ORAL ARGUMENT NOT YET SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

GILEAD SCIENCES, INC., and GILEAD SCIENCES IRELAND UC IDA, Plaintiffs-Appellees, v. MERITAIN HEALTH, INC., PROACT INC., RX HEALTH, LLC, ADVANCED PHARMACY, LLC, AQUA ENTERPRISES INC. dba AFFORDABLE RX MEDS, and GREGORY SANTULLI, Defendants-Appellants	Appeal Nos. 25-1828, 25-1829, 25-1849, 25-1850 (Consolidated)

MOTION FOR LEAVE TO FILE AN AMICUS BRIEF IN SUPPORT OF PLAINTIFFS-APPELLEES' BRIEF AND FOR AFFIRMANCE BY AMICI CURIAE, THE HIV AND HEPATITIS POLICY INSTITUTE, THE ADAP ADVOCACY ASSOCIATION, THE INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS, THE AUTOIMMUNE ASSOCIATION, AND HEALTHHIV

(Counsel on next page)

Dated: December 26, 2025

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Amici Curiae, the HIV and Hepatitis Policy Institute (HIV+Hep), the ADAP Advocacy Association (ADAP Advocacy), the International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), the Autoimmune Association, and HealthHIV, all patient and health advocacy groups, move this Court, by and through counsel, under Federal Rule of Appellate Procedure 29(a) for leave to file an amicus brief in support of Plaintiffs-Appellees and for affirmance of the district court. The proposed Amici Curiae brief is attached as Attachment A. This appeal raises a series of critically important patient health and safety issues and focuses on a practice--the rapidly increasing importation of unapproved drugs--that Amici have long opposed. So-called "alternative benefit programs" (AFPs) like the one at issue in this case are a serious threat to patient health and safety. As patient and health advocates, Amici have devoted significant resources to investigating AFPs, educating patients and policymakers about them, and communicating about the risks they create.

Amici Curiae believe that their brief will significantly deepen the Court's understanding of the dangers posed by AFPs, in general, and Appellants' model, in particular, both of which Amici oppose. From our

perspective, it is critically important that the district court's injunction be upheld by this Court. The injunction is clearly in the public interest, and as patient and health advocates, Amici wish to speak to that public interest, on behalf of people living with HIV and the other chronic and rare disease patients whom we serve.

Amici's distinctly patient-oriented perspective is reflected in Amici's understanding of the origins of these AFPs; their dangerous expansion; the negative impact of AFPs on patients, including those living with HIV; and why, from a patient perspective, the unapproved product they introduce into the United States is materially different than Appellees' approved domestic product and inevitably causes patient confusion. Amici also have a distinct view on why Gilead's Lanham Act claims are not precluded by the Food, Drug, and Cosmetic Act (FDCA) and, consistent with precedent, act to "complement" the FDCA.

The HIV and Hepatitis Policy Institute (HIV+Hep) is a not-for-profit organized under Section 501(c)(3) of the Internal Revenue Code that promotes quality and affordable health care for people living with or at risk of HIV, hepatitis, and other serious and chronic health

conditions. HIV+Hep (1) monitors policies that impact the prevention and treatment of HIV, viral hepatitis, and other health conditions, (2) communicates with members of the HIV, hepatitis, and other patient group communities on key policy issues that impact their access to health care, and (3) educates policymakers about efforts to end both HIV and hepatitis and to improve access to quality and affordable health care.

Health care, and particularly prescription drug access, is a central area of focus for HIV+Hep. HIV+Hep promotes programs and policies that support access to care and treatment. As part of that core focus, HIV+Hep seeks to assist people with and at risk of HIV, hepatitis, and other serious and chronic health conditions gain and maintain access to comprehensive, quality, and affordable health care. HIV+Hep has been deeply involved in advocating against and educating patients about the dangers of AFPs for a number of years.

The mission of the ADAP Advocacy Association (ADAP Advocacy) is to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for persons living with HIV/AIDS. ADAP Advocacy works with advocates, the community, government,

patients, pharmaceutical companies and other stakeholders to raise awareness, offer patient educational programs, and foster collaboration. It has long expressed its serious concerns about the negative health and safety impacts of AFPs and has made that issue a focus of its public education efforts.

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis) represents patients with roughly two dozen autoimmune or autoinflammatory conditions that increasingly report being forced into AFPs. AiArthritis seeks to both advocate for those patients and to educate stakeholders about the dangers of these programs.

For over 30 years, the Autoimmune Association has been a pioneer in serving autoimmune patients, sponsoring research, advocating for access to healthcare, and fostering collaboration to identify and explore the common threads that link autoimmune diseases. Autoimmune diseases are a major cause of serious and chronic health conditions for millions of individuals. AFPs require patients to navigate a maze of delays and procedures with lengthy applications and treatment roadblocks, including providing sensitive, confidential

financial information to the AFP. This process can take several weeks - sometimes months -- during which the patient may ration their existing medicine supplies or choose to forgo the drug -- which can lead to irreversible negative health outcomes. AFPs using foreign drug products add additional (and disturbing) health and safety risks that threaten the well-being of the patients that we serve.

