and Oregon would "arrive more slowly under the new standards").

acute or recent HIV infection, it is the standard of care for antiretroviral therapy to begin as soon after diagnosis as possible. *Id*. All newborns born from people living with HIV are also recommended to start a three-drug antiretroviral regimen immediately, even before receiving a diagnosis.[12] This recommended regimen has a prophylactic purpose and can protect newborns from acquiring HIV from exposure *in utero*, during the birthing process, or during breastfeeding. For newborns who do acquire HIV, immediate treatment is essential and can lead to better health outcomes than for babies whose treatment is delayed.[13] For anyone who needs to initiate antiretroviral therapy immediately, delays due to mail-order pharmacy processing requirements and mail delivery can result in further weakened immune systems and increased risk of transmission. *National HIV Guidelines* at E-2.

Delays in mail-order processing and delivery can also disrupt timely modification of treatment regimens, if modification becomes necessary due to resistance testing. As discussed, *supra*, some people living with HIV may develop resistance to their

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[12] HHS, *Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States* 22, https://perma.cc/8LYH-CNWS.

[13] *Id.* At least one study has shown that newborns with HIV who began treatment immediately had better outcomes than newborns who began treatment slightly later in life. Gueorgui Dubrocq & Natella Rakhmanina, *Antiretroviral Therapy Interruptions: Impact on HIV Treatment and Transmission*, 10 HIV/AIDS—Research and Palliative Care 91, 98 (2018).

prescribed antiretroviral therapy or may discover they are resistant after initiating treatment. *National HIV Guidelines* at C-12. As a result, some people will need to switch to a new treatment regimen in a timely manner; delays due to processing and delivery can threaten health outcomes.[14]

In addition, processing and delivery delays can also *cause* drug resistance when these delays create unplanned treatment interruptions for people whose medication would otherwise have remained effective. *WHO Drug Resistance* ("A continuous supply of antiretroviral drugs is essential to avoid treatment interruption and prevent the emergence and spread of HIV drug resistance."). When antiretroviral therapy is successful, it results in an undetectable viral load. But depending on the prescribed regimen, when a person who already achieved an undetectable viral load loses access to their medication and stops treatment, viral

[14] The possibility of drug resistance particularly affects people living with HIV who are pregnant, because resistance can severely "limit options for therapy during pregnancy and potentially complicate obstetrical care for HIV-infected women." Gweneth B. Lazenby et al., *Antiretroviral Resistance and Pregnancy Characteristics of Women with Perinatal and Nonperinatal HIV Infection*, Infectious Diseases in Obstetrics and Gynecology 1, 2 (2016). In particular, people living with perinatal HIV are more likely to develop antiretroviral resistance. *Id.* When people living with perinatal HIV become pregnant, they may need therapies "which are less well studied in pregnancy and may have unknown toxicities," which can lead to further complications. *Id.* For people in this situation, immediate access to their newly-prescribed drug regimen is essential, because continuing to take currently-prescribed drugs may increase resistance and impact future care.

rebound may occur "within days to weeks after [antiretroviral therapy] cessation and has been observed as early as 3 to 6 days after stopping treatment." *National HIV Guidelines* at F-3. People who do not have undetectable viral loads or who experience viral rebound can also develop resistance to one or more components of their antiretroviral therapy. *Id*. at I-1. When a patient develops resistance to one or more of the drugs they are taking, it can potentially limit future treatment options, further complicating decision making and access to care.[15]

#### iv. Tactics typically used to bridge gaps in medication can have a particularly harmful impact on people living with HIV.

Delays in mail-ordered medication can disrupt a person's ability to keep taking their treatment regimen as prescribed and thus their ability to lower their viral load. People with unreliable access to medication sometimes engage in short-term practices that can have long-term harmful effects, such as taking less than the prescribed dose of their medication, or even skipping doses, in order to preserve the supply on-hand.

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[15] When a person living with HIV develops drug resistance to a particular drug, this can limit the efficacy of other drugs the patient has never taken before, because "the potential exists for cross-resistance among drugs from the same class." *National HIV Guidelines* at I-4. Additionally, drug resistance is "cumulative"; if a mutation has *ever* been detected in a patient's resistance assay, it should be considered present in that patient going forward, even if it does not appear on subsequent assays. *Id.*

*USPS Hearing* at 06:51 (telling the story of a woman with epilepsy who began rationing medication due to postal delays, and suffered seizures serious enough to warrant hospitalization as a result). This type of treatment disruption can particularly affect patients who have concerns about physical access—such as that caused by mail delays or far-away, inaccessible pharmacies—as well as concerns about financial access, or being able to afford the cost of the medication.

