IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GILEAD SCIENCES, INC., *et al.*,	:	
	:	
Plaintiffs,	:	Case No. 1:24-cv-03566
	:	
v.	:	
	:	
MERITAIN HEALTH, INC., *et al.*,	:	
	:	
Defendants.	:	
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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER, EXPEDITED DISCOVERY ORDER, AND ORDER TO SHOW CAUSE FOR A PRELIMINARY INJUNCTION

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Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, "Gilead" or "Plaintiffs") submit this memorandum of law in support of their application seeking immediate injunctive relief under the Lanham Act against newly added defendants CanaRx Services Inc., CanaRx Group Inc., and CRX International Inc. (together, "CanaRx"); Giles Robert Howard ("Bob Howard"); John Howard; ElectRx Health and Solutions, LLC ("ElectRx"); Jeffrey Dinsmore ("Dinsmore"); ScriptSourcing, LLC ("ScriptSourcing"); and Gary Becker ("Becker") (collectively "Defendants"). Gilead seeks (1) a temporary restraining order, to be followed by a preliminary injunction; and (2) an order authorizing expedited discovery. This is Gilead's first motion for injunctive relief against these Defendants.

The newly added Defendants at issue in this motion are participants in the same illegal importation scheme as the originally named defendants. As a result, many of the factual and legal issues presented in this motion are identical to those addressed in the Court's recently issued preliminary injunction against those original defendants. To create a full record, in the instant motion Gilead presents the relevant factual and legal issues below, including those that overlap with the issues presented with regard to the originally named defendants; where appropriate, portions of the motion below are copied verbatim or nearly verbatim from Gilead's previously filed memoranda of law.

INTRODUCTION

Gilead brought this action to put an immediate stop to Defendants' infringing and unsafe scheme to illegally import non-FDA-approved prescription medicines from foreign markets and deliver them via unsecured, unregulated and unmonitored supply chains to American patients. These patients have U.S. commercial health insurance and have received prescriptions from U.S. doctors for Gilead medication to treat serious diseases like HIV, and they should receive the

same FDA-approved, securely distributed Gilead medicines as every other American. But rather than safely securing FDA-approved medicine, these patients' health insurers instead direct them to the insurers' "international mail order partners." These "partners" fill American patients' prescriptions by having pharmacies in international locations ship non-FDA-approved versions of the medicine in foreign-labeled bottles to patients' doorsteps in Maryland and around the nation.

Gilead brought this suit after receiving a whistleblower complaint from a Maryland doctor whose patient received Turkish BIKTARVY® in the mail. Gilead originally named as defendants the entities and individuals who were involved in advertising, facilitating, and shipping that illegally imported, infringing Gilead-branded HIV medicine to that one John Doe patient. But as became clear in expedited discovery, there is a wealth of companies dedicated to turning an illicit profit by illegally importing foreign pharmaceuticals to fill U.S. patients' prescriptions – companies that work with multiple insurers, third-party administrators, and pharmacy benefit managers to unlawfully bring infringing, non-FDA-approved drugs into this country.

The newly added corporate Defendants that are the subject of this motion – CanaRx, ElectRx, and ScriptSourcing – are all business partners of one or more of the originally named defendants, and they received notice of this lawsuit and this Court's injunctions against the sale of infringing international Gilead-branded medicines. These new Defendants are some of the largest players in the illegal-importation industry, and they have long known that their business models are illegal and dangerous to patients. Indeed, the FDA said as much to CanaRx and ElectRx in official Warning Letters instructing them to cease and desist their illegal importation scheme, which both entities willfully defied. And as Gilead and the Court learned from

expedited discovery, ScriptSourcing presided over the horror of importing a supposedly "international version" of a drug that was in reality a counterfeit, causing serious harm to the patient. And yet after being given notice of this lawsuit and learning of this Court's injunctions against trafficking international Gilead products in the United States, these entities have continued their efforts to supply commercially insured U.S. patients with non-FDA-approved, infringing foreign Gilead-branded medicines. Gilead therefore moves for immediate injunctive relief to put a stop to these large-scale infringers' ongoing violations of Gilead's trademarks, which continue to put innocent U.S. patients at risk.

The law and the relevant facts concerning the material differences between Gilead's U.S. and international medications are the same here as they were with regard to the originally named defendants. As this Court has already found in determining Gilead likely to succeed on its Lanham Act claims against the originally named defendants, all international Gilead-branded medicines are infringing when used in U.S. commerce under the material-differences and quality-control doctrines. The newly added Defendants are all direct infringers who make use of Gilead's registered trademarks to advertise and broker the sale of infringing international products to U.S. consumers, and while they are all clearly willful infringers, they are all strictly liable under the Lanham Act. As with the originally named defendants, the illicit, unregulated, and unsecured supply lines that the newly named Defendants have established breach the closed U.S. pharmaceutical supply chain and put patients at risk. This Court should not allow these Defendants to profit at the expense of patient safety and Gilead. The Defendants' trafficking of infringing, non-FDA-approved drugs should be immediately enjoined.

STATEMENT OF FACTS

I. GILEAD'S TRADEMARKED PHARMACEUTICAL PRODUCTS

Gilead is a biopharmaceutical company headquartered in Foster City, California. Gilead has developed some of the world's leading antiviral medications, including drugs used in the treatment of HIV, as well as COVID-19, influenza, hepatitis C, and other serious illnesses. Hundreds of thousands of patients rely on Gilead's antiviral drugs to live normal, healthy lives. For example, Gilead's medicines BIKTARVY® and GENVOYA® are both once-daily tablets for the treatment of HIV infection. Declaration of Brian Nilstoft ("Nilstoft Decl.") at ¶ 5, attached hereto as Exhibit 1 to the Declaration of Geoffrey Potter dated September 30, 2025 ("Potter Decl."). Taken daily as prescribed, BIKTARVY® and GENVOYA® can reduce a patient's viral load to undetectable levels.

As this Court already found, Gilead owns a number of registered and well-established trademarks that appear on the packaging of all genuine Gilead-branded medications. *Gilead Scis., Inc. v. Meritain Health, Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *11 (D. Md. June 24, 2025), *appeal filed*, Nos. 25-1828, 25-1829 (4th Cir. Jul. 21, 2025). Those trademarks and proof of their registration are set forth as Exhibit 1 of the Declaration of Gretchen Stroud, dated Dec. 5, 2024 ("Stroud Decl."), attached hereto as Exhibit 2 to Potter Decl. Ms. Stroud's declaration also sets forth evidence of the marks' use in interstate commerce.

II. OVERVIEW OF THE NEWLY NAMED DEFENDANTS' SCHEME TO IMPORT GILEAD-BRANDED MEDICINES

As set forth in more detail below, the newly named Defendants are all members of the same scheme as the originally named defendants. CanaRx, ElectRx, and ScriptSourcing are all in the business of arranging for insured U.S. patients' prescriptions to be filled with infringing,

illegally imported, non-FDA-approved brand-name medicines from foreign countries, including Gilead-branded HIV medicines. *See infra* pp. 12-21, 23-28.

None of these newly added Defendants is a third-party administrator ("TPA") like defendant Meritain, or a pharmacy benefits manager ("PBM") like defendant ProAct. Instead, CanaRx, ElectRx, and ScriptSourcing are all entities that partner with numerous health plans, TPAs and PBMs, brokering the delivery of infringing, illegally imported medicines to patients covered by the health plans affiliated with those TPAs and PBMs. *See* Potter Decl., Exs. 3, 4; 5; 6; 7 at 13. CanaRx, ElectRx, and ScriptSourcing are then paid by the health plans, often through the affiliated TPA and/or PBM for that plan. *See id.* It is no secret that these Defendants engage in illegal importation of prescription drugs: it is their avowed business model. Each of these Defendants openly advertises its illegal-importation business to patients and health plans, and each Defendant hosts its own patient-facing website that lists multiple international Gilead-branded medicines that insured U.S. patients can obtain through that Defendant. *See* Potter Decl., Exs. 8, 9 (flyer from ElectRx website), 10.

The newly named corporate Defendants conspired with the originally named defendants in their illegal-importation scheme For example:

- CanaRx [redacted]. *See* Potter Decl., Ex. 11.
- CanaRx [redacted]. *See* Potter Decl., Exs. 12, 13.
- [redacted] worked with [redacted] to source international Gilead-branded medicines like BIKTARVY®. *See* Potter Decl., Ex. 14 at -982.
- ScriptSourcing was the subject of Meritain's private and public decrying of the "horror story" where ScriptSourcing caused grievous physical harm to a patient by providing a counterfeit medication disguised as a gray-market import – but even after that, Meritain continued paying ScriptSourcing's invoices for illegally

imported medications. *See* Potter Decl., Exs. 15, 16, 104 (Prelim. Inj. Hearing Tr. at 85:25-86:19).