HealthHIV is a national non-profit advancing effective prevention, care, support, and health equity in HIV, HCV, STIs, LGBTQ health and harm reduction by providing education, training, capacity building, health services research, communications and advocacy to organizations, communities, and professionals. HealthHIV works closely with providers, clinics, and communities to address barriers to HIV, STI, mpox, and viral hepatitis prevention and treatment within broader syndemic contexts across the country. HealthHIV's interest in this case comes from what is seen every day in practice. When coverage work-arounds or importation schemes get in-between providers and the medications they prescribe, people fall out-of-care, treatment plans are disrupted, and the healthcare workforce ends up trying to manage problems that should not even exist in the first place. AFPs and similar

models create real gaps in access and use, threaten patient health and safety, and imperil the ability of patients to stay engaged with their medications and in preventive services.

No party's counsel authored this brief, in whole or in part, and no party, its counsel, or any other person—other than Amici Curiae or its counsel—contributed money intended to fund preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). Amici's select counsel is an unpaid volunteer. No party asked for Amici to file this brief, and no party has reviewed it or suggested any part of its content. Plaintiffs-Appellees consent to this Motion; the Defendant-Appellants oppose this Motion.

In analyzing the important questions implicating the public interest here, we urge this Court to hear and consider Amici and the distinctively patient-oriented perspective Amici bring to the important issues raised by this case and grant Amici leave to file their attached Brief as Amici Curiae in Support of Plaintiffs-Appellees' Brief and for Affirmance. Amici submit the proposed amicus brief to assist this Court in better understanding the patient health and safety risks created by Appellants' importation of foreign, unapproved drugs (particularly for people living with HIV), the material differences between Gilead's U.S.

product and the foreign drugs distributed by Appellants, the serious patient confusion Appellants' AFP creates, and the inadequacy of the Food and Drug Agency's enforcement mechanism in addressing this dangerous and rapidly expanding conduct.

Respectively submitted,

Dated: December 26, 2025

/s/_____

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing will be served this 26th day of December, 2025, electronically through the Court's CM/ECF system on all registered counsel.

/s/
William A. Sarraille

Attachment A

Case No. 25-1828 (L),
25-1829, 25-1849, 25-1850

United States Court of Appeals for the Fourth Circuit

GILEAD SCIENCES, INC., and GILEAD SCIENCES IRELAND UC IDA,

***Plaintiffs-Appellees*,**

v.

MERITAIN HEALTH, INC., PROACT INC., RX HEALTH, LLC, ADVANCED PHARMACY, LLC, AQUA ENTERPRISES INC. dba AFFORDABLE RX MEDS, and GREGORY SANTULLI,

Defendants-Appellants.

Appeal from the United States District Court for the District of Maryland, No. 1:24-cv-03566-JRR

BRIEF OF AMICI CURIAE THE HIV AND HEPATITIS POLICY INSTITUTE, THE ADAP ADVOCACY ASSOCIATION, THE INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS, THE AUTOIMMUNE ASSOCIATION, AND HEALTHHIV, IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE OF THE DISTRICT COURT

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CORPORATE DISCLOSURE STATEMENT

Amici Curiae the HIV and Hepatitis Policy Institute, the ADAP Advocacy Association, the International Foundation For Autoimmune & Autoinflammatory Arthritis, the Autoimmune Association, and HealthHIV, are each patient and/or health advocacy groups, each has no parent companies or subsidiaries, each is not a publicly held corporation, and no part of the ownership of any is held by any publicly held corporation.

CONSENT TO FILE

Plaintiffs-Appellees consented to the filing of this amicus brief; Defendants-Appellants oppose.

/s/ William A. Sarraille
William A. Sarraille

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IDENTITY AND INTEREST OF AMICI

Amici are all patient and health advocacy organizations dedicated to helping different patient populations through public advocacy and education. They all are alarmed by the rapid growth of so-called "alternative benefit programs" (AFPs) that target chronic and rare disease patients who depend on drug therapies that, for many of those patients, are life-sustaining. They are all deeply disturbed by the serious health and safety threats created by these AFPs, including their impact on people living with HIV.

The HIV and Hepatitis Policy Institute (HIV+Hep) is a not-for-profit organized under Section 501(c)(3) of the Internal Revenue Code that promotes quality and affordable health care for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. HIV+Hep (1) monitors policies that impact the prevention and treatment of HIV, viral hepatitis, and other health conditions, (2) communicates with members of the HIV, hepatitis, and other patient group communities on key policy issues that impact their access to health care, and (3) educates policymakers about efforts to end both

HIV and hepatitis and to improve access to quality and affordable health care.

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RULE 29(a)(4)(E) STATEMENT

No party's counsel authored this brief in whole or in part, and no party, its counsel, or any other person—other than Amici Curiae—contributed money intended to fund preparation or submission of this

brief. Counsel for Amici who is responsible for this brief serves as the volunteer Special Counsel for Amici. No party requested the filing of this amicus brief, and the content of this brief and the points made in it have not been suggested by any party or its counsel. Amici have solely directed and controlled the content of this brief.

SUMMARY OF ARGUMENT

Appellants' conduct, as set out in the district court's Memorandum Order dated June 24, 2025 (Order), clearly violates the Lanham Act (15 U.S.C. §§ 1051 et seq.). Further, because the importation of foreign drugs threaten patient health and safety, the injunction entered below is in the public interest. Amici, as advocates for patients, make five points in this brief, motivated by their shared concerns about AFPs generally and, in particular, by those that use foreign product.