In a recent report about common cost-saving strategies for people living with HIV, 7% of participants reported that they sometimes skipped doses, took less than their prescribed daily dose, or delayed filling their prescriptions because they were worried about money. Linda Beer et al., *Nonadherence to Any Prescribed Medication Due to Costs Among Adults with HIV Infection—United States, 2016-17*, CDC Morbidity & Mortality Wkly. Rep. 1129, 1132 (2019). People whose treatment was disrupted in this way were less likely to be virally suppressed, were "more likely to seek care at emergency departments and be hospitalized," and "were nearly twice as likely to not be engaged in HIV medical care, which might contribute to poorer health outcomes." *Id*. "Because of the strong relationship between HIV infection and unsuppressed viral load, nonadherence among persons with HIV infection leads to increased morbidity, mortality, and risk for HIV transmission." *Id.* at 1133.

When mail delivery is unreliable, people living with HIV are sometimes forced to resort to refilling their prescriptions locally, even if these refills are not

covered by their insurance plans. Where they are otherwise subject to mail-order mandates, such people will face higher cost-sharing burdens and may even be forced to shoulder the entire cost out-of-pocket. For those who cannot afford the additional cost of refilling prescriptions out-of-pocket, this could mean being forced to skip treatment altogether. In this way, mail-order mandates contribute to treatment disruption.

For many people living in rural areas, the access problems posed by mail-order mandates are further compounded by an inability to access brick-and-mortar pharmacies that are in the specialty pharmacy network. People with concerns about mail delivery to their home address (e.g., due to privacy concerns) may prefer to have medications shipped to a brick-and-mortar pharmacy instead. Unfortunately, mail-order programs often restrict which brick-and-mortar pharmacies can receive and distribute mail-order deliveries, leaving people in areas that lack access to a specialty network pharmacy (e.g., because an area lacks sufficient access to a CVS retail pharmacy[16]) with no realistic option to safely and timely obtain their prescription drugs.

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[16] While CVS retail stores may be a common sight in some areas of the United States, it is not an accessible option for everyone. For example, a person living in South Dakota has access to just three CVS locations within their home state: one in Rapid City and two in Sioux Falls. *CVS Pharmacy, Store Locator: CVS Pharmacy Stores by State*, https://perma.cc/WZG2-ST96. Other states with low numbers of CVS retail stores include Idaho (four locations); North Dakota (six locations); Montana (fifteen locations); New Mexico (twenty-four locations); and Nebraska (thirty locations). *Id*.

### v. Mail delivery can compromise the integrity of the medication.

Many specialty drugs required to be obtained through mail delivery programs have specific temperature directions listed on their Food & Drug Administration (FDA) labels. *See*, *e.g.*, FDA Drug Label for TIVICAY at 29 (July 9, 2021), https://perma.cc/J3WR-CZFN ("Store at 25°C (77°F); excursions permitted 15° to 30°C (59° to 86°F)"). When the drugs are subject to temperatures outside of the recommended range, the integrity of the drug can be compromised. Mail-order programs have subjected drugs to unsafe temperature either through the delivery process (e.g., at storage facilities) or at the end location (e.g., outside a house in an uncovered area or inside a metal mailbox).[17]

While newer HIV medications have improved stability, drugs are still recommended to be kept within a certain temperature range. For example, the FDA

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[17] *See*, *e.g.*, Karl Fiebelkorn, Letter to the Editor, *Mail Order Medication Delivery can be Complex*, Buffalo News, Jan. 12, 2021, https://perma.cc/KAR9-E7CQ; Adiel Kaplan et al., *Millions of Americans receive drugs by mail. But are they safe?*, NBC, Dec. 8, 2020, https://perma.cc/Y2ZV-ALEL (describing individuals with organ transplants, cystic fibrosis, diabetes, migraines, and oral cancer experiencing temperature-related issues with their mail-ordered medications); Alex Smith, *Extreme Temperatures May Pose Risks to Some Mail-Order Meds*, NPR, Jan. 7, 2019, https://perma.cc/XQ34-VCKX (describing an incident where drugs used to treat a liver transplant were left outside in temperatures above 100 degrees Fahrenheit; the customer later sought a waiver to pick up the medication from a brick-and-mortar pharmacy).