In addition to these newly added corporate Defendants, Gilead seeks injunctive relief against individuals responsible for these companies' importation of prescription drugs to the United States. As with the originally named individual defendant Gregory Santulli, the CEO of Rx Valet, these new individual Defendants are officers and directors of their respective companies, and are active and moving forces behind their respective corporate entities' international importation programs.

III. U.S. FEDERAL LAW STRICTLY PROHIBITS IMPORTATION OF PRESCRIPTION DRUGS AS A MATTER OF PATIENT SAFETY

As set forth below, Gilead seeks injunctive relief in this motion solely on the basis of its claims for federal trademark infringement. However, it is important to recognize that the importation of international Gilead-branded products not only violates the Lanham Act, but also violates the Food, Drug, and Cosmetics Act ("FDCA") and is a strict-liability federal crime. *See Gilead Scis., Inc. v. Meritain Health, Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *25-27, 31 (D. Md. June 24, 2025). To be clear: Gilead does not attempt to assert any private cause of action under the FDCA. But as this Court has recognized, it is certainly relevant here that Congress has determined that importation of prescription drugs poses a threat to patient health and safety. *Id*. Moreover, Defendants cannot be prejudiced by being enjoined under the Lanham Act from engaging in activity that is already illegal as a matter of federal regulatory and criminal law. *See id.* at *31.

1. Importation of Prescription Drugs by Anyone Other Than the Manufacturer Is Illegal and a Strict-Liability Crime

"[V]irtually all importation of drugs into the United States" violates the FDCA. *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 788-89 (8th Cir. 2006) (rejecting antitrust claims

alleging a conspiracy to prevent importation of prescription drugs from Canada, holding that plaintiffs could assert no injury from the alleged conspiracy because importing prescription drugs is already prohibited by federal law); *see also Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *25-27, 31 ("importation into the U.S. of prescription medication is illegal under the FDCA"); *PharmacyChecker.com v. Nat'l Ass'n of Bds. of Pharmacy*, No. 19-CV-7577 (KMK), 2023 WL 2973038, at *20-21 (S.D.N.Y. Mar. 28, 2023) ("[F]oreign pharmaceuticals – manufactured and distributed abroad and later imported into the United States – are 'unapproved' drugs within the meaning of 21 U.S.C. § 355") (citations omitted); *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238, 1247-48 (N.D. Okla. 2003) ("Rx Depot's importation of prescription drugs [from Canadian pharmacies] clearly violates the law."); *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 471, 474 (D. Vt. 2005) (explaining that "[t]here is no question" that a program purporting to facilitate "orderly… importation" of prescription drugs to U.S. would violate the FDCA); *Pharm Rsch. & Mfrs. of Am. v. Dep't of Health & Human Servs.*, 656 F. Supp. 3d 137, 143-44 (D.D.C. 2023); *Montgomery Cnty., Md. v. Leavitt*, 445 F. Supp. 2d 505, 509-10 (D. Md. 2006). Federal law prohibits not only importing prescription drugs, but also "causing" them to be imported. 21 U.S.C. § 331(t). Even prescription drugs manufactured inside the U.S. cannot be re-imported except by the original manufacturer. *See* 21 U.S.C. § 381(d)(1).

Prescription drugs in the United States, including Gilead-branded medications, are subject to strict regulatory requirements for the safety of U.S. patients. *See, e.g.*, 21 U.S.C. §§ 352, 355, 21 C.F.R. §§ 208.20, 208.24. International medications "are not approved pursuant to this statutory framework" – even if they have the same chemical composition as the FDA-approved version of the drugs – and thus are "unapproved" pursuant to 21 U.S.C. § 355 and

"misbranded" (and unlawful to sell) pursuant to 21 U.S.C. § 353. *Canadian Imp. Antitrust Litig.*, 470 F.3d at 789-90; *see also Leavitt*, 405 F. Supp. 2d at 473 (explaining that "even a foreign version of an FDA approved drug" is "unapproved" within the meaning of 21 U.S.C. §§ 331(a) and (d) when it does not meet "packaging, labeling, and dosage requirements"). The sale of unapproved or misbranded drugs is a strict-liability crime – one of very few strict-liability crimes in the federal system. 21 U.S.C. §§ 331(a), 333(a).

These anti-importation laws were passed in the wake of several high-profile incidents of American patients receiving counterfeit drugs, including birth-control pills, disguised as "authentic" foreign imports. *See* Potter Decl., Ex. 17 at 8. They reflect Congress's determination that a "closed system" that "excludes noncompliant and potentially unsafe pharmaceuticals" best serves the interests of American patients. *Canadian Imp. Antitrust Litig.*, 470 F.3d at 790 (citation omitted); *see also* Potter Decl., Ex. 17 at 11 (explaining that the U.S.'s "closed" drug distribution network "evolved as a result of legislative requirement that drugs be treated as potentially dangerous consumer goods that require professional oversight to protect the public health"). Congress has created strict guardrails on the U.S. supply chain for prescription drugs, which protect the integrity of drugs dispensed to U.S. patients and prevent the introduction of counterfeit and adulterated products. *See Prescription Drug Marketing Act of 1987*, Pub. L. 100-293 (HR 1207), § 2(4), 102 Stat. 95, 95 (1988) (reciting Congressional findings that drugs imported to the U.S. "are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping"); *see also* Potter Decl., Ex. 18 at 3 (warning U.S. citizens that "[t]he FDA cannot ensure the safety and effectiveness of medicine purchased over the Internet from foreign sources"). This concern is not just theoretical: for example, in 2018, a Canadian online pharmacy that purported to ship

prescription drugs to the United States pled guilty to shipping to U.S. patients counterfeit cancer drugs, which contained no active ingredients.[1] For these reasons, the FDA has issued public Warning Letters to Defendants CanaRx and ElectRx, stating that their involvement in importing international prescription drugs – specifically including Gilead-branded HIV medicines – violates U.S. law and poses "significant health risks to U.S. consumers." *See* Potter Decl., Exs. 20 at 2; 21 at 2.

2. The "Personal Importation" Myth

The originally named defendants argued that the importation they facilitated was legal under the FDA's supposed "Personal Importation" policy, and this Court correctly rejected those arguments in granting the preliminary injunction against them. *See Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *31. The newly named Defendants make the same arguments about "personal importation" in their public statements and advertising, which continue to be flatly wrong as a matter of law.

As an initial matter, the FDA's "personal importation" policy does not, and cannot, take an activity that is criminal and illegal pursuant to multiple federal statutes and transform it into lawful activity. At most, the personal-importation policy is an act of prosecutorial discretion on behalf of individual FDA agents. Not only is this true as a matter of law and common sense, but the FDA also directly states as much in articulating its personal-importation policy: it states flatly that "[i]f a drug is approved for use in another country but is an unapproved new drug in the U.S. it is illegal to import," but that the FDA, like all enforcement agencies, attempts to "gain the

[1] *See* Potter Decl., Ex. 19 (U.S. Attorney's Office for the District of Montana, *Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States* (Apr. 13, 2018), https://www.justice.gov/usao-mt/pr/canadian-drug-firm-admits-selling-counterfeit-and-misbranded-prescription-drugs).

greatest degree of public protection with allocated resources," and so "FDA personnel may consider a more permissive decision" with regard to enforcement against imported drugs that fall within the stated parameters of the personal-importation policy. *See* Potter Decl., Exs. 18; 22 at 21; 24. The FDA's granting enforcement discretion to its personnel in defined, highly restrictive circumstances does not, of course, somehow render the importation of foreign pharmaceuticals legal.