First, the federal agencies charged with protecting public health and safety, Congress, and patient and health advocates, like Amici, have repeatedly warned that AFPs create unacceptable risks to patient health and safety. These serious risks frame and shape every aspect of this case.

Second, Turkish unapproved drugs like those Appellants provided to a U.S. patient are "materially different" than U.S. product, both because they are physically different in their packaging and labeling and because foreign drugs are subject to vastly different (and inferior) quality controls.

Third, Appellants' scheme is not only "likely" to create consumer "confusion", the compelling example of John Doe (Doe) shows that it created actual confusion. Indeed, patient confusion is inevitable given Appellants' scheme of providing foreign product with non-English labeling, denying patients any useful instructions for use and other critical health and safety information, including a "black box" warning.

Fourth, the Food, Drug, and Cosmetic Act in no way precludes Appellees' quite distinct and separate Lanham Act claims.

Fifth, the limited resources of the Food and Drug Administration (FDA) and its limited enforcement action targeting AFPs shows the important public interest served by the Lanham Act claims here and the district court's injunction.

ARGUMENT

I. AFPs that Use Foreign Product Raise Disturbing Health and Safety Risks.

Although Appellants dismiss the health and safety risks inherent in the importation of foreign product, their dismissive attitude is at odds with the federal government and a host of others, including Amici, that have spoken out repeatedly against AFPs and their risks.

The federal government could not be clearer about the substantial health and safety risks AFPs present. As the FDA recently stated in commenting on AFPs, "[m]edicines from outside the legitimate U.S. drug supply chain do not have the same assurance of safety, effectiveness, and quality as drugs subject to FDA oversight". S. Zamost, et al., "Cheaper Medicines, Free Beach Trips: U.S. Health Plans Tap Prescriptions that Feds Say Are Illegal", CNBC Investigations, available at https://www.cnbc.com/2025/11/13/employer-health-plans-afp-prescriptions-feds-illegal.html (Nov. 14, 2026) (CNBC Report), at 5. An FDA warning letter issued to an AFP flatly concludes that importation of foreign product "poses significant health risks to U.S. consumers". *Id.* (quoting FDA, Warning Letter to ElectRx and

Health Solutions, LLC, MARCS-CSM 614251, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023 (March 2, 2023)).

The FDA is not alone in sounding the alarm about AFP health and safety risks. The Department of Homeland Security, responsible for the customs inspections of imported drugs that are thwarted by the convoluted mechanisms used by AFPs to import foreign drugs, warns that AFPs are importing foreign drugs "through unverified suppliers" and online pharmacies. CNBC Report. at 2 (quoting an agency spokesperson). Because of the evasive means used to import these foreign drugs, "Customs has no idea" what the volume of foreign product being imported into the U.S. is. *Id*.

The U.S. House Appropriations Committee, for its part, recently expressed its "deep concern over the health risks posed by illegal importation of unapproved and misbranded drugs" involving AFPs. U.S. House Committee on Appropriations, House Report 119-172 (June 25, 2025). These "unapproved drugs", the Committee warned, "lack FDA

oversight" and are a health and safety risk, particularly for "vulnerable patients", like those living with HIV. *Id*.

But the government is by no means alone in seeing the disturbing health and safety risks that flow from AFPs. One of the Amici here, ADAP Advocacy, for instance, recently discussed these risks from a patient-advocate perspective. *See* R. Simons, "Alternative Funding Programs for Prescription Drugs Are Putting Patient Lives at Risk", *ADAP Blog*, available at https://adapadvocacyassociation.blogspot.com/2025/12/alternative-funding-programs-for.html (Dec. 4, 2025). Foreign product, it notes, is imported illegally, is misbranded and unapproved for use in the U.S., is dispensed through pharmacies that are not licensed in this country, is not subject to U.S. pedigree and recall procedures, and is distributed in a manner to "avoid" customs inspections. As a consequence, ADAP Advocacy cautions, patients are forced to "risk their lives" to obtain their medications. *Id*. Another leading patient group echoes this same concern, recently describing AFPs as a "gamble" where the stakes are patient health. *See* CNBC Report, at 13. And, as a recent investigative

report concluded, AFPs come "with a major catch", the significant "risks to patients' health" they bring. *Id*. at 2.

At the outset, then, it is critical to appreciate how AFPs engaged in foreign drug importation, like Appellants', are responsible for creating substantial risks to patient health and safety. That fact shapes and frames each of the issues discussed below.

II. Foreign Product Is Clearly and Materially Different than U.S. Product.

Many courts have recognized that a trademark holder is entitled to an injunction of the sale of products sold by others under "conditions materially different from those offered by the … owner". *See Iberia Foods Corp. v. Romeo*, 150 F.3d 298, 302 (3d. Cir. 1998); *see also Warner-Lambert Co. v. Northside Dev. Co.*, 86 F.3d 3 (2d Cir. 1996); *Shell Oil, Inc. v. Commercial Petroleum, Inc.*, 928 F.2d 104 (4th Cir. 1991) (discussing differences in quality control systems). The foreign product AFPs like Appellants provide to unsuspecting patients is materially different both on its face and based on the very different quality controls that apply to them.

