No. 20-1374

In the Supreme Court of the United States

CVS PHARMACY, INC., ET AL.,

Petitioners,

v.

JOHN DOE, ONE, ET AL.,

Respondents.

On a Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF OF AIDS HEALTHCARE FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS AND AFFIRMANCE

JONATHAN M. EISENBERG*
Deputy General Counsel – Litigation
THOMAS A. MYERS
General Counsel
AIDS HEALTHCARE FOUNDATION
6255 West Sunset Blvd., 21st Flr.
Los Angeles, CA 90028
(323) 860-5200
jonathan.eisenberg@ahf.org

* *Counsel of record*

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INTERESTS OF *AMICUS CURIAE*[1]

AIDS Healthcare Foundation (AHF), a nonprofit organization, is the world's largest provider of medical care for people living with Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS), serving over 1.6 million people in 45 countries. AHF provides its cutting-edge medical care regardless of patients' ability to pay. AHF operates over 60 pharmacies and serves nearly 100,000 patients in the United States. AHF also advocates for people living with HIV/AIDS, to remove barriers to proper care and treatment and to end discrimination and stigmatization. As part of those efforts, AHF occasionally files *amicus curiae* briefs in lawsuits, like this one, that raise issues of concern to people living with HIV/AIDS. AHF filed an *amicus curiae* brief in this case when it was in the U.S. Court of Appeals, Ninth Circuit. Indeed, AHF believes that the outcome of this case could have material consequences for the drive to eradicate HIV/AIDS in the United States.

SUMMARY OF ARGUMENT

For people living with HIV/AIDS, strict lifetime adherence to antiretroviral therapies (ART), consisting of complex combinations of

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[1] The parties to this appeal have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no entity or person, other than *amicus curiae* AIDS Healthcare Foundation itself, made any monetary contribution intended to fund the preparation or submission of this brief.

pharmaceuticals consumed daily, is vitally important, and can be literally a life-or-death matter. Plus, when people living with HIV/AIDS adhere to ART, because it almost always reduces the presence of HIV in the body to undetectable levels, the risk of transmission of HIV to other people goes way down. For people living with HIV/AIDS, so-called specialty pharmacies[2] and pharmacists that focus on HIV/AIDS and in-person treatment provide demonstrably superior care than do mail-order pharmacies and retail pharmacies. Coercing people living with HIV/AIDS into using only mail-order pharmacies is thus guaranteeing inferior care and worse health outcomes, and is disability discrimination by both intent and impact.

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[2] The term "specialty pharmacy" has no universally agreed-upon definition. Adam J. Fein, PhD, *The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* 60 (Mar. 2020). One definition is a pharmacy that is licensed by a U.S. state and that provides medications that are only or largely for the treatment of serious human health conditions requiring complex therapies. *See id.* (citing definition from National Association of Specialty Pharmacies). An HIV/AIDS specialty pharmacy would be one that provides medications that are only or largely for the treatment of HIV/AIDS.

ARGUMENT

I. U.S. Statutory Law Requires Courts to Protect People Living with HIV/AIDS from Disability Discrimination by Healthcare Providers

People living with HIV/AIDS continue to be subject to irrational stigma and discrimination throughout the United States.[3] Some forty

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[3] See, e.g., HIV/AIDS Alliance for Region Two, et al., *The Louisiana Stigma Index Project: Results and Next Steps* 32-43 (Mar. 14, 2017) (detailing stigma and discrimination experienced by people living with HIV/AIDS in Louisiana), https://www.stigmaindex.org/wp-content/uploads/2019/11/USA_Louisiana_PLHIV-Stigma-Index-Report_2017.pdf (last visited Oct. 22, 2021); Michael P. Arnold, MSW, PhD, et al., *The U.S. People Living with HIV Stigma Index: Michigan Wave 1 Findings, 2014-2016* (2016) (similar re: Michigan), https://www.stigmaindex.org/wp-content/uploads/2019/11/USA_Michigan_PLHIV-Stigma-Index-Report_2016.pdf (last visited Oct. 22, 2021); Ann D. Bagchi and Dwight Peavy, *Findings from the People Living with HIV Stigma Index Survey* (Mar. 1, 2018) (similar re: New Jersey), https://www.stigmaindex.org/wp-content/uploads/2019/11/USA_New-Jersey_PLHIV-Stigma-Index-Presentation_2018.pdf (last visited Oct. 22, 2021); Lambda Legal, *HIV Stigma and Discrimination in the U.S.: An Evidence-Based Report* (Nov. 2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_hiv-stigma-and-discrimination-in-the-us_1.pdf (last visited Oct. 22, 2021); Gabriela Martínez, *People Living with HIV Ask for 'Dehumanizing' State Laws to Be Taken Off the Books*, WITF (Oct. 7, 2021), https://www.witf.org/2021/10/07/people-living-with-hiv-