In any event, even interpreting the parameters of the FDA's "Personal Importation" policy as generously as possible, on its face the policy simply does not apply – ever – to the importation of international Gilead-branded prescription medications. For prescription medicines (as opposed to over-the-counter drugs), the personal-importation policy applies only where the international medication "is unapproved and for a serious condition for **which effective treatment may not be available domestically either through commercial or clinical means**." *See* Potter Decl., Ex. 22 at 24 (emphasis added). Similarly, the FDA specifies that the personal-importation policy applies only where "[t]here is **no known commercialization or promotion of the product to persons residing in the United States**." *Id.* (emphasis added). In other words, the FDA's personal-importation policy only applies – *i.e.*, only provides FDA agents prosecutorial discretion – with regard to prescription drugs that are *unavailable in the United States*. All Gilead-branded medications are commercialized and promoted in the United States and are widely available in the United States with a valid prescription; they are thus outside the scope of the personal-importation policy. *See* Potter Decl., Ex. 2 (Stroud Decl.) at ¶ 16. Indeed, the FDA has expressly rejected Defendants' position, declaring that its personal-

importation policy "is not intended to permit personal importation of cheaper versions of FDA-approved drugs from Canada or other foreign countries."[2]

IV. DEFENDANTS' ILLEGAL DISTRIBUTION NETWORK PUTS AMERICAN PATIENTS AT RISK OF RECEIVING COUNTERFEIT MEDICINES

The dangers posed by breaching the highly secure U.S. pharmaceutical supply chain are apparent here. Defendants instruct patients to disregard the differences between the illegally imported medicines they receive through the mail and the authentic U.S. medicines they are used to receiving, and offer empty blanket assurances that the foreign medicines they receive are "safe." *See* Potter Decl., Exs. 7 at 5; 24 at 2; 25; 26. Defendants deliver those international medications through an unsecured, unregulated and unmonitored pharmaceutical supply line directly from a foreign pharmacy to American patients' front doors. The creation of any such illicit supply chain creates an unacceptable risk of counterfeit medications being delivered to American patients disguised as foreign imports. *See, e.g.*, *Rx Depot, Inc.*, 290 F. Supp. 2d at 1246-48 (explaining that even re-importation of prescription drugs manufactured at FDA-approved facilities in the U.S. creates "an unacceptable risk that counterfeit … drugs will be sold to American consumers" unless the manufacturer itself is doing the re-importation) (citation omitted). Foreign pharmaceutical counterfeiters are continually looking for opportunities to penetrate the closed U.S. drug distribution system. Defendants have handed pharmaceutical counterfeiters that opportunity. Indeed, as the Court is already aware, it was widely known in Defendants' industry that ScriptSourcing was responsible for importing a supposedly

[2] Potter Decl., Ex. 23 (U.S. Food and Drug Admin., *Personal Importation Policy (PIP) Frequently Asked Questions (FAQs)*, https://fda.report/media/83411/PIP-Faqs.pdf.).

"international" prescription medication that turned out to be counterfeit, with devastating health consequences for the patient. *See infra* at 27-28.

V. EACH OF THE NEWLY ADDED DEFENDANTS WILLFULLY CAUSED ILLEGALLY IMPORTED GILEAD-BRANDED MEDICINES TO BE DISTRIBUTED TO U.S. PATIENTS

Each of the newly named Defendants is a knowing and willful infringer who intentionally engages in the illegal importation of Gilead-branded medications.

A. CanaRx

CanaRx, a self-described "international prescription service provider," has dedicated its entire business model to providing U.S. patients with illegally imported, non-FDA-approved foreign prescription medicines. *See* Potter Decl., Ex. 27. CanaRx openly advertises its brokering, importation, and sale of international Gilead-branded HIV medicines to U.S. patients, including BIKTARVY®, GENVOYA®, ODEFSEY®, and VIREAD®. *See* Potter Decl., Ex. 28 (CanaRx formulary dated Sept. 23, 2025), *see also id.* Exs. 29; 30; 31; 32; 33; 34; 35.[3]

1. CanaRx's Business Model

As noted above, CanaRx partnered with originally named defendant ProAct to mutually advertise and solicit patients into CanaRx's illegal-importation scheme. Potter Decl., Ex. 11. [redacted]. *See* Potter Decl., Ex. 36 [redacted]).

[3] On February 27, 2024, a healthcare provider reported to Gilead that CanaRx shipped a U.S. patient international GENVOYA®. The patient sent sample photographs of the carton and label obtained by CanaRx, which bore an overlabel that identified a pharmacy based in Australia. Based on the photographs, the carton and label were consistent with international GENVOYA® packaged for the Australian market.

But ProAct is just one of many entities with which CanaRx works in its illegal-importation scheme. CanaRx works with numerous health plans, PBMs, and TPAs, who, at minimum, (1) advertise CanaRx to their members; (2) agree to provide health insurance coverage for prescription drugs sourced by CanaRx from foreign locations; (3) provide access to eligibility information about members to ensure that CanaRx is shipping foreign medicines to individuals who have health insurance coverage that will pay for them; and (4) process CanaRx's invoices and provide payment for the prescription drugs that CanaRx illegally imports to U.S. patients. *See, e.g.*, Potter Decl., Exs. 37; 38; 39 (advertising the "numerous benefits to plan sponsors" from CRX's international sourcing program, "including no administrative costs, liability insurance coverage, plan design and development assistance, website design and hosting, and, of course, the savings").

In its patient-facing materials, CanaRx says that its international-importation program is "[redacted] but simultaneously tells patients that if they do not choose to use CanaRx to fill their prescriptions internationally, [redacted]. For example:

[redacted]

See Potter Decl., Ex. 33 at -649. These patient-facing enrollment forms also contain [redacted]. *Id.* at -652. These enrollment forms also advertise the availability of international Gilead-branded medications by using their trademarked brand names. *Id.* at -650.

2. The FDA Warning Letter to CanaRx

The FDA sent an official Warning Letter to CanaRx Services Inc., CRX International Inc., "and all entities conducting business by or on behalf of CanaRx" in 2019, stating that "CanaRx operates as a prescription drug provider that engages in activities to cause the introduction of unapproved new drugs from foreign sources into the United States," and so was "in violation of sections 301(a), 301(d), and 505(a)" of the FDCA. Potter Decl., Ex. 20 at 2. In other words, because international prescription medications are *not* approved by the FDA and do *not* follow the FDA's requirements for packaging, labeling, dosage, and the like, they are considered "unapproved new drugs" in the United States. Indeed, the Warning Letter noted that CanaRx tells its patients that "[d]epending on your country, our medications may appear to be different in size, shape or color," and stated that "[h]aving this disclaimer in each invoice demonstrates that CanaRx has designed its business to operate in a manner that substitutes the FDA-approved drugs prescribed by the U.S. healthcare provider with unapproved drugs." *Id.* The FDA's Warning Letter further noted that because international prescription medications are not labeled in accordance with FDA regulations, they also constitute misbranded drugs, and that "[b]y causing these products to be shipped to U.S. consumers, CanaRx is causing the introduction of misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act." *Id.* at 4.

The FDA's Warning Letter also stated that CanaRx's "substitution of FDA-approved prescription drugs with unapproved drugs poses significant health risks to U.S. consumers," and noted that risk was especially high where the imported drugs were "indicated to treat serious conditions such as HIV." *Id.* at 2. The Warning Letter called out several aspects of CanaRx's importation program that posed a serious health risk to U.S. patients, including that: (1) importation undermines "established processes to recall" drugs, rending recalls ineffective; (2)

differences in the labeling of foreign drugs "can cause patient confusion and lead to medication errors"; and (3) foreign drugs "do not have the same assurance of safety and efficacy as drugs subject to FDA oversight and may be subpotent, superpotent, or adulterated with unknown active ingredients," which is especially dangerous to "vulnerable patient populations that suffer from serious conditions such as HIV." *Id.* The Warning Letter listed "as examples of drugs on CanaRx's medication lists" fourteen drugs that CanaRx was illegally importing from foreign countries. *Id*. at 2-3. On that list is TRUVADA®, a Gilead-branded HIV medication. *Id.*

3. CanaRx's Defiance of, and Misinformation Campaign About, the Warning Letter

CanaRx was not deterred in the slightest by being directly told, in writing, by the FDA that its business model was both illegal and dangerous for patients. Instead, CanaRx continued to willfully put U.S. patients at risk by illegally importing prescription medications – while simultaneously engaging in a public misinformation campaign about the Warning Letter. Even today on its website, CanaRx continues to falsely claim that it merely assists U.S. patients in engaging in "personal importation" and proclaims: "Personal importation is the right and choice of every American Citizen." Potter Decl., Exs. 24, 25. And in the "Q&A" section of its website, CanaRx poses the question: "What are the most common misunderstandings about CanaRx's products and services?" CanaRx answers its own question by telling consumers that they should not care whether the medicine they receive is FDA-approved, because, according to CanaRx, FDA approval is just a rubber-stamp process: "The medications on our formulary are the Tier 1 equivalent approved for distribution in the U.S…. It's just a matter of who applied the rubber stamp (FDA versus Health Canada, for example)." Potter Decl., Ex. 41. And, despite the FDA's warning that telling patients to ignore subtle differences between international and U.S. medication could be dangerous, CanaRx's website continues to reassure patients that they can

and should take international prescription medicine that is different from prescription medicine intended for sale in the United States: "Although the drugs you receive may in limited circumstance [*sic*] look slightly different or have a different name than what you are used to, for all intents and purposes they are identical." Potter Decl., Exs. 24, 25.