A. Appellants' Foreign Product Is Materially Different on Its Face.

A "good" is not just the physical product itself, but the packaging and labelling that are sold with it—and that are often substantially responsible for ensuring that the product produces the intended result. Ensuring that a product is used as intended is a critical part of creating and maintaining a mark's value. This is particularly important in the case of medications. For these specialized products, packaging and labeling are the difference often between safe and unsafe use—addressing such critical issues as correct dosing, contraindications, complications, and other important health and safety issues. Because of the wholesale differences in labeling and packaging that exist between domestic product and the foreign product that Appellants imported into the U.S., Appellants' product was clearly "materially different".

Many courts recognize that, even with products that are not as dependent on packaging and labeling for safe use as drugs, the use of different packaging and labelling renders products "materially different". *See, e.g., Societe des Produits Nestle v. Casa Helvetia*, 982 F.2d 633 (1st Cir. 1992) (chocolates with packaging and language

differences); *Original Appalachian Artworks v. Granada Electronics*, 816 F.2d 68 (2d. Cir. 1987) (toy with use of Spanish language materials, instead of English); *Abbott Laboratories v. Adelphina Supply USA*, 15-CV-5826 2019 WL 5696148 (E.D.N.Y. July 14, 2016) (gray goods medical test strips, themselves physically identical, were materially different because infringing product used "atypical warnings, international units of measure, and different languages" in the labeling), *aff'd* No. 16-2659 (2d Cir. Nov. 3, 2016) (nonprecedential, but adopting the district court's reasoning).

The district court's decision below, much like in *Abbott*, *supra,* demonstrated how Appellants' foreign product is "materially different' from Gilead's domestic product on its face. Significantly, the labeling on Appellants' product was in Turkish, making the information provided useless for English speakers. Beyond that, additional differences included packaging, international units for temperature control to avoid loss of potency, the location and placement of patient information, and the absence of the "Rx only" symbol (which restricts the product to prescription only use). Order, at 21-23. The Gilead toll free 1-800

patient hotline number also is not present on the Turkish product, which fails to provide even an international number. *Id*.

The differences between domestic and Turkish product also involved the applicable warnings, including a "black box" warning, the highest-level warning in the U.S. Gilead's domestic product includes the "black box" warning, but it is entirely missing from what Appellants imported into the U.S. *Id*. The "black box" warning, importantly, addresses the risk of Hepatitis B exacerbation with the discontinuation of the drug.[1] The U.S. product, but not the Turkish product, only includes warnings related to the safe use of the product with other drugs and the importance of keeping it out of the reach of children. *Id*.[2]

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[1] The label reads, in part, "[s]evere acute exacerbations of hepatis B have been reported in patients with HIV-1 and HBV… and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months …." BIKTARVY is a highly effective drug, but, like any drug, there are important issues to consider in its use.

[2] Confronted with the concerns about the lack of health and safety information available in connection with foreign product, the Quartet Brief shockingly says that patients can perform "[a] Google search" to obtain that basic information. Quartet Brief, at 30. This callous disregard of a serious health and safety issue underscores the importance of this Court upholding the district court's injunction. Appellants' cavalier attitude about health and safety issues also

Amici, as patient advocates, cannot overstate the significance—and the health and safety risks—of these fundamental differences. The court below was absolutely right to conclude that these differences are "strong and clear", "material", and matter to patients. *Id*. at 23.[3] In the face of such material product differences, patients receiving Appellants' foreign product, like Doe, quite clearly do not receive the product they think they are purchasing. *See Iberia*, 150 F.3d at 303. As patient and health advocates regularly engaged with patients, we know that these differences are, without question, highly "relevant" to consumers. *See Janssen*, 2025 U.S.LEXIS 62483, at *4-5.[4]

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supports the district court's correct decision not to deny the injunction on "mootness' grounds.

[3] The Quartet Brief argues that this case does not involve any "lack of disclosure" in an effort to distinguish cases like *Janssen v. TLC Xpress Pharmacy*, 22-CV-1983, 2025 U.S. Dist. LEXIS 62483, at *21-22 (E.D.N.Y. Apr. 1, 2025), but that argument is belied by Doe's confusion in receiving foreign product with labeling in Turkish. Clearly, based on his confused reaction, the origin and labeling of the product was not disclosed to him. The Quartet Brief fails to list where all of the differences in foreign and domestic product are ever explained to patients. Based on our review of their public facing materials, we see no evidence of adequate or comprehensive disclosures.

[4] The Quartet Brief states that patients are not a "relevant consumer" for purposes of the analysis in this case, only employer sponsors are.

B. Quality Control Differences Also Render Appellants' Products Materially Different.

Differences in the quality control applied to domestic and foreign product also serve as a separate basis to conclude that products are "materially different". *See Iberia,* 150 F.3d at 303; *see also Shell Oil*, 928 F.2d at 106-107 (discussing the significance of differences in quality control systems). A trademark holder's "quality control and inspection procedure" has "often been recognized" as the "basis of a material difference" between products. *Iberia*, 150 F.3d at 304. In *U.S. v. Farmer*, 370 F.3d 435 (4th Cir, 2004), this Court upheld a criminal trademark conviction on the grounds that, among other things, even though the products were allegedly physically "identical," quality control differences existed. Given the vast differences in the quality control for Gilead domestic product and those that apply to Appellants' Turkish product, it is clear that the products are also "materially different" on that basis.