labels for Biktarvy and Triumeq (both key HIV drugs) list an acceptable storage range of 68-77°F with excursions allowed between 59-86°F. FDA Drug Label for BIKTARVY at 39 (Oct. 7, 2021), https://perma.cc/T4QB-A35K; FDA Drug Label for TRIUMEQ at 40 (March 23, 2021), https://perma.cc/YU2L-Z3DX. In February 2021, only 51 counties in the entire country had an average temperature above 59°F. National Oceanic and Atmospheric Administration, *Climate at a Glance: County Mapping*, https://perma.cc/3A7T-RXRC. Test bubble mailers sent by NBC News showed that temperatures within the mailers could easily reach above 104°F or below 32°F, sometimes for hours. Adiel Kaplan et al., *Millions of Americans receive drugs by mail. But are they safe?*, NBC, Dec. 8, 2020, https://perma.cc/Y2ZV-ALEL (noting that four out of five test bubble mailers sent by NBC News experienced temperatures above 104°F; a similar test in the winter showed three out of five were kept below freezing, sometimes for more than 38 hours); *see also* Press Release, American Society of Health-System Pharmacies, *Mail-order Medications Often Exposed to Unsafe Temperatures, Study Shows* (Dec. 9, 2020), https://perma.cc/2TLJ-HHKH (describing a study that found test shipments with temperature data loggers were subject to temperatures outside of the 68-77°F range 68-87% of the delivery time in the winter and 27-54% of the delivery time in the summer). Some people living with HIV may live in areas where packages can be kept within temperature-controlled settings or may have flexibility in their professional lives to work remotely to monitor package delivery. However, others may not

be able to accommodate mail-order programs in this manner and should not be required to rely on mail-order pharmacies for their HIV medications.

### C. Mail-order mandates undermine important relationships with HIV providers and pharmacies that are crucial to effective HIV treatment.

#### i. Mail-order mandates can disrupt the critical physician-pharmacist-patient relationship.

Restricting people to mail-order pharmacies for their HIV drugs removes their current pharmacist, a trusted and vital resource for patients, from the care equation. People living with HIV need the advice and support of their physicians *and* their pharmacists—working in tandem—to maximize their chances of remaining adherent to their course of treatment.[18] Because the consequence of nonadherence is potentially so severe, maximizing patient support during the process of acquiring their needed medication is crucial.

Further complicating the task is the fact that many people living with HIV are prescribed medication for non-HIV related conditions, in addition to

[18] "Pharmacists have long been recognized as essential members of the HIV patient care team, and their involvement in managing HIV-infected patients has been associated with improved outcomes." Jason J. Schafer et al., *ASHP Guidelines on Pharmacist Involvement in HIV Care*, 73 Am. J. Health-Syst. Pharm. e72, e72 (2016).

their antiretroviral therapy. Polypharmacy, or "the prescription of medications for multiple underlying disease states, or . . . a threshold number of active prescriptions—such as the concurrent administration of 5 or more medications," can increase the risk of adverse health outcomes.[19] The National Coordinating Council for Medication Error Reporting and Prevention recommends that patients take several steps to reduce the risks associated with polypharmacy. Included among them are recommendations to "[c]ommunicate any bad effect from [their] medications to [their] providers"; to ask, when a new drug is discussed or prescribed, "if any medications should be continued, which should be stopped, and which medication supplies should be thrown away"; to limit medications to those geared toward achieving the best outcome, "[u]nder the direction of [their] physician or pharmacists"; and to consider having a single "pharmacy home," where "[their] pharmacist has access to [their] complete medication history and current regimen."[20]

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[19] HIVPractice, *Polypharmacy and HIV*, https://perma.cc/R9Z4-HJE9 (footnote omitted). Many HIV drugs are contraindicated when a patient is taking other medications. For example, Prezista/ritonavir (which may be recommended for people who need a treatment regimen with a higher barrier to resistance) is contraindicated in people taking certain cholesterol medications, including lovastatin and simvastin. *National HIV Guidelines* at G-7; FDA Drug Label for PREZISTA at 7 (Aug. 17, 2021), https://perma.cc/3YDJ-KU6X.

[20] Nat'l Coordinating Council for Med. Error Reporting & Prevention, *Recommendations for Improving Medication Safety by Reducing Inappropriate Polypharmacy*, https://perma.cc/DR9T-F37F.