And in a self-authored "article" on its website dedicated specifically to the FDA Warning Letter, CanaRx brazenly attempts to mislead U.S. consumers into believing that its operations are permitted by the FDA:

> In February 2019, CANARX received a warning letter from the FDA that was highly publicized. The regulatory agency expressed a number of concerns relating to 14 specific medicines involving complicated or specialized administration that the FDA would prefer to see dispensed by local pharmacists who can hold frequent, direct, hands-on follow-up visits with the patients. CANARX reviewed the FDA's letter, responded thoroughly to it, and, in an abundance of caution, decided to stop assisting patients in personally importing each of the 14 medications flagged by the FDA.
>
> "We recognized their concerns and, though we have never had an issue with any of the medications in question, we agreed to remove them and show the FDA our willingness to work with them for the greater good," said Bob Howard, President of CANARX.

See Potter Decl., Ex. 42, at 1. This representation that the Warning Letter was confined to "14 specific medications … that the FDA would prefer to see dispensed by local pharmacists" is a shameless attempt to dupe U.S. patients who did not actually read the letter. *Id*. at 2. The Warning Letter could hardly have been clearer that *any* prescription drug manufactured and labeled for a foreign country is not FDA-approved, constitutes an unapproved drug and misbranded pharmaceutical in the U.S., is illegal to dispense in the United States, and poses a serious health risk to U.S. patients. And after the Warning Letter repeatedly called out imported HIV medicines as posing an especially high risk to patients, the idea that CanaRx "showed the FDA [its] willingness to work with [the FDA] for the greater good" by discontinuing its sales of

international TRUVADA®, while continuing to endanger patients by selling multiple other international Gilead-branded HIV medicines subject to the same concerns, is a farce.

But CanaRx's misinformation campaign goes even further, and perversely attempts to spin the Warning Letter into an FDA *endorsement* of CanaRx's illegal-importation scheme. For example:

> "Some may see a letter from the FDA as a bad thing – we do not. We believe the FDA's attention provides an extra layer of regulation and safety for our clients. It's our willingness to work with them that makes all the difference," Howard said. "We at CANARX are eager to have and to comply with clear guidance from regulators." Some of our competitors – the same people who call attention to the fact that we received an FDA letter – flout the very cautions set forth in the FDA letter and routinely ignore numerous other FDA and safety standards."

Id. at 2. That paragraph is immediately followed by a large-font callout box in which CanaRx calls the Warning Letter an FDA "validation" of CanaRx's illegal business model:

> We see it as an example of collaboration and validation of our ongoing efforts to ensure the safety of our program.

Id. The CanaRx "article" about the Warning Letter concludes: "CANARX believes it offers the highest-quality, safest products on the market **and its compliance with the FDA is proof of that commitment.**" *Id.* at 3 (emphasis added).

In sum, in obvious and direct contravention with the FDA's Warning Letter, CanaRx continues to brazenly violate the law by causing international medicines, including Gilead-branded HIV medicines, to be delivered to U.S. patients. CanaRx's lie that its program is now in "compliance with the FDA," and its attempt to spin the FDA's written condemnation of its entire business model as "an example of collaboration and validation" is nothing more than a con job

intended to trick U.S. patients into believing that the FDA has blessed CanaRx's illegal-importation scheme.

4. CanaRx's Business Practices Violate the Laws of the Foreign Countries from Which They Import Medications

CanaRx's business practices do not just violate multiple U.S. civil and criminal laws: they also violate the laws of the jurisdictions from which CanaRx imports medications. For example, on October 3, 2024, the Ontario College of Pharmacists ("OCP") – the body responsible for regulating the pharmacy profession in Ontario, Canada – took disciplinary action against an Ontario pharmacist whose pharmacy had entered a contractual agreement with CanaRx to dispense prescription medicines to U.S. patients. *See* Potter Decl., Ex. 43. OCP stated it received records regarding the case "from the execution of a search warrant at the offices of CanaRx Services Inc., a company suspected of operating a scheme to sell prescription drugs by retail from Ontario to US patients." *Id.* at 7.

OCP found that the Canadian pharmacist had engaged in professional misconduct and violated multiple Canadian pharmacy practice standards and laws through his dealings with CanaRx, including: that the pharmacist had dispensed prescription drugs to U.S. patients without confirming that the prescriptions were based on a valid physician-patient relationship; had dispensed prescription drugs based on prescriptions issued by healthcare providers who were not practicing in the relevant Canadian province; and had filled prescriptions based on invalid refill authorizations. *Id.* at 7-10. Among other findings, OCP held that CanaRx had recruited Canadian physicians who "agreed to 'co-sign' or reissue prescriptions issued by US-based physicians for their US-based patients"; OCP stated that practice "arguably renders the prescriptions superficially valid," but noted that the "problem with such arrangements, though, is that the Canadian-based physicians have no physician-patient relationship with the patient, or if

they do, have only a limited ability to assess the patient and the appropriateness of the prescription for that patient." *Id*. at 7-8. The Canadian pharmacist admitted the charges against him, but noted as a mitigating factor that "he relied upon the Pharmacy Referral Agreement with CanaRx," in which CanaRx (falsely) promised that the prescriptions it provided would be compliant with Canadian law. *Id.* at 10. In reality, of course, there is no way for CanaRx's business model to be compliant with the laws that OCP cited: as CanaRx's advertising to U.S. patients makes clear, CanaRx is paying Canadian doctors to rewrite U.S. prescriptions *en masse*, not to have anything resembling an actual doctor-patient relationship with the U.S. patients to whom foreign medications are being shipped.

5. CanaRx's Corporate Structure

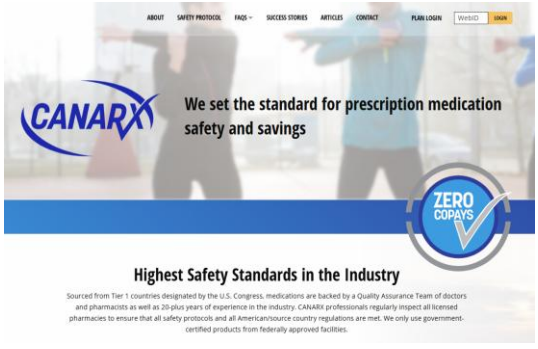
CanaRx is a series of related entities, all sharing the same officers and – ultimately, through parent holding corporations – a common headquarters. Each of them is directly liable for infringing Gilead's registered trademarks.

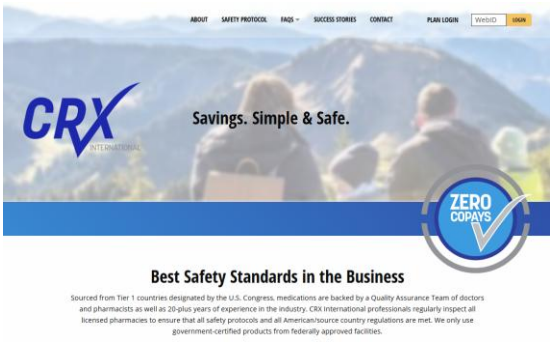
Defendant CanaRx Services Inc. ("CanaRx Services") is a Canadian company based in Windsor, Ontario, Canada that markets itself as an "International Prescription Service Provider (IPSP)" and the "the first-ever IPSP to serve U.S. residents." *See* Potter Decl., Ex. 38 at 1.

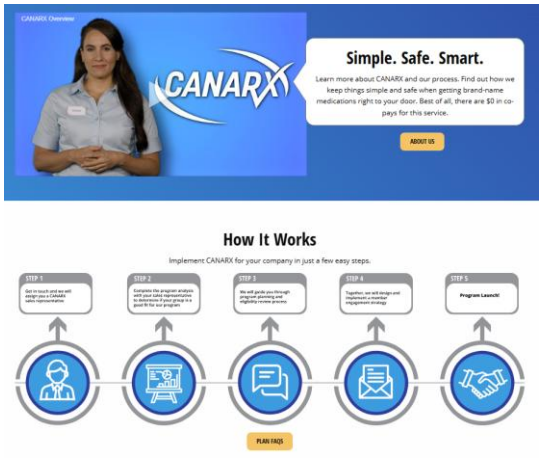
Defendant CanaRx Group Inc. ("CanaRx Group") is a Barbados corporation based in Christ Church, Barbados and is a subsidiary of an Ontario entity named 1646237 Ontario Inc., which has same registered headquarters in Windsor as CanaRx Services. Potter Decl., Ex. 44 (showing headquarters of CanaRx Services); Ex. 45 at 36, 108 (CanaRx Group "is owned by 1646237 Ontario Inc., a Company incorporated in Canada"); Ex. 46 (showing headquarters of CanaRx Group). The directors and officers of 1646237 Ontario Inc. are the same as the directors and officers of CanaRx Services. Potter Decl., Exs. 44, 46.