The material differences flowing from different quality control measures has been applied to a wide variety of products, many of which

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Quartet Brief, at 38. That argument reflects a breathtaking dismissal of patients and their health and safety.

implicate health and safety much less than medications. *See, e.g., El Greco Leather Products Co. Inc. v. Shoe World, Inc.,* 806 F.2d 392, 395 (2d Cir. 1986) (shoes). But even in products with far fewer health and safety implications—or none at all—the reason that differences in quality control create a trademark injury is readily "evident". *Iberia,* 150 F.3d at 303. Products subject to different quality control are materially different precisely because those controls are a "necessary part of maintaining consumer goodwill" in any mark. *Id.* at 304. Because quality control mechanisms are so clearly "important to consumers", courts do not require trademark owners to "show that the actual quality" of the goods is different. *Iberia*, 150 F.3d at 304; *see also El Greco*, 806 F.2d at 395.

The factual findings made by the district court fully support the conclusion that Appellants' foreign product and domestic product are subject to vastly different quality control mechanisms. Order, at 19-26. Perhaps most fundamentally, the regulations governing the manufacturing of U.S. and Turkish product are different. Order, at 19. Further, where U.S. product is thereafter subject to pedigree requirements, Turkish product is not. *Id.* at 22. Where U.S. product is

subject to targeted recalls here, under U.S. procedures, an event triggering a recall in Turkey generates a recall there, under its very different procedures. *Id*. at 23. The quality control mechanisms applicable to Turkish product are, as the court correctly concluded, "far inferior". *Id*. at 24.

Indeed, the difference in the quality control systems that apply is not even really a point of dispute between the parties. The Quartet Brief itself is replete with admissions that its foreign products are not subject to the same quality control mechanisms as U.S. product.

To cite just a few differences that Appellants effectively concede, the brief asserts that some non-U.S. countries have drug "track and trace" requirements, *see* Quartet Brief, at 6, but that, of course, means that some do not--and others that do still lack the U.S. system that applies to domestic product. The brief states that recall procedures exist in other countries, *see id*. at 17, but those procedures are not the same of the U.S. procedure. In this vein, Appellants do not dispute that a temperature issue when it arises does not create a "quality event" in Turkey, where it does in the U.S. *Id*. at 22. Appellants' repeated attempts to dismiss the importance of maintaining temperature control

over a product with strict temperature control requirements is deeply disturbing. *See* Quartet Brief, at 28.[5]

In a case like this, where quality control differences unquestionably exist, the Lanham Act is plainly violated.[6] Quality control differences matter to patients, including the patients that Amici represent; they are material to the patients we serve. *See Janssen*, 2025 U.S.LEXIS 62483, at *4-5.

[5] Further, U.S. product is dispensed by U.S. licensed pharmacies and pharmacists, subject to U.S. disciplinary standards; Turkish product, quite clearly, is not. *Id*. The brief claims that Appellants work with "vetted" foreign pharmacies using a company to perform that (undescribed) "vetting", Quartet Brief, at 2, but, by definition, those foreign pharmacies are not the U.S. licensed pharmacies. Appellants' "international pharmacy accreditor" is not a U.S. state licensing board. *Id*. The brief asserts that "counseling" is available for patients with questions about their medication, *see id*., but international pharmacists providing any counseling do not do as U.S. state-licensed professionals or subject to board of pharmacy standards.

[6] The first sale defense that Appellants make much of is inapplicable to this case because of the material differences that exist between the infringing product and Gilead's. *See, e.g., Beltronics US, Inc. Midwest Inventory Distribution, LLC*, 562 F.3d 1067, 1071 (10th Cir. 2009) (defense inapplicable where material differences are present).

III. Patients Are Confused by Foreign AFP Product.

Lanham Act cases require that consumer confusion is "likely" to occur. *See George & Co. v. Imagination Entertainment, Ltd.*, 575 F.3d 383, 398 (4th Cir, 2009); *Tools USA and Equip., Co. v. Champ Frame Straightening Equip., Inc.*, 87 F.3d 654, 661 (4th Cir. 1996). The evidence shows that patients are routinely confused by AFPs and their foreign product. Indeed, although not required, this case includes evidence of "actual confusion" in the compelling case of Doe.

Doe received his BIKTARVY, a drug he uses to treat his HIV, from Appellant Affordable, "a company with which Doe was unfamiliar and of which he had never heard". Order, at 4-6. Worse yet, the labeling on the product—the very information intended to inform patients about exactly what they have received and how it should be used—was written entirely in Turkish.[7] *Id.* Confronted by product from an entity he had never heard of and packaged and labeled in a language he could not read, Doe was "quite [u]nderstandably …

[7] To add to the concern here, "Turkey is one of the world's largest suppliers of counterfeit medicines". CNBC Report, at 4 (citing the Office of the United States Trade Representative).

confused". *Id.* at 5. Alarmed, Doe contacted his physician, and his physician, also confused, contacted Gilead to complain. *Id.* at 5-6. Given these circumstances, how could any patient not be confused?