years into the HIV/AIDS pandemic, the Centers for Disease Control and Prevention (CDC) still finds it necessary to fund an "evidence-based campaign aimed at stopping HIV stigma and promoting HIV testing, prevention, and treatment,"[4] to fight the disease effectively.

Although there is no cure yet for HIV/AIDS, in the last quarter century, because of ART, people living with HIV/AIDS can have prolonged survival, approaching that of the general human population.[5] But ART requires patients to take complex combinations of prescription drugs daily, indefinitely; and to see medical doctors four to six times per year, for tests and monitoring, especially because HIV regularly mutates in reaction to these medicines.[6] Thus treating HIV/AIDS is

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ask-for-dehumanizing-state-laws-to-be-taken-off-the-books/ (last visited Oct. 22, 2021).

[4] Joynecia Clements-Powell, *CDC Awards More than $2 Million to National Organizations to Amplify Let's Stop HIV Together Campaign*, HIV.gov (Oct. 13, 2021), https://www.hiv.gov/blog/cdc-awards-more-2-million-national-organizations-amplify-let-s-stop-hiv-together-campaign (last visited Oct. 22, 2021).

[5] Sally Spencer Long and Daniel J. Skiest, *HIV Care Coordination*, in *Fundamentals of HIV Medicine, 2019 Edition, for the HIV Specialist* 175 (Long), 175 (2019).

[6] CDC, *HIV Treatment* (May 20, 2021), https://www.cdc.gov/hiv/basics/livingwithhiv/treatment.html (last visited Oct. 22, 2021); *see also* Joanna V. Theiss, *It May Be Here to Stay but Is It Working? The Implementation of the Affordable Care Act Through An Analysis of Coverage of HIV Treatment and Prevention*, 12 J. Health & Biomed. L. 109, 115-20 (2016).

extremely costly – around $500,000 for one person, over a lifetime.[7]

Given that high level of costs, health-insurance companies and their affiliates, including pharmacy benefits managers (PBMs),[8] have powerful financial incentives to discourage people living with HIV/AIDS from enrolling in insurance plans, or utilizing available services.[9] As the CDC found, "Historically, people living with HIV and AIDS have had a difficult time obtaining private health insurance and have been particularly vulnerable to insurance industry abuses."[10]

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[7] CDC, *HIV Cost-effectiveness* (Oct. 1, 2021), https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html (last visited Oct. 22, 2021) (money represented in approximated 2021 dollars).

[8] "Pharmacy benefit managers (PBMs) […] serve as intermediaries between prescription-drug plans and the pharmacies that beneficiaries use. When a beneficiary of a prescription-drug plan goes to a pharmacy to fill a prescription, the pharmacy checks with a PBM to determine that person's coverage and copayment information. After the beneficiary leaves with his or her prescription, the PBM reimburses the pharmacy for the prescription, less the amount of the beneficiary's copayment. The prescription-drug plan, in turn, reimburses the PBM." *Rutledge v. Pharmacy Care Mgmt. Ass'n*, __ U.S. __, __, 141 S. Ct. 474, 478 (2020).

[9] *See, e.g., McNeil v. Time Ins. Co.*, 205 F.3d 179, 184 (5th Cir. 2000) (concerning health insurer that provided only $10,000 total coverage over two-year period for person living HIV/AIDS).

[10] CDC, *The Affordable Care Act Helps People Living with HIV/AIDS* (May 12, 2020), https://www.cdc.gov/hiv/policies/aca.html (last visited Oct. 21, 2021).

