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)

REPLY TO OPPOSITION TO 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: January 9, 2026

William A. Sarraille (D.C. Bar No. 431872)
SPECIAL COUNSEL TO AMICI CURIAE
1602 BELMONT STREET, N.W.
SUITE 500
WASHINGTON, D.C. 20036
Telephone: (202) 390-5679
williamsarraille@icloud.com

Special Counsel for the HIV and Hepatitis Policy Institute, the ADAP Advocacy Association, the International Foundation for Autoimmune and Autoinflammatory Arthritis, the Autoimmune Association, and HealthHIV

Amici Curiae, the HIV and Hepatitis Policy Institute, the ADAP Advocacy Association, the International Foundation for Autoimmune & Autoinflammatory Arthritis, the Autoimmune Association, and HealthHIV, hereby file this reply in support of their Motion for Leave to file their proposed amicus brief. We make four points.

First, the criteria for acceptance of an amicus are clear, broad and permissive, which is why amicus briefs, from patient advocacy groups like Amici, are so common in health care litigation.

Second, multiple, overlapping reasons to accept the amicus are present here, including the special expertise and unique perspective Amici have, as leading patient groups with direct experience with patients, including patients living with HIV and patients forced to use Alternative Funding Programs (AFPs). In addition, Amici speak directly to the issues of patient-consumer "confusion" and why patients see foreign, unapproved, and misbranded product as "materially different". On the critical issue of the "public interest", it is, in fact, Amici and only Amici that can speak to the relevant "public", because they represent and advocate for those patients.

Third, Defendants-Appellants' Opposition betrays their complete disregard of patients, which only further underscores the importance of the patient perspective that Amici bring to this appeal.

Fourth, Amici reiterate that Amici, and only Amici, have contributed to the proposed amicus, which reflects their and only their perspective.

I. The Standards for Acceptance of Amicus Briefs Are Clear, Broad, and Permissive.

The standards that courts use to evaluate whether to permit an amicus brief are well-known and expansive. As Defendant-Appellants concede, courts are "assist[ed]" by amicus briefs where they "present[] ideas, arguments, theories, insights, facts, **or** data that are not to be found in the parties' briefs". *Voices for Choices v. Illinois Bell Tel. Co.,* 339 F.3d 542, 545 (7th Cir. 2003) (emphasis added). Any one of these criteria are particularly likely to be met when "the amicus has a unique perspective" that is "beyond what the parties can provide", as is the case here. *Id*. Despite Defendants-Appellants' suggestion to the contrary, an amicus can and often does provide important assistance to the court "[e]ven when a party is very well represented". *See Neonatology Associates, P.A. v. Commissioner*, 293 F.3d 128, 132 (3d Cir. 2002).

This is true for multiple reasons, all of which apply in this case. "Some friends of the court", like Amici, are, for instance, able to "explain the impact a potential holding might have" on a particular group, like the patients targeted by AFPs. *Id*. But this is also true where an amicus "collect[s] background or factual references that merit judicial notice." *Id*. As a consequence—and quite unsurprisingly--patient advocacy groups and similar organizations commonly serve as amici, where health care issues affecting patient access are particularly difficult to place into context, given the complicated nature of our health care system.

II. Multiple, Overlapping Reasons Support the Amicus Brief Here.

The proposed amicus easily meets the criteria for an amicus that will assist the Court. Amici, who represent the very patient-consumers whose "confusion" at receiving foreign product is central to this case, have direct experience with how deeply patients are, in fact, confused by AFP schemes. The proposed amicus also speaks directly to the question of whether the misbranded, unapproved HIV treatment product supplied unlawfully by Defendants-Appellants is "materially different" from a patient perspective. Beyond that, the brief adds

additional facts, additional information, and additional arguments not contained in the parties' briefs. That additional information includes new information regarding the government's rejection of the so-called personal importation "defense" that Defendants-Appellants have mischaracterized to this Court.

The special expertise and, therefore, the special perspective of Amici could not be clearer. The parties to this litigation offer their own expertise, from their various business perspectives, and Plaintiffs-Appellees add the important perspective of an innovator in developing therapies, including drugs that treat HIV and AIDS. But no party to this litigation represents or can speak for the patient-consumer, other than Amici, who are patient advocates and, in many cases, themselves patients. No party can address, as Amici can, the unique patient perspective that lies at the heart of so much of this case, including how the district court's injunction so clearly serves the public interest. Amici's patients are the relevant "public" here, making Amici uniquely qualified to speak to this critically important question.

But the support for the proposed amicus brief hardly ends there. On both the "confusion" and the "materially different" questions—both

central to this case—Amici draw from their direct experience to address those questions. Amici know—first hand—the confusion and fear experienced by patient-consumers when forced to use AFPs and to risk their health and safety by doing so. Amicus Brief, at 19-23. That experience, as reflected in the proposed amicus, shows that patient-consumers see the different packaging, the fundamentally different labelling, and the lack of health and safety warnings associated with AFP product as "materially different". *Id*. at 12-14. This is not a guess or speculation on Amici's part. It reflects Amici's direct experience with patients and AFPs.