From Amici's perspective, working with patients harmed by AFPs, Doe's reaction is no surprise. Members of the Amici group have heard from other patients similarly confused by AFPs and their convoluted schemes. ADAP Advocacy recently made this very point. Though "some patients" are aware that they are receiving foreign drugs from AFPs, "many are not". *ADAP Blog*, at 4. Even those patients that are aware their drugs are foreign in origin do not understand what that means or what risks they therefore face, except in the rarest of circumstances. This means that even those patients who know of the foreign *origin* of their drugs are typically confused by the *nature* of the product they have received.

Experts in the field say the same. The former head of the FDA's Office of Drug Security, Integrity, and Response warns that the average patient simply does not "understand the complicated nature of the distribution practice" in foreign product AFPs. CNBC Report, at 7. Patients "typically don't know the full extent of how AFPs work, or that

their medication may be illegally crossing borders". *Id*. The bottom line is that drug importation "misleads consumers". N. Quasba, *et al*., "What Should Prescribers and Policy Makers Know about US Drug Importation?", *AMA Journal of Ethics* (Apr. 2024).

Congress recently echoed these very same concerns about patient confusion. After recounting the many risks created by AFPs, the House Appropriations Committee specifically concluded that AFP product "can cause patient confusion". *See* House Report, at 80-81. The House Committee calls this a "significant danger[]". *Id*.

The fact that there is evidence here of "actual confusion" is all the more noteworthy because of the sensitivity around a consumer raising such a concern. Doe wishes to have his identity not disclosed to protect his health information. Order, at 5, 11. That understandable sensitivity illustrates why patients forced to use foreign product often will not make complaints or seek information when confused by non-English instructions on dosing, use, complications, or other essential safety issues. Consistent with Amici's own experience with patients, "personal privacy" concerns do, as the district court found, "dampen the likelihood that a confused consumer would complain". *Id*.

That, in many of Amici's experience, is all the more true when a product is used to treat a stigmatized disease like HIV. *Id.* The research on stigma, particularly in HIV and AIDS, and how it suppresses communication about medications, medication use, and other treatment issues is replete.[8]

Beyond that, however, the "dampening effect" is even greater—and has greater health and safety implications—here because these programs involve employer sponsors. Employee patients often fear

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[8] *See, e.g.*, L. Beer, et al., "HIV Stigma Among a National Probability Sample of Adults with Diagnosed HIV—United States, 2018-2019", *AIDS Behav*. (Jan. 2022) (concerns about public disclosure of health status and stigma are "common"); Centers for Disease Control (CDC), "HIV Stigma Page", available at https://www.cdc.gov/stophivtogether/hiv-stigma/ (last visited December 19, 2025); CDC, "HIV Stigma and Health Care Discrimination Experienced by Hispanic and Latino Persons with HIV—United States, 2018-2020", *Morbidity and Mortality Weekly Report*, 71(41);1293-1300 (Oct. 14, 2022) (stigma as a fundamental issue in addressing issues involving all aspects of "HIV care and treatment", with an impact so severe as to constitute a "national priority"); L. Mitzel, et al., "HIV-Related Stigmatization and Medication Adherence: Indirect Effects of Disclosure Concerns and Depression", *Stigma Health*, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC6824541/ (Aug. 2019) (Stigma and disclosure concerns interfere with "disease management"); J. Bonavitacola, "Stigma Remains Primary Health Concern in Patients with HIV/AIDS", *AJMC* (Dec. 19, 2024) (stigma and disclosure concerns lead to "hiding health problems").

losing their jobs if they make any complaint about their employment, including their employer-sponsored health coverage. *See, e.g.*, A. Bernhardt, *et al.*, "Broken Laws, Unprotected Workers: Violations of Employment and Labor Laws in America's Cities", *National Employment Law Project*, available at https://www.nelp.org/insights-research/broken-laws-unprotected-workers-violations-of-employment-and-labor-laws-in-americas-cities/ (last visited December 25, 2025).[9]

The evidence of patient confusion supporting the preliminary injunction is more than sufficient to show that Gilead is "likely to prevail on the merits". Patient confusion under the facts established by the court below is not merely "likely", it is inevitable.

IV. The Claims at Issue Here Are Separate from an FDA Enforcement Action, and Appellants Have No FDA "Defense" to Assert.

Although Appellants argue that the claims here represent an impermissible attempt to enforce the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (FDCA), Gilead's claims are quite distinct from an

[9] As patient advocates, we ask this Court in its forthcoming opinion to commend Doe for his bravery in raising his concern. All of us in patient and health advocacy owe him a debt of gratitude.

FDA enforcement action. It is, in fact, Appellants who (unsuccessfully) attempt to insert an FDA question into this appeal.

A. Lanham Act Claims Are Not an FDA Enforcement Action, and Gilead's Claims Do Not Require Any Consideration of Any FDA Question.

The case law is clear regarding the fundamental difference between an action to enforce the FDCA and one to address a Lanham Act violation--and the fact that each has its own complementary role to play. Where the former is "designed primarily to protect the health and safety of the public", *see POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014), the latter is "primarily intended to protect commercial interests", *see Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th. Cir. 1993).

No part of Gilead's Lanham Act claims required the court below or this Court to interpret or enforce the FDCA. Gilead does not seek to challenge an FDA approval decision, an FDA regulatory determination, or FDA's interpretation of the FDCA; Gilead's Lanham Act claims do not impinge in any way on the FDA's regulatory expertise or dictate how FDA chooses to deploy its enforcement resources. *Cf. Amarin*

Pharm., Inc. v. Int'l Trade Comm'n., 923 F.3d 959. 967-68 (Fed. Cir. 2019).