Coerced mail-order pharmacy use continues this unfortunate pattern.

With the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116, flatly forbidding disability discrimination in any health program receiving any federal funds, the courts should be inclined by that law to protect people living with HIV/AIDS from such abuses. *See also* 42 U.S.C. § 18022(b)(4)(B)-(C) (requiring certain healthcare-coverage providers not to make coverage decisions or design benefits in ways that discriminate against people because of their disabilities).

II. Coerced Use of Mail-Order Pharmacies Is Highly Detrimental to People Living with HIV/AIDS

PBMs, like CVS Health Corp.'s subsidiaries herein (CVS), use many means claimed to lower the costs of delivering pharmacy services to people with prescription-drug benefits plans associated with healthcare insurance. (Br. of Pharmacy Care Mgmt. Ass'n as *Amicus Curiae* ISO Pet'rs and Reversal (Sept. 10, 2021), on file herein (PCMA *Amicus* Brief), at 6-13.) The technique at issue in this case is requiring pharmacy customers to use mail-order pharmacies or pre-designated pick-up locations – associated with the PBM – instead of local pharmacies, which often have or develop relationships with those customers, and that therefore can provide more personalized, in-person care. (*Doe One v. CVS Pharmacy, Inc.*, 348 F. Supp. 3d 967, 977 (N.D. Cal. 2018), aff'd

in part and vacated in part by *Doe One v. CVS Pharmacy, Inc.*, 982 F.3d 1204 (9th Cir. 2020), cert. granted in part by *CVS Pharmacy, Inc. v. Doe One*, 141 S. Ct. 2882 (2021) (this case).)

But coerced use of mail-order pharmacies or other impersonal healthcare alternatives is uniquely and extremely detrimental to people living with HIV/AIDS.

For people living with HIV/AIDS, "[a]dherence to [ART] is critical to achieve and maintain viral suppression and improve immune function."[11] Indeed, what sets HIV patients apart from other mail-order users is their dependence on quite strict adherence for sustained HIV suppression and survival and the virus's long incubation period.[12] "Poor retention [in care] is associated

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[11] Elizabeth Barnes, PharmD, BCACP, AAHIVP, et al., *The Effect of an Integrated Health System Specialty Pharmacy on HIV Antiretroviral Therapy Adherence, Viral Suppression, and CD4 Count in an Outpatient Infectious Disease Clinic*, J. Managed Care & Specialty Pharmacy (Feb. 2020) 95 (Barnes), 95, https://www.jmcp.org/doi/pdf/10.18553/jmcp.2020.26.2.95 (last visited Oct. 22, 2021); accord Long 176; James Zhang, PharmD, CSP, *Role of Specialty Pharmacists in Treating Patients with HIV*, Pharmacy Prac. News (Aug. 18, 2020).

[12] Karishma Rohanraj Desais, PhD, MS, B. Pharm, et al., *Mail-order Pharmacy Experience of Veterans Living with AIDS/HIV*, Research in Soc. & Admin. Pharmacy (2007) (Desai), https://dx.doi.org/10.1016/j.sapharm.2017.02.005 (last visited Oct. 21, 2021) (emphasis added); Barnes 96; *see also* James Myrhe and Dennis Sifris, MD, *How Much HIV Drug Adherence Is Enough?*, Verywell Health (May 23, 2021), https://www.verywellhealth.com/how-much-

with higher morbidity and mortality for the person with HIV and has significant implications for HIV transmission."[13]

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adherence-is-enough-adherence-49307 (last visited Oct. 22, 2021).