Patients stand a much better chance of receiving care consistent with these standards if they are confident that their physician and pharmacist are on the same page and if their providers do in fact communicate with each other about their needs. This triangular communication not only reduces the possibility of confusion or conflict between the physician's advice to the patient and the pharmacist's, it also gives the patient assurance that *both* trusted care providers deem the prescribed course of treatment safe in the context of the patient's unique needs.

#### ii. Mail-order mandates can isolate patients from HIV providers and pharmacies that are connected with wraparound services.

People living with HIV often develop important relationships with provider organizations, including those with a history of serving people living with or at

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> [P]atients should also . . . use a single pharmacy, preferably one specialized in caring for people living with HIV and with an integrated network connected to the patient's electronic medical record. Utilizing a specialty pharmacy has been associated with improved HIV care, with benefits including: fewer contraindicated medications; improved medication adherence; and improved pharmacist-prescriber communication regarding [drug-drug interactions], medication reconciliation, monitoring adherence, and providing adherence aids.

*Polypharmacy and HIV*, *supra* note 19 (footnote omitted).

risk of HIV and with in-house pharmacy clinics that regularly stock the component drugs of recommended antiretroviral therapy. Close provider-patient relationships expand access to care for people in underserved communities, including people of color, people who use drugs, people who experience housing instability, and people who live in rural areas. Equally as important, strengthening the fiber of the provider-patient relationship promotes overall engagement in the health care system. Providers can connect patients to a variety of wraparound services (such as medically tailored meals that support the absorption of and adherence to certain HIV medications) and can connect—through the provision of comprehensive, integrated pharmacy services—patients to steady access to the HIV- and non-HIV-related medications and programs that support their health.[21] Unfortunately, mail-order mandates prevent these key providers, who regularly stock specialty medication and keep abreast of evolving HIV

[21] Key HIV providers with in-house pharmacies are also familiar with the role patient assistance programs play in helping people living with HIV afford life-saving medications. *See* Rita Rubin, *Mandating Mail-Order Pharmacies*, POZ, Aug. 6, 2013, https://perma.cc/W2E2-YH3K (describing a mail-order pharmacy program that required payments from a manufacturer's patient assistance program to be coordinated separately after shipping).

research, from providing the full spectrum of care to people living with HIV.[22]

## CONCLUSION

Antiretroviral therapy for people living with HIV is a transformative medical intervention that has improved the lives of millions of people living with HIV in the United States over the past quarter century. But this advancement means little without robust, predictable access to the medicine itself. People living with HIV who have steady, reliable access to antiretroviral

[22] Mandated mail-order programs can also present financial concerns for certain providers who operate 340B contract pharmacies.

> Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. [These] pharmacies (through the Health Resources & Services Administration, which oversees Ryan White HIV service programs) typically provide patients with supportive service health care navigation education, support, referrals, and information about their condition, and they are often housed in clinics closely associated with other HIV service organizations. . . . And covered entities depend on locally-generated program savings through the [340B] rebates program to support their patient navigation work. . . .

National Coalition for LGBT Health, *Gilead Sciences Proposes Change to Patient Assistance Program* (April 2021), https://perma.cc/6PF3-8AHV.

therapy can achieve undetectable viral loads, leading to a stronger immune system, a lower risk of AIDS-related and non-AIDS-related health events, increased life expectancy, and effectively no risk of sexually transmitting HIV to HIV-negative partners. But mandated mail-order pharmacy programs disrupt access to treatment. Mail delays prevent prescribed drugs from arriving in a timely manner, leading to worse health outcomes and an increased risk of drug resistance. Shipments of medication can be exposed to inappropriate temperatures, damaging the drugs. Misdelivered packages and indiscreet packing labels can put people living with HIV at risk of their diagnosis being disclosed without their consent, subjecting them to stigma, discrimination, and violence. Finally, mandatory mail-order pharmacy programs can undermine important relationships with providers, including pharmacists. They cut the pharmacist out of the HIV care team and divorce the patient from community-oriented provider organizations with in-house pharmacies and wraparound services that have been shown to increase patient engagement in care. Mandatory mail-order pharmacy programs have a disparate impact on people living with HIV and other chronic conditions,

and the Court should uphold the judgment of the Ninth Circuit Court of Appeals.

Respectfully submitted,

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