Defendant CRX International is a Barbados corporation based in Christ Church, Barbados and is a subsidiary of an Ontario entity named 2266578 Ontario Inc., which has the same registered headquarters in Windsor as CanaRx Services. Potter Decl., Ex. 47 at 11; Ex. 101 (CRX International "is owned by 2266578 Ontario Inc., a Company incorporated in Canada"); Ex. 48 (showing headquarters of CRX International). The directors and officers of 2266578 Ontario Inc. are also the same as the directors and officers of CanaRx Services. Potter Decl., Ex. 48. In a publicly available document, CRX describes "CanaRx" as its "parent company." *See* Potter Decl., Ex. 49 at 2. CRX International also markets itself as an international prescription service provider and operates as an "international mail order program." Potter Decl., Ex. 25.

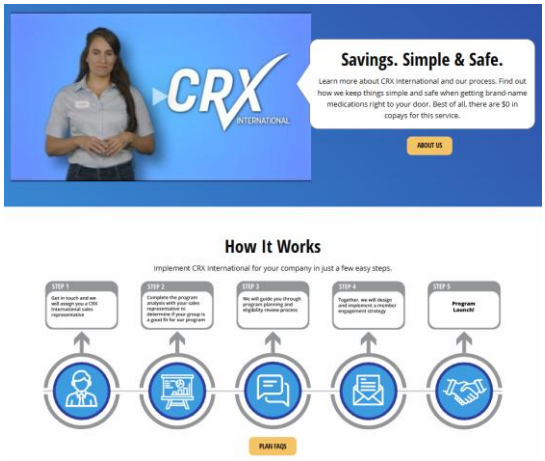
The FDA Warning Letter was addressed to "CanaRx Services Inc/CRX Intl," but noted "the violations discussed apply to all entities conducting business by or on behalf of CanaRx." Potter Decl., Ex. 20. In correspondence with the FDA, CanaRx has stated that "two CanaRx entities, CanaRx Services, Inc. and CRX International, Inc., serve American clients, and both conduct their operations in Windsor[, Ontario]." Potter Decl., Ex. 50 at 0381-0385. The two companies maintain separate websites, but they are nearly identical in appearance and content, and they both advertise their provision of internationally sourced medicines to insured U.S. patients.







Screenshots from CanaRx.com homepage



Screenshots from CRXIntl.com homepage

In its member enrollment packets, which advertise international Gilead-branded products by their trademarked brand names, CanaRx [redacted]." Potter Decl., Ex. 33 at -652.

In short, all three of these entities collectively referred to herein as "CanaRx" – CanaRx Services, CanaRx Group, and CRX International – use Gilead's registered trademarks to advertise international Gilead-branded medicines to U.S. patients and in fact cause those infringing medicines to be delivered to U.S. patients. For the reasons set forth below, all three of those entities are directly liable under the Lanham Act, and all three of them should be enjoined.

6. Bob Howard and John Howard

Bob and John Howard are both directors and officers of CanaRx. Specifically, for the following companies Bob Howard is president, John Howard is treasurer, and both are members of the board of directors: (1) CanaRx Services; (2) the shell company that owns CanaRx Group (1646237 Ontario Inc.); and (3) the shell company that owns CRX International (2266578

Ontario Inc.). Potter Decl., Exs. 44, 46, 48. Bob and John Howard are the sons of the late Tony Howard, who founded CanaRx. *See* Potter Decl., Ex. 51.

Bob and John Howard are personally involved in the illegal importation of prescription drugs to the United States that is CanaRx's *raison d'être*. For example, both Bob and John Howard personally met with David Schryver, the president of ProAct, multiple times in connection with CanaRx's business of importing international prescription medicines from foreign sources to U.S. patients. Potter Decl., Ex. 52 (Schryver Dep. Tr.) at 54:21-55:6; 56:22-57:14; 58:17-20. And both Bob and John Howard received notice of this Court's December 13, 2024 temporary restraining order against ProAct, [redacted]. Potter Decl., Ex. 53. [redacted]. Potter Decl., Exs. 54, 55, 56, 57, 58, 59, 60. He is identified as a contact person for CanaRx in multiple industry-facing documents. Potter Decl., Exs. 61 at -490; 62 at 39.

In addition to serving as CanaRx Services' president, Bob Howard has made public media comments on behalf of CanaRx, including statements defending CanaRx's importation business model after the FDA Warning Letter in 2019. *See* Potter Decl., Ex. 42. Bob Howard has also publicly touted CanaRx's safety procedures, asserting – falsely – that, by (purportedly) shipping products in the "manufacturer's sealed packaging," CanaRx "giv[es] everything to the patient" that he or she would need to assess the safety of the medicine. Potter Decl., Ex. 63. In short, Bob and John Howard are active and moving forces behind all three CanaRx entities' acts of infringement, including with regard to Gilead-branded medicines.

B. ElectRx

ElectRx is a self-described "pharmacy benefits strategist" that purports to help health plans import prescription drugs from foreign countries. ElectRx claims to have arranged for more than a million prescriptions to be filled through foreign suppliers for U.S. patients insured by health plans. *See* Potter Decl., Ex. 64. ElectRx publicly advertises its provision of infringing international Gilead-branded medicines, using Gilead's trademarked brand names, including GENVOYA®, BIKTARVY®, DESCOVY®, COMPLERA®, EMTRIVA®, ODEFSY®, STRIBILD®, and VEMLIDY®, to both patients and health insurance companies. *See* Potter Decl., Exs. 5; 9 (flyer on ElectRx website); 65; 66 (spreadsheet produced by ElectRx in response to third-party subpoena reflecting international Gilead-branded medicines provided to U.S. patients).

1. ElectRx's Business Model

ElectRx's business model relies on cooperation and facilitation of its illegal-importation scheme by health insurance entities, including plans, TPAs, and PBMs. [redacted]. *See* Potter Decl., Ex. 67 at -036. [redacted]." *Id.* [redacted]; if the patient's health plan provides coverage for the international medicine prescribed, ElectRx will arrange for it to be shipped to the patient and will provide an invoice for the medicine to be processed by the PBM or TPA. *Id.*

Slide from ElectRx presentation

2. The FDA Warning Letter to ElectRx

In March 2023, the FDA issued an official Warning Letter to ElectRx that in many ways mirrored the FDA's prior Warning Letter to CanaRx: it concluded that ElectRx was "in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)," and described ElectRx's provision of international prescription medications as the "introduction of unapproved new drugs and misbranded drugs into interstate commerce." Potter Decl., Ex. 21 at 1. Quoting ElectRx's statements to U.S. patients about the differences between U.S. and international versions of brand-name prescription drugs, the FDA concluded that "ElectRx has designed its business to operate in a manner that substitutes the FDA-approved drugs prescribed by the U.S. healthcare provider with unapproved drugs." *Id.* at 2. The Warning Letter to ElectRx also repeated the same warnings about the threat to patient health and safety posed by ElectRx's illegal-importation scheme, including the heightened dangers posed to U.S. patients taking HIV medications, and listed as examples several medications that ElectRx was illegally importing, including TRUVADA®. *Id.* at 2-3.

3. ElectRx's Defiance of the Warning Letter

ElectRx's response to the Warning Letter was one of open defiance. ElectRx continued its illegal importation of prescription medications, including Gilead-branded HIV medicines, willfully putting patients at risk in exchange for an illicit profit. On its website, ElectRx posted an open letter "to clients and participants" titled "FDA Response" in which ElectRx simply declares the FDA to be wrong:

> ElectRx and Health Solutions LLC ("ElectRx") recently received a letter from the United States Food and Drug Administration ("FDA") regarding the importation of medication to the United States. It is apparent by the content of this form letter that the FDA is unaware of the type of personal importation programs supported by ElectRx and the extensive care, custody, and control procedures that exist for you and your plan sponsors.

Potter Decl., Ex. 26 at 1. After declaring that it knows more about drug safety than the FDA, ElectRx goes on to declare that it knows the law better than the FDA, too:

> Your personal importation of medications directly from specific Tier 1 Countries, including Canada, are within the permissive acts established under the proposed regulations and the intent of the [*sic*] numerous executive orders, postal regulations, and language of the Medicare Modernization Act.