Similarly, Amici's direct experience with the Food and Drug Administration is relevant to the Court's determination of the public interest. Amici have sought enforcement action against AFPs, but the agency has only been able to respond with limited efforts, given its resource limitations. *Id*. at 29-30. This is a part of why it is so clearly in the public interest that the district court's injunction be upheld on appeal.

The support for the proposed amicus brief is broader still. In the case of Defendants-Appellants' baseless suggestion that they are

protected by a personal importation "defense", the amicus informs the Court of recent published statements from both the Food and Drug Administration and the Department of Homeland Security rejecting that very assertion. *Id*. at 25-27, *citing* 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). Based on our review, that information does not appear in any of the parties' briefs. Similarly, we point to an interview of one of the Defendant-Appellants where he is confronted by one of the reasons that the purported "defense" could not apply here, and he offers no rebuttal, effectively conceding the point. *Id*. at 26. We see no evidence of that damning interview in the parties' briefing. Further, from a patient perspective, Amici explain how there is nothing "personal" about the importation of foreign drug under these AFP schemes. These schemes are initiated and directed by business entities for their own (profit-driven) business purposes, not by patients.

These observations are, again, a function of direct experience with patients.[1]

III. Defendants-Appellants Betray Their Disregard of the Patient in Their Opposition to the Amicus.

Defendants-Appellants' Opposition, dismissive of Amici's role as advocates and representatives of patients, including people living with HIV, is a sad reflection of their disdain for the patient and the health and safety risks that their scheme has created. Even after being chided by Amici for Defendants-Appellants' rejection of the patient as a relevant "consumer" in this case, *Id*. at 14, they double down in the Opposition, weakly trying to parry Amici's serious concerns about the disturbing patient safety and health at issue here as merely "partisan" questions. Defendants-Appellants' anti-patient attitude, which permeates both their scheme and their briefing to this Court,

[1] Similarly, where Defendants-Appellants argue that Plaintiffs-Appellees purportedly "delayed" bringing this action, Amici report to this Court the difficulties Amici have faced in attempting to investigate AFPs, given the attempts made to hide the manner in which these schemes often operate and the reluctance of employees, who fear retaliation from their employers, to share their experiences on the record. Amicus Brief, at 22-23 and 29-30.

underscores why the special perspective of Amici, as advocates and representatives of patients, is needed here.

IV. Amici Offer a Distinct Voice and the Proposed Brief Reflects Only Their Views.

Defendants-Appellants, themselves profiting off of the health and safety risks to which they subject patients, criticize Amici because they note a board member of one of Amici is an employee of Plaintiffs-Appellees and the same Amicus and one other patient group have received some of their funding from that entity (among many others). Defendants-Appellants are able to make these points precisely because the not-for-profits both publicly disclose them. In any event, these arguments are entirely irrelevant to the ability of Amici to serve the Court by offering their uniquely patient perspective.

As Amici certified, Plaintiffs-Appellants did not ask Amici to file the amicus, made no financial contribution used to support the brief, did not review the brief, and suggested none of its content.[2] Amici, completely independent of Plaintiffs-Appellants, identified this case and

[2] The board member Defendants-Appellants cite did not receive any draft of the amicus brief and provided no input into its contents whatsoever.

the critical importance of it to the patients Amici represent. On the financial contribution point, as Amici have previously certified, there were no costs for the select counsel who authored this brief, as he is a volunteer to these organizations.

Amici operate under independent governance structures and with autonomous boards and missions. No funder—either a manufacturer or otherwise—exercises control over Amici policy positions, advocacy priorities, or litigation and other engagement. Amici's participation in this litigation is grounded in their missions and roles as national patient and provider focused organizations, including some that advocate for people living with HIV. It is a function of their long-standing expertise in patient and medical education, patient access, drug therapy, and the real-world experience of patients when confronted by confusing parts of the health care systems, including convoluted AFP schemes.

Defendants-Appellants' arguments here do nothing to call into question the fulsome certification, already before the Court, that shows that the proposed amicus brief is the product of Amici—and only Amici.

***

For all of these reasons and for the reasons set out in the Motion for Leave, Amici ask that this Court grant that motion.

Respectively submitted,

Dated: January 9, 2026

/s/ *William Sarraille*

William A. Sarraille (D.C. Bar No. 431872)
SPECIAL COUNSEL TO AMICI CURIAE
11322 BEACH MILL ROAD
Great Falls, VA 22066
Telephone: (202) 390-5679
williamsarraille@icloud.com

Special Counsel for the HIV and Hepatitis Policy Institute, the ADAP Advocacy Association, the International Foundation for Autoimmune and Autoinflammatory Arthritis, the Autoimmune Association, and HealthHIV

CERTIFICATE OF COMPLIANCE

1. This motion complies with Rule 32(a)(7)(B) and Rule 29(a)(5) because it contains 1,665 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: January 9, 2025 *<u>/s/ William A. Sarraille</u>*

William A. Sarraille

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing will be served this 9th day of January, 2026, electronically through the Court's CM/ECF system on all registered counsel.

/s/ *William Sarraille*

William A. Sarraille