Appellants argue, in essence, that Gilead's Lanham Act claims should be precluded because Appellants' conduct *also* is illegal under the FDCA. That is not only not the law, but adoption of that position would eviscerate the Lanham Act in medical product cases. As a matter of law, no Lanham Act plaintiff is barred from "referenc[ing] FDA regulations" or the statute in articulating its Lanham Act claims. *See, e.g., Nestle USA, Inc. v. Ultra Distribuciones Mundiales S.A. De C.V.*, 516 F. Supp. 3d 633, 648-648 (W.D. Tex. 2021).

Appellants' argument here is absurd, and this Court should reject Appellants' invitation to adopt it.

B. It Is Appellants that Try to Inject an FDA Question Into This Case.

Appellants fault Gilead, without basis, for something it is not doing—trying to inject an FDA question into this case. Ironically, it is *Appellants* that actually try to do this. Specifically, Appellants argue that FDA's exercise of enforcement discretion for personal importation of a foreign drug is a "defense" to Gilead's Lanham Act claims. Quartet Brief, at 17. Appellants' argument is doubly wrong. First, the

exemption clearly does not apply; second, even if it did, it would be irrelevant.

FDA's personal importation enforcement discretion does not apply to Appellants. As a threshold matter, that discretion does not typically permit the "import [of] prescription drugs from other countries … as substitutes for FDA-approved drugs." *See* CNBC Report, at 6 (quoting FDA spokesperson); *see also* FDA, Regulatory Procedures Manual, Chapter 9-2, available at https://www.fda.gov/media/71776/download (last visited December 25, 2025). Appellant Santulli appears to understand the quandary that Appellants face here. When pressed by a reporter how his company's importation meets the requirements for enforcement discretion -- since Appellants imported medications, like Gilead's, are "already available for sale in the United States" -- Santulli "declined to comment further". CNBC Report, at 11. His silence speaks volumes.

More fundamentally, Appellants' importation scheme is not the "personal" act of an individual, but the product of a complicated and interconnected group of business entities acting in concert. The "personal" importation enforcement discretion guidance only permits an

individual person to import a supply of the drug for personal use. What Appellants do is decidedly not a *personal* act of importation.

The entire scheme to import foreign product is a business-initiated and -directed activity where corporate participants in the scheme advertise that business to "clients" that are not individual patients but healthcare coverage sponsors. The calls made to uninformed patients about this scheme are "*outreach* calls" initiated by a corporate participant in the scheme, not the patients. Order, at 4 (emphasis added). The patients do not identify or contact the foreign entity supplying the drug. The patients have no pre-established relationship with these pharmacies of any kind when the importation is initiated. *Id*. It is a corporate participant in the scheme that "contracts" with the foreign pharmacy, not the patient. *Id*.

Consequently, federal agencies have repeatedly rejected the claim that AFP vendors can lay claim to enforcement discretion. *See, e.g.*, CNBC Report, at 2 (Homeland Security spokesperson stating that patients required to use AFPs to gain access to drugs "are not actually importing the drugs themselves"). FDA warning letters reflect this same conclusion. *See* FDA, Warning Letter to Suprimo Imports,

available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/suprimo-imports-657631-06222023 (June 22, 2023); FDA Warning Letter to ElectRx and Health Solutions, LLC (March 2, 2023).

Finally, even if the exemption did apply in this case, it would not matter, as Lanham Act claims are not precluded by conduct that complies with the FDCA. *See POM Wonderful*, 573 U.S., at 113-117. It was on this basis that the district court correctly held that the personal importation enforcement discretion policy simply is not "relevant to this action". Order, at 7 n.5.

V. The Limited Nature of FDA's Enforcement Resources Underscores the Importance of Appellants' Separate Claims.

Entirely appropriate Lanham Act claims, like Gilead's, though primarily commercial in nature, may also result in "end customers", like Doe, realizing an indirect "benefit". *See POM Wonderful*, 573 U.S. at 107, 116 (Lanham Act "indirectly" protects "the public at large"). Thus, the lower court (quite correctly) found that the injunction is in the public interest because it enjoins Appellants' illegal conduct that creates patient health and safety risks. Order, at 59. Although Gilead's

claims are separate from an FDA enforcement action, the FDA's limited resources show why the claims made here are so important and in the public interest.

As the Supreme Court has held, the FDCA and the Lanham Act "complement each other". *See POM Wonderful*, 573 U.S. at 113-117. The FDA, for its part, "does not have the same perspective or expertise" in assessing activities in the market that "day-to-day competitors", like Gilead, possess. *Id*. Manufacturers with a self-interest in protecting their marks have better knowledge as to "how consumers rely upon" sales and marketing practices. *Id*. Accordingly, manufacturers often develop more accurate information than "agency rulemakers and regulators"—as was the case here, where Gilead, not FDA, identified Appellants' scheme. *Id*.