Id. at 2. ElectRx closes its open letter by thanking the patients that the FDA told ElectRx it was endangering: "Thank you for your continued belief in the benefits of personal importation, and its effectiveness. Sincerely, Your Friends at ElectRx and Health Solutions LLC." *Id.*

4. Jeffrey Dinsmore

Jeffrey Dinsmore is the member, managing partner, and authorized agent of ElectRx. Potter Decl., Exs. 68; 69; 70; 71. As managing partner, Dinsmore signs contracts with health plans regarding ElectRx's provision of international medicine – including Gilead-branded medicine – to U.S. patients. Potter Decl., Ex. 72 at pp. 24, 28, 30, 33. He is also the contact person for those health plans under their contracts with ElectRx. *Id.* at pp. 28, 30, 33. And Dinsmore personally makes representations on behalf of ElectRx to health insurance plans about

the ElectRx international prescription drug importation program, misrepresenting, *inter alia*, that "Prescription drug products shipped through the supply chain meet or exceed all safety concerns of the Food and Drug Administration (FDA)." Potter Decl., Ex. 73. In sum, Dismore is an active and moving force behind ElectRx's infringement.[4]

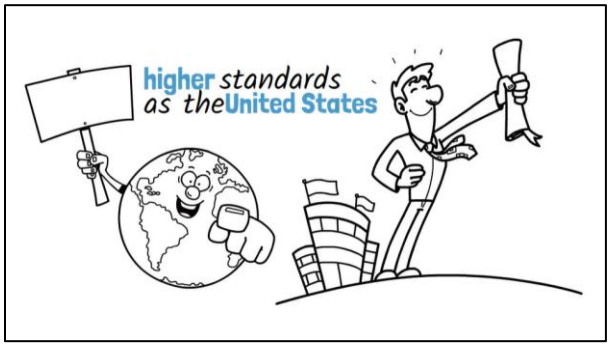
C. ScriptSourcing

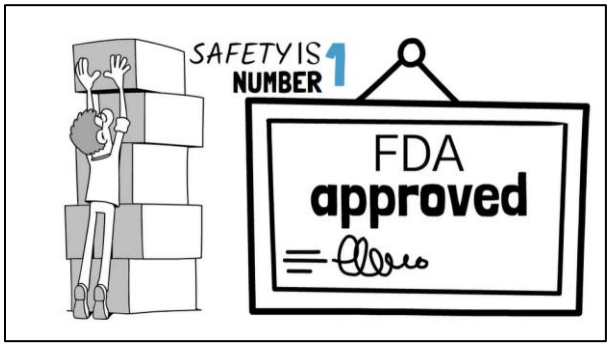
ScriptSourcing describes itself as partnering with "benefit consultants, PBMs, and TPAs" to provide "alternative medication sourcing options" – namely, illegally importing brand-name prescription medicine. *See* Potter Decl., Ex. 82. ScriptSourcing openly advertises on its website that it provides international Gilead-branded medicines, using Gilead's trademarked brand names, including BIKTARVY®, DESCOVY®, GENVOYA®, ODEFSY®, STRIBILD®, TRUVADA®, and VEMLIDY®. *See* Potter Decl., Exs. 83; 84; 85; 86; 87; 88; 89. Among ScriptSourcing's partners in illegally importing Gilead-branded medicines is Defendant CRX International. *See* Potter Decl., Ex. 90.

On its website, ScriptSourcing features a patient-facing advertisement entitled "International Pharmacy Explainer Video." The advertisement begins with a voiceover telling patients: "We have a new and exciting prescription program that will save you a lot of money by providing you no-cost, brand-name medications." *See* Potter Decl., Ex. 91. It promises patients: "We can guarantee the pedigree, safety, and security of every single med that is shipped. Safety is number one." *Id.* And the advertisement claims that through its "international pharmacy"

[4] Disnmore is also involved in other efforts to illegally import prescription drugs into the United States. He is the vice president and a director of Canusa Health, Inc., a Canadian entity that imports prescription drugs to the United States. Potter Decl., Exs. 74; 75. And Dinsmore has multiple other corporate entities associated with the healthcare business: Canusa Health, LLC; Global Rx International Health Solutions LLC; Global Rx Strategies LLC; and PharmaPlans Management, LLC. Potter Decl., Exs. 76; 77; 78; 79; 80; 81.

program, **"we will only ship FDA-approved maintenance name-brand meds**." *Id.* (emphasis added).





Screenshots from ScriptSourcing's video advertisement

ScriptSourcing's advertisement intentionally and fraudulently misleads consumers. As ScriptSourcing well knows, the international medications – including Gilead-branded HIV medicines – that it illegally provides to U.S. patients are ***not*** FDA-approved. The FDA has specifically described those international medications as unapproved. And despite ScriptSourcing's empty "guarantee" of the "pedigree, safety, and security of every single med that is shipped," as the Court heard at the prior preliminary injunction hearing, it was well known in the industry that ScriptSourcing was responsible for importing a counterfeit medication that was disguised as a gray-market import, causing grievous physical harm to the patient. *See* Potter Decl., Exs. 15; 104. This illegal-importation "horror story" was so devastating that defendant Meritain publicly advertised the incident as a warning not to import medications. *See* Potter Decl., Ex. 92. (As the Court knows, the illicit profits to be made from illegal importation led Meritain to nevertheless continue working with ScriptSourcing to facilitate even more foreign drugs being delivered to Meritain's patients. *See Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *14.)

1. Gary Becker

Gary Becker is the founder, CEO, member, and registered agent of ScriptSourcing, LLC. Potter Decl., Exs. 93; 94. Becker first registered "ScriptSourcing" as a trade name used by his insurance brokerage, Becker Benefit Group; the following year, in 2016, Becker registered ScriptSourcing as a Maryland limited liability company with the business purpose of "provid[ing] prescription mitigation services[.]" Potter Decl., Exs. 95; 96.

Becker's own email address, gary@scriptsourcing.com, is publicized as ScriptSourcing's contact information to permit health plans, PBMs, and benefits consultants to contact the company about ScriptSourcing's business. Potter Decl., Exs. 97; 98. He also personally [redacted]. *See* Potter Decl., Ex. 99 at -1490.

Becker publicly touts ScriptSourcing's international sourcing program in interviews and on social media. Potter Decl., Exs. 100; 101. In a June 2025 interview published in *The Self-Insurer*, Becker bragged with regard to his business of importing non-FDA approved drugs: "There are no consequences for doing this. There's no fine or jail time." Potter Decl., Ex. 102. In sum, Becker is an active and moving force behind ScriptSourcing's infringement.

ARGUMENT

I. GILEAD IS ENTITLED TO A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION

Gilead seeks a temporary restraining order ("TRO"), to be converted into a preliminary injunction, on its infringement claims under the Lanham Act, 15 U.S.C. §§ 1114(1)(a) and 1125(a). This Court already granted both a TRO and a preliminary injunction against the originally named defendants, who engaged in the same drug-importation scheme and against whom Gilead asserted the same causes of action under the Lanham Act. *See, e.g.*, *Gilead Scis.*,

Inc., No. 1:24-cv-03566-JRR, 2025 WL 1745669, at *4. As the Court held, Gilead bears the burden to demonstrate "1) they are likely to succeed on the merits; 2) they are likely to suffer irreparable harm absent preliminary relief; 3) the balance of the equities favors the requested injunctive relief; and 4) that relief is in the public interest." *Id*. at *5 (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

A. Gilead Has a Strong Likelihood of Success on the Merits

The newly added Defendants are all directly liable for trademark infringement under the Lanham Act. To establish direct liability, Gilead must show that "(1) it owns a legally protectable trademark; (2) Defendants used the trademark in commerce without Gilead's consent; (3) Defendants used the mark 'in connection with the sale, offering for sale, distribution, or advertising' of goods or services; and (4) Defendants' use of the mark is likely to cause confusion, mistake, or deception among consumers. *Gilead Scis., Inc.*, No. 1:24-cv-03566-JRR, 2025 WL 1745669, at *6 (internal citations omitted); *see also Rosetta Stone Ltd. v. Google, Inc.*, 676 F.3d 144, 152 (4th Cir. 2012); 15 U.S.C. §§ 1114(1)(a), 1125(a).