[13] Kathy K. Byrd, MD, MPH, et al., *Retention in HIV Care Among Participants in the Patient-Centered HIV Care Model: A Collaboration Between Community-Based Pharmacists and Primary Medical Providers*, 33(2) AIDS Patient Care & STDS (Feb. 2019) (Byrd); Zihao Li, PhD, et al., *Vital Signs: HIV Transmission Along the Continuum of Care – United States, 2016*, 68(11) Morbidity & Mortality Wkly. Rep. 267, 268 (Mar. 22, 2019) (reporting that 37.6% of estimated transmissions of HIV came from persons unaware that they were infected, 42.6% came from people aware that they were infected but not in care, and 19.8% came from persons in care but not virally suppressed; "The rate was zero among those taking ART and virally suppressed"), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6811e1-H.pdf (last visited Oct. 22, 2021); see also Geoffrey Maina, et al., *A Systematic Review of Best Practices in HIV Care*, 15(1) J. HIV/AIDS Soc. Serv. 119 (Mar. 22, 2016) ("[A]lthough HIV is regarded as a chronic illness, it is still an exceptional disease. It commands attention and investment in order to reduce HIV transmission, morbidity, and mortality. Concerted and coordinated efforts are needed to enable PHAs [People with HIV/AIDS] to live and participate fully in the community. PHAs' adherence to care can be affected by issues such as stigma, poor access, poverty, mental health, and addictions (Andersen et al., 2003; Hull, Wu, & Montaner, 2012). Subsequently, they need support to be linked to care and to have access to comprehensive services (medical and social) to stay on a path to wellness and be active members of the community").

[13] Erica Conroy, PhD, and Kyle Grimslid, PharmD, RPh, *Help Patients Obtain HIV Medications*, 88(9) Pharmacy Times 58 (Sept. 2020) (Conroy).

Clinical pharmacists and pharmacies focused on HIV have demonstrated the ability to increase ART medication adherence.[14] Several studies have shown that community pharmacies with specially trained and educated HIV pharmacists had higher ARV refill adherence," which leads to better health outcomes.[15] "The improved outcomes achieved through suppressed viral loads […] are attributed to the enhanced pharmacy services provided to each patient. These services expand the role of the pharmacy staff…."[16] "HIV clinical pharmacists make ideal treatment advocates because they are knowledgeable about ART and may help bridge the gap between patients and their providers. They offer personalized patient education regarding HIV disease, HIV treatment and opportunistic infection prophylaxis, and management of adverse effects."[17]

In 2012, a group of scholars of pharmacy and public health working for Walgreens Co. conducted a pertinent study of a total of over 14,000 people living with HIV/AIDS in seven U.S. states.[18] The scholars determined that the

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[14] Barnes 95.

[15] *Id.* (citing three other published studies).

[16] Marc O'Connor, *Enhanced Pharmacy Services: Improving Outcomes for Patients with HIV*, 6(4) Specialty Pharmacy Times (Jul./Aug. 2015).

[17] Jennifer Cocohoba, *The Pharmacist's Role in Caring for HIV-Positive Individuals*, in *Fundamentals of HIV Medicine, 2019 Edition, for the HIV Specialist*, *supra*, 183, 185.

[18] Patricia Murphy, M.P.H., et al., *Impact of HIV-Specialized Pharmacies on Adherence and Persistence with Antiretroviral Therapy*, AIDS Patient Care & STDs

best health outcomes for people living with HIV/AIDS were achieved in HIV-focused specialty pharmacies, which distinguish themselves from traditional pharmacies by offering tailored services in the areas of medication review, adherence assessment, refill synchronization, and availability of HIV/AIDS medications at all times.[19] The scholars concluded that "[g]iven the value of specialized community pharmacies, [healthcare] payers should consider implementing policies to encourage the use of such pharmacies for filling ART in preference to generalized community pharmacy or mail order."[20]

In 2017, a group of scholars of surgery and pharmacy conducted another pertinent study of the HIV/AIDS-treatment experiences of 57 HIV-positive U.S. Military Veterans who obtained their medications from the U.S. Veterans Administration, which used a mail-order system.[21] The vast majority of these Veterans had had HIV or AIDS for more than 10 years each.[22] With so much personal experience dealing with the virus, the Veterans were able to manage their medications via the mail-order system – but not without considerable difficulty.[23] Most scandalously, 47 percent of the Veterans reported sometimes,

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(Sept. 2012), http://europepmc.org/article/PMC/4088351 (last visited Oct. 22, 2021).

[19] *Id.*

[20] *Id.*

[21] Desai, *supra*.

[22] *Id.*

[23] *Id.*

usually, or almost always running out of their HIV medications.[24] Some patients had to resort to obtaining temporary medications in person from on-site pharmacies.[25] And 53 percent of the Veterans indicated that more frequent conversations with pharmacists would be helpful to managing HIV/AIDS.[26] In sum, that study revealed significant deficiencies of mail-order systems for medications for people living with HIV/AIDS, even people living with HIV/AIDS for a long time.