The need for the "complement" of the Lanham Act could not be clearer. Although the FDA has stated that AFP foreign importation schemes are illegal, FDA has been able to do little from an enforcement perspective, given its limited resources. FDA has issued only two warning letters. *See* CNBC Report, at 8. There are also some public reports of some criminal investigations, but those investigations

notoriously take a long time. *Id*. at 2 (citing Homeland Security spokesperson). Members of the Amici group have urged FDA to take substantially more extensive enforcement action, but to no avail. The indirect public interest value of the Lanham Act in circumstances like this is evident, underscoring the critical importance that this Court uphold the district court's injunction.[10]

Appellants defend their scheme, despite the disturbing health and safety risks it creates, based on a claim that BIKTARVY is "expensive".

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[10] In what appears to be a nod to the weakness of their argument on the merits, Appellants try to manufacture a defense by criticizing how quickly Gilead brought this case after FDA revealed that its limited resources would not support an enforcement action here. Absurdly, Appellants suggest that Gilead should have taken no more than two months to investigate the complicated arrangements here involving six parties spread over two continents and to undertake the other demanding work necessary to develop and bring this case.

Amici could not agree more with the finding of the court below that efforts to investigate AFPs are exceptionally difficult, in part because they actively seek to "avoid detection". Order, at 58. Amici, some of whom have experience with the frustrating exercise of trying to piece together these complicated AFP schemes, understand how much time it takes to undertake this kind of forensic work. Among the many complications present is the difficulty of convincing patients, worried about retaliation from their employers and afraid of public disclosure of their medical conditions, to participate in litigation.

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Though Amici appreciate the importance of trying to ensure that drug costs do not undermine patient access to treatments, foreign importation is simply not an acceptable means to try to improve access. Even if foreign importation reduces costs in a meaningful way, which is entirely inconsistent with the research, cost control that occurs by risking patient health and safety is unacceptable and contrary to the public interest.

Appellants' premise that importation will reduce the cost of drug therapy is unsupported by the literature. In part because drugs pass through a very complicated supply chain--with many intermediaries that assert their own charges, fees, and rebate demands--there is substantial evidence that foreign importation and AFPs do not meaningfully produce cost savings for either insurance sponsors or patients. *See* B. Lee, "Reimportation: A First Step or False Step Toward Transparency in the Prescription Drug Market?", *DASH.Harvard.edu* (2005), at fn. 525 (any importation savings may simply go to "intermediaries instead of consumers"); FDA, "Importation of Prescription Drugs", Docket No. FDA-2019-n-5711, available at https://www.federalregister.gov/documents/2019/12/23/2019-

27474/importation-of-prescription-drugs (Dec. 23, 2019) (declining to offer any estimate of what, if any, savings would be produced by foreign importation); N. Schaefer, "Debunking the Myths of Drug Importation", *Heritage Foundation*, available at https://www.heritage.org/health-care-reform/report/debunking-the-myths-drug-importation (July 20, 2024) (citing a Congressional Budget Office analysis concluding that foreign importation "would reduce prescription drug spending by only 1 percent", a decidedly "negligible" reduction). This is not surprising, as foreign importation trades one group of intermediaries for a different group, which are not subject to the same health and safety requirements.[11]

Regardless of a product's expense, however, the "price of AFPs is too high" given the health and safety risks they pose and the "hoops" that chronic and rare disease patients with life-threatening conditions are forced to "jump through" by them. *See* CNBC Report, at 12 (quoting a prominent patient advocacy organization). As another patient group

[11] Even a single negative outcome tied to the use of foreign product with use, dosing, and warning language not in English threatens to wipe away—entirely—the purported "savings" that an AFP generates for an employer sponsor.

has concluded, "[n]o matter how inexpensive" any drug appears to be under an AFP, it is too expensive when the "price of taking it" is a threat to the patient's health.[12] *ADAP Blog*, at 6. The answer to a concern about price cannot be to put patients' health and safety at risk.[13]

[12] Cost-based justifications for AFPs do not excuse patient confusion (and the health and safety risks that confusion creates); indeed, they make matters worse by encouraging and rewarding opacity in healthcare and the attendant derogation of the patient, both of which undermine patient engagement, agency, and access.

[13] Appellants point to some public policy efforts to consider foreign importation in some quite limited circumstances. *See* Quartet Brief at 40. But that public debate about whether there may be some limited, carefully controlled circumstances in which foreign importation might be permitted is no help to them. None of those circumstances apply here. Further, all of those efforts are premised on the adoption of heightened quality control mechanisms to deal with the widely acknowledged health and safety risks. Appellants have not adopted those mechanisms, let alone complied with existing law.

CONCLUSION

For all of these reasons, Amici ask this Court to affirm the district court. That result is the only one that can protect the health and safety of the patients that Appellants' conduct has put in jeopardy.

Dated: December 26, 2025 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with Rule 32(a)(7)(B) and Rule 29(a)(5) because it contains 6,317 words, excluding the parts preempted by Rule 32(f).
2. This brief also complies with Rule 32(a)(5)-(6) because it is prepared in a proportionately spaced face using Microsoft Word 365 in 14-point Century Schoolbook font.

The electronic version of the brief has been scanned for viruses and is virus-free.

Dated: December 26, 2025 *<u>/s/ William A. Sarraille</u>*

William A. Sarraille

CERTIFICATE OF SERVICE

I hereby certify that, on December 26, 2025, the foregoing was filed with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all counsel of record and all participants in the case are registered CM/ECF users, and that service will be accomplished by the CM/ECF system.

Dated: December 26, 2025 */s/ William A. Sarraille*

William A. Sarraille