This is a case about gray-market goods: *i.e.*, products manufactured for, and originally sold in, a foreign market, but then imported into the United States without the consent of the U.S. trademark holder. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *6. As this Court has noted, gray-goods cases differ from traditional Lanham Act actions in certain respects, including in that the first-sale doctrine (also known as trademark exhaustion) does not apply. *Id*. at *7-8; *see also e.g., Shell Oil Co. v. Com. Petroleum, Inc.*, 928 F.2d 104, 107 (4th Cir. 1991) (noting the first-sale rule applies only to "genuine" product, and holding "[a] product is not truly 'genuine' unless it is manufactured and distributed under quality controls established by the manufacturer."); *Sprint Nextel Corp v. Simple Cell, Inc.*, No. CCB-13-617, 2013 WL 3776933, at *8 (D. Md. July 17, 2013) (citation omitted) ("[T]he first sale doctrine does not

apply when an alleged infringer sells trademarked goods that are materially different than those sold by the trademark owner.") (quoting *TracFone Wireless Inc. v. Pak China Grp Co.*, 843 F. Supp. 2d 1284, 1296-97 (S.D. Fla. 2012)); *Abbott Labs. v. Adelphia Supply USA*, No. 15-CV-5826 (CBA) (MDG), 2015 WL 10906060, at *5 (E.D.N.Y. Nov. 6, 2015) (granting preliminary injunction against sale of imported international medical devices), *aff'd*, 670 F. App'x 6 (2d Cir. 2016).[5] More generally, "in a gray goods case, the alleged infringement is not premised on a putative customer duped (intentionally or not) into buying, for example, a bogus look-alike; rather, in a gray goods case, the plaintiff's bundle of rights in its mark is jeopardized or damaged because the defendant has wrested from the plaintiff the right to control the use of its mark to the detriment of the consumer and the mark holder's goodwill and reputation in the market." *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *7.

The Defendants here have conspired to import, sell, and distribute infringing Gilead-branded medicines that were manufactured for, and originally sold in, foreign countries. As this Court has already held in finding Gilead likely to succeed on its claims against the original

[5] Moreover, as this Court has already explained, gray-goods cases do not employ the multi-factor *Polaroid* test to determine likelihood of confusion. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *9, n.12; *cf. Perini Corp. v. Perini Constr., Inc.*, 915 F.2d 121, 127 (4th Cir. 1990) (citing *Polaroid Corp. v. Polarad Elec. Corp.*, 287 F.2d 492 (2d Cir. 1961)). This is because the *Polaroid* test presumes the existence of two entities using two similar, but not identical, marks and thus is "inapplicable" in a gray-goods case. *Novartis Animal Health US, Inc. v. LM Connelly & Sons, Pty. Ltd*, No. 04 Civ 10213 (BSJ), 2005 WL 1902085, at *3 n.3 (S.D.N.Y. Jun. 14, 2005); *see also, e.g., Prince of Peace Enters. v. Top Quality Food Mkt, LLC*, No. 07 Civ. 00349 (RJH), 2007 WL 704171, at *4 (S.D.N.Y. Mar. 7, 2007) (holding the Polaroid test "is not useful in the context of gray market goods, since such goods typically utilize the exact same marks, sold in the original packaging legitimately obtained from the manufacturer.") (citations and internal quotations omitted); *Societe Des Produits Nestle, S.A. v. Casa Helvetia, Inc.*, 982 F.2d 633, 640 (1st Cir. 19992) (holding that in gray-goods cases, the existence of a material difference "creates a presumption of consumer confusion as a matter of law.") *Martin's Herend Imps., Inc. v. Diamond & Gem Trading USA, Co.*, 112 F.3d 1296, 1301 (5th Cir. 1997) (courts "presume[] a likelihood of confusion as a matter of law when the products are materially different.").

defendants, when sold in U.S. commerce, all foreign Gilead-branded medicines infringe Gilead's trademarks under two separate Lanham Act doctrines: the **material-differences doctrine** and the **quality-control doctrine**. *Id.*, at *9-13. The infringing foreign Gilead-branded medications at issue here remain infringing for the same reasons this Court found in granting Gilead's motions for a TRO and preliminary injunction against the originally named Defendants.

1. Gilead Owns the Registered Gilead Marks

As a threshold matter, Gilead owns several well-established trademarks, all registered with the U.S. Patent and Trademark Office, that appear on the packaging and labeling of all domestic and international Gilead-branded medications. *See* Potter Decl., Ex. 2 at ¶¶ 4-19*; see Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *11.

2. Imported International Gilead Medications Are Infringing Under the Material-Differences Doctrine

The material-differences doctrine provides that a product bearing the plaintiff's own trademarks is infringing under the Lanham Act when that product (1) was not intended to be sold in the United States and (2) is materially different than the product that is authorized for sale in the United States. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *9 (citations omitted); *see Sprint Nextel*, 2013 WL 3776933 at *8; *Novartis Animal Health US, Inc. v. Abbeyvet Export Ltd.*, 409 F. Supp. 2d 264, 266 (S.D.N.Y. 2005) (hereinafter *Abbeyvet*); *Martin's Herend Imps., Inc.*, 112 F.3d at 1301-02.

The material-differences doctrine recognizes that American consumers are likely to be confused when, instead of receiving the trademarked product that the manufacturer intended for sale in the United States, the consumer receives a product bearing the same trademarks but created and/or packaged for foreign markets. *See, e.g.*, *Bordeau Bros., Inc. v. Int'l Trade Comm'n*, 444 F.3d 1317, 1320 (Fed. Cir. 2006) ("To the extent that foreign goods bearing a

trademark have different characteristics than those trademarked goods authorized for sale in the United States, the public is likely to become confused or deceived"); *Nestle*, 982 F.2d at 641 ("The probability of confusion is great . . . when the same mark is displayed on goods that are not identical but that nonetheless bear strong similarities in appearance or function.").

A material difference is "no more than a slight difference which consumers would likely deem relevant when considering a purchase of the product." *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *9 (quoting *Zino Davidoff, S.A. v. CVS Corp.*, 571 F.3d 238, 246 (2d Cir. 2009)). "The doctrine – and what constitutes a material difference – is flexible; the threshold is low to account for consumer purchasing considerations across a wide spectrum of markets." *Id.*; *see also, e.g.*, *Davidoff CIE, S.A. v. PLD Int'l Corp.*, 263 F. 3d 1297, 1302 (11th Cir. 2001) ("Because a myriad of considerations may influence consumer preferences, the threshold of materiality must be kept low to include even subtle differences between products."); *Nestle*, 982 F.2d at 641 ("[I]t is by subtle differences that consumers are most easily confused. For that reason, the threshold of materiality must be kept low enough to take account of potentially confusing differences – differences that are not blatant enough to make it obvious to the average consumer that the origin of the product differs from his or her expectations"); *Zino Davidoff*, 571 F.3d at 246 ("In the context of gray-market goods, in comparing the trademark holder's product with the gray-market product, we apply a low threshold of materiality.").

Thus, courts have found differently colored figurines, *Martin's Herend Imps., Inc.*, 112 F.3d at 1302, or different flavors of pet medicine, *Abbeyvet*, 409 F. Supp. 2d at 267, to constitute a material difference. A difference in domestic and international packaging can also be material under this doctrine, regardless of whether the products themselves are identical. *See, e.g.*, *Dentsply Sirona Inc. v. Net32, Inc.*, No. 1:17:CV-01530, 2020 WL 1082593, at *5 (M.D. Pa.

Mar. 4, 2020). Indeed, the doctrine arose from a case involving imported dolls that were identical to the U.S. dolls, but included "adoption papers" that were in Spanish instead of English. *Original Appalachian Artworks, Inc. v. Granada Elecs., Inc.*, 816 F.2d 68, 70-74 (2d Cir. 1987). "[E]ven the use of British English spellings on the [f]oreign [p]roduct instead of American English spellings is a material difference," such as the use of *colour* versus *color*. *Bayer Corp. v. Custom Sch. Frames, LLC*, 259 F. Supp.2d 503, 509 (E.D. La. 2003) (citing *Ferrero U.S.A., Inc. v. Ozak Trading, Inc.*, 753 F. Supp. 1240, 1244 (D.N.J. 1991)). And intangible differences in the services or terms that come with a product, as selling a product that does not come with the manufacturer's warranty, can constitute a material difference. *Sprint Nextel*, 2013 WL 3776933, at *8 (citations omitted).

In highly regulated industries that fall under the ambit of FDA, courts routinely find material differences between U.S. products, which comply with FDA regulations, and imported international versions of those products, which comply with the different regulations imposed by foreign regulatory bodies. *See, e.g.*, *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *10 (finding material differences to include "foreign language packaging and labeling, international units of measure, and deviation from FDA regulations"); *Abbott Labs.*, 2015 WL 10906060, at *7 (noting "numerous cases have found deviations from FDA regulations to be material," and entering preliminary injunction against sale of imported medical devices where the devices were identical but the packaging had differences in language and regulatory markings) (citation omitted); *Nestle USA, Inc. v. Ultra Distribuciones Mundiales S.A. de C.V.*, 516 F. Supp. 3d 633, 648-649 (W.D. Tex. 2021) (noting that "[i]n gray market goods cases, courts often find that regulatory compliance is a material difference," and finding differences between labeling of domestic and international food and beverage products constituted material

differences); *Sueros & Bebidas Rehidratantes, S.A. de C.V. v. A&N Ice Cream LLC*, No. 4:24-cv-02527, 2024 WL 4449503, at *1-2 (S.D. Tex. Oct. 8, 2024) (finding material differences where international versions of sports drinks "comply with applicable regulations in the countries where [they are] authorized to be sold," and so did not follow FDA labeling regulations such as listing ingredients); *PepsiCo, Inc. v. F & H Kosher Supermarket, Inc*., No. 11-CV-0425 (RRM)(ALC), 2011 WL 6181907, at *5 (E.D.N.Y. Aug. 26, 2011) (international products materially different where labeling did not "comply with the FDA regulations or the labeling standards followed by [p]laintiff and its authorized bottlers in the United States").