AHF has had a similar experience with CVS as the Veterans had with the Veterans Administration. One patient came to an AHF pharmacy and said that CVS had said that it could not fill the patient's prescription timely, because of mail-order delays. CVS advised the patient to go to an AHF pharmacy to obtain a short-term supply of the medications, because AHF surely had the medications on hand and would give the medications out for free. (AHF's slogan is "cutting-edge medicine and advocacy regardless of ability to pay.") AHF was able to provide that crucial care to the patient, but the incident exposes serious flaws in CVS's business model and how it discriminates against people with HIV/AIDS, abandoning these patients to fend for themselves and to rely on the kindness of strangers in moments of need created by CVS.

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[24] *Id.*
[25] *Id.*
[26] *Id.*

In 2019, a group of scholars of HIV/AIDS, pharmacy, biostatistics, and epidemiology published a relevant study of 765 people living with HIV/AIDS.[27] The scholars hypothesized, "A lack of coordinated HIV care may contribute to poor retention and viral suppression."[28] "Even when people with HIV receive care from multiple health care providers, they often receive all their medicines from one pharmacy, making the pharmacist a key point of contact. Pharmacist-led interventions have led to improvement in a variety of therapeutic and adverse events outcomes for several disease states."[29] There is a model of care for people living with HIV/AIDS that is called the "Patient-Centered HIV Care Model" (PCHCM).[30] The model involves information-sharing between pharmacy teams and clinic teams; collaborative medication-related action planning among pharmacists, medical providers, and patients; and quarterly follow-up visits.[31] The scholars set up 10 project sites implementing PCHCM.[32] The scholars then

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[27] Byrd.
[28] *Id.*
[29] *Id.*
[30] *Id.*; see also CDC, *Patient-Centered HIV Care Model (PCHCM)*, in *Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention* (Jun. 21, 2021), https://www.cdc.gov/hiv/pdf/research/interventionresearch/compendium/si/cdc-hiv-Patient_Centered_HIV_Care_Model_PCHCM_SI_EI.pdf (last visited Oct. 22, 2021).
[31] Byrd.
[32] *Id.*

studied what occurred at the sites from 2014 to 2016,[33] and reported as follows:

> Overall, retention in care improved 12.9% from 60.7% to 68.5% (p = 0.002), pre- to post-model implementation. Retention improved among persons aged ≥50 years [12.3% increase; 62.5–70.2% (p = 0.029)], males [13.9% increase; 60.4–68.8% (p = 0.005)], persons seen in the Ryan White/ADAP [AIDS Drug Assistance Program] clinics [22.4% increase; 63.9–78.2% (p = 0.023)], and non-Hispanic black persons [22.6% increase; 59.7–73.2% (p < 0.001)]….[34]

"The model sought to build stronger relationships between both the pharmacists and patients, and between the pharmacists and clinic providers. …[E]nhanced personal contact with patients has been shown to increase retention."[35] "In conclusion, the PCHCM demonstrated how collaborations between community-based pharmacists and medical providers can lead to increased retention in HIV care. This model of care may be particularly useful for non-Hispanic black persons, who often are less likely to be retained in care."[36] This study affirms the great value of the PCHCM model, with high levels of human contact – the opposite of coerced mail order.

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[33] *Id.*
[34] *Id.*
[35] *Id.* (footnotes omitted).
[36] *Id.*

Forced mail order can also result in splitting a patient's prescriptions between the anonymous, HIV mail-order pharmacy and the patient's preferred home pharmacy. AHF knows firsthand that splitting prescriptions this way is bad for the patient's care. Neither of the two pharmacists sees the patient's complete medication history, and it is harder to identify duplicate prescriptions or potential adverse drug interactions.

Last year, two other scholars, associated with CoverMyMeds, reviewed how some mail-order pharmacies have breached the privacy of people living with HIV/AIDS by indiscreetly delivering medications, leading to lawsuits.[37] The scholars concluded that "maintaining distribution through both retail and specialty pharmacies can help reach the most patients with HIV, while also providing an appropriate level of support based on personal circumstances."[38] Mail-order pharmacies were not mentioned as helpful.

As APLA Health has commented in connection with a California Legislature bill (that was not enacted), mail-order pharmacies can cause significant privacy and safety issues for people living with HIV/AIDS, especially people living in congregate settings, people experiencing domestic violence, people living in rural areas (where pharmacies are often few and far between), and other people who may need to protect the confidentiality of their

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[37] Conroy.
[38] *Id.*

health and medical information.[39] Medication arriving via mail may be intercepted by someone who is not aware of the health status of the person living with HIV/AIDS, and this breach of privacy may result in loss of employment, housing, or physical safety.[40]

In sum, for a person living with HIV/AIDS, it is critical to be able to have a pharmacist who is especially knowledgeable about HIV/AIDS, and familiar with the patient and sensitive to the patient's specific needs. For those reasons, a local, specialized pharmacy is frequently invaluable to the patient, and a mail-order pharmacy is a hindrance.[41]

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[39] California Senate, Committee on Health (Consultant Teri Broughton), Report on Senate Bill 524, *Health Care Coverage: Patient Steering* 5 (Apr. 19, 2021), https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=202120220SB524 (providing link to report; last visited Oct. 22, 2021).

[40] *Id.*

[41] PCMA, the self-described "national trade association representing PBMs," asserts that allowing CVS to coerce people living with HIV/AIDS into using mail-order pharmacies serves the purpose of "foster[ing] consumer choice." (PCMA *Amicus* Brief, *supra*, at 2.) This assertion is illogical. What CVS is doing undeniably, literally decreases consumers' choices.

PCMA also asserts that coercing patients to use mail-order pharmacies, instead of in-person pharmacies, actually enhances patients' physical safety and adherence to prescription-medicine regimens. (PCMA *Amicus* Brief, *supra*, at 4, 8-9.) But PCMA does not address whether coerced use of mail-order pharmacies helps or harms people living with HIV/ AIDS. Neither of the two publications (one by Elena V. Fernandez, et al., and the other by John D. Jones) that PCMA cites (at page

III. Coercing People Living with HIV/AIDS to Use Mail-Order Pharmacies Is a Disability-Rights Violation, by Both Intent and Impact

As can be seen, coercing people living with HIV/AIDS into using only mail-order pharmacies is condemning those people to inferior care and worse health outcomes. The practice is cruel and potentially deadly. CVS and other PBMs know (or should know) about all this evidence. The practice thus betrays an intent to discriminate, or at minimum a callousness toward discriminating, against people living with HIV/AIDS. *Cf. Gebser v. Lago Vista Indep. Sch. Dist.*, 524 U.S. 274, 290-91 (1998) (articulating deliberate-indifference definition for intentional disability discrimination). The practice also has a significant, disparate impact on people living with HIV/AIDS. By either of two measures, intent or impact, the practice should be seen as and deserves to be an actionable civil-rights

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8 of the PCMA brief) as establishing the benefits of mail-order pharmacies addresses their efficacy for people living with HIV/AIDS. Instead, the publications focus on "hypertension, high cholesterol and diabetes." (PCMA *Amicus* Brief, *supra*, at 8.)

PCMA also asserts, "By leveraging scale and expertise, specialty pharmacies dramatically improve patient outcomes and reduce costs for those with conditions like HIV, multiple sclerosis, or some cancers." (PCMA *Amicus* Brief, *supra*, at 9.) AHF agrees with that assertion, but also notes that CVS's so-called specialty pharmacies are little more than places to pick up medications and staffed telephone call-in lines.

violation, under 29 U.S.C. §§ 794(a) and 794a and 42 U.S.C. § 18116(a).

CONCLUSION

For the foregoing reasons, the Court should affirm the judgment of the Ninth Circuit.

Respectfully submitted,

JONATHAN M. EISENBERG*
Deputy General Counsel – Litigation
THOMAS A. MYERS
General Counsel
AIDS HEALTHCARE FOUNDATION
6255 West Sunset Blvd., 21st Flr.
Los Angeles, CA 90028
(323) 860-5200
jonathan.eisenberg@ahf.org

* *Counsel of record*