Here, there is no question that the international Gilead-branded products Defendants are illegally importing, selling, and dispensing to U.S. consumers are materially different from authentic U.S. Gilead-branded product.

a. The Illegally Imported Gilead-Branded Medicines Are Not Intended for Sale in the United States

The first element of the material-differences doctrine is easily met: the imported international Gilead-branded medications are not intended for sale in the United States. As this Court already recognized, Gilead sells only authentic, FDA-compliant, U.S. versions of its Gilead-branded medications in the United States. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *11; Potter Decl. Ex. 1 at ¶¶ 6-8, 14-17. Defendants have conspired to import international Gilead-branded medications that are labeled and packaged to meet the regulations of the particular country into which they are intended for sale, and thus do not comply with FDA regulations. *See, e.g.*, *Abbeyvet*, 409 F. Supp. 2d at 266 (finding defendant's goods not intended for sale in the United States because "the product inserts and packaging design [were] specifically tailored for use in the U.K. and designed to meet U.K. regulatory requirements").

b. International Gilead-Branded Medicines Bear Numerous Material Differences from Authentic FDA-Approved, U.S. Medicines

The FDA-compliant packaging and labeling of every authentic U.S. Gilead-branded medication is unique to the United States, meaning that every international version of every medication that Gilead manufactures has different labeling and packaging as compared to the U.S. version of that medication. Potter Decl., Ex. 1 at ¶ 14; *see also Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *11. Of course, every international Gilead product has its own unique differences based on the packaging and labeling of the particular foreign market for which the medicine was manufactured. But Gilead has already established that, because the U.S. packaging and labeling of every domestic Gilead-branded medication is unique to the United States, there are numerous material differences between the U.S. version and *all* international versions of *every* Gilead-branded medicine, regardless of the country from which they are imported. *Id*. at *10-13; *see also* Potter Decl., Ex. 1 at ¶¶ 14-17, 19.

For example, the Patient Information documents for all U.S. Gilead-branded drugs provide Gilead's 1-800 toll-free patient hotline that patients can call with questions or concerns, including to report potential quality problems or adverse events. Potter Decl., Ex. 1 at ¶ 13(b). None of the Patient Information documents for any international version of any Gilead-branded drugs provides the U.S. 1-800 toll-free number, and so U.S. patients receiving international Gilead-branded medicines do not receive this crucial information and safety resource. *Id.*; *see Sprint Nextel*, 2013 WL 3776933, at *7-8 (selling phones without services or warranties provided by manufacturer a material difference); *Bel Canto Design, Ltd. v. MSS Hifi, Inc.*, 837 F. Supp. 2d 208, 231 (S.D.N.Y. 2011) (lack of warranty for diverted goods was a material difference).

Moreover, the Patient Information documents for all U.S. Gilead-branded drugs also provide instructions on how to contact the FDA to report side effects or adverse events, and include the statement: "This Patient Information has been approved by the U.S. Food and Drug Administration." None of that information is included on any the patient information documents for any international version of any Gilead-branded medication. Potter Decl., Ex. 1 at ¶¶ 13(c), 15. American patients are likely to be confused by Patient Information documents for prescription drugs that neither reference the FDA nor provide instructions on how to contact it. This Court has already "place[d] particular emphasis" on "the absence of critical patient safety information, including the 1-800 Gilead hotline, as well as contact information for the FDA" in finding international Gilead-branded medicines to be materially different. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *13.

Additionally, the FDA requires that every label of every prescription drug sold in the United States bear the phrase "Rx only," typically stylized as  . 21 U.S.C. § 353(b)(4). Indeed, the FDCA is explicit in stating that a prescription drug without the plain-text or stylized "Rx only" symbol on the label "shall be deemed to be misbranded," *id.* – and, again, the sale of misbranded drugs is a strict-liability crime, 21 U.S.C. § 331(a), 333(a). The stylized symbol that appears on the label of every U.S. Gilead-branded medication thus stands as a representation that the product is an FDA-approved prescription drug, and its omission from the international versions of those medications constitutes a material difference. Potter Decl. Ex. 1 at ¶¶ 12(b), 15, 16.[6]

[6] The sole exception is the unique labeling for a relatively small number of bottles of Gilead-branded medications distributed abroad through Gilead's Access Program, a program that provides low cost medications to certain low- and lower- income nations around the world to support Gilead's vision of creating a healthier world for all people – no matter where they live or

Similarly, the labeling of every U.S. Gilead-branded medication bears the drug's National Drug Code, or NDC, number. Every dosage or form of every prescription drug for sale in the United States receives its own individual NDC number, which is widely used by distributors, pharmacies, and others to identify the precise unit of medication being sold and dispensed. Indeed, defendant Meritain discussed the importance of NDC numbers to U.S. patients in a public advertisement about the dangers of using imported medications. Potter Decl., Ex. 92, at – 830 ("Medications filled internationally don't include accompanying claims with the National Drug Code (NDC) or other important drug information."). The NDC code is unique to the United States. The phrase "NDC" followed by the applicable number appears on the label of every U.S. Gilead-branded medication, and it does not appear on any international Gilead-branded medication. Potter Decl., Ex. 1 at ¶¶ 12(c), 15, 16.

Given the low threshold for materiality, any one of these differences, standing on its own, would be sufficient to find international Gilead-branded medication infringing. Taken together, there can be no reasonable dispute that the international medications are infringing products under the material-differences doctrine.

3. The Illegally Imported International Medicines Are Also Infringing Under the Quality-Control Doctrine

The international Gilead-branded medications that Defendants have caused to be imported into the United States are also infringing under the quality-control doctrine. That

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who they are. Potter Decl., Ex. 1 at ¶ 18. Drugs distributed through the Access Program bear a unique label and packaging, that, among other things, prominently displays "GILEAD ACCESS PROGRAM" to indicate they are intended solely for countries within Gilead's Access Markets, i.e. low- and lower-income countries. *Id.* Those unique labels are materially different from U.S. labels – a U.S. consumer would certainly be confused why his or her medication was prominently labeled for international distribution – but they may have features, such as the ℞only symbol, that do not appear on any other international Gilead-branded medications. *Id.*

doctrine derives from the judicial recognition that "[o]ne of the most valuable and important protections afforded by the Lanham Act is the right to control the quality of the goods manufactured and sold under the holder's trademark." *El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 395 (2d Cir. 1986). As the Fourth Circuit has held, "[a] product is not truly 'genuine' unless it is manufactured and distributed under quality controls established by the manufacturer," and the sale of non-genuine products is an act of infringement under the Lanham Act. *Shell Oil*, 928 F. 2d at 107 (citing *El Greco*, 806 F.2d at 395-96); *see also Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *10.

In *Shell Oil*, the defendant was an unauthorized distributor that re-sold Shell's motor oil under Shell's trademarks, but outside of "Shell's quality control standards," including Shell's requirements for "storage facilities and transportation procedures." *Id.* at 105-07. The Fourth Circuit affirmed that the Shell product sold by the defendant was therefore non-genuine and infringing under the Lanham Act. *Id.* at 107. In so holding, the Fourth Circuit rejected the defendant's arguments that its product was of identical quality because the defendant "employ[ed] its own standards that guarantee the quality of the oil." *Id.* The court held that "the actual quality of the goods is irrelevant; it is the control of quality that a trademark holder is entitled to maintain." *Id.* (quoting *El Greco*, 806 F.2d at 395-96). Thus, "by marketing the bulk oils under Shell's trademarks according to its own quality controls [and not Shell's], [the defendant] violated Shell's right under the Lanham Act to retain control of the use of its trademark in the sale of the product to the end user," and the defendant was liable for trademark infringement. *Id.*

Here, Defendants' scheme to illegally import Gilead-branded medications bypasses and undermines Gilead's quality-control procedures in several ways, each of which is independently

sufficient to render the international medications non-genuine and infringing under the Lanham Act. When all these ways are taken together, the infringing nature of international Gilead-branded medicines is even more obvious.

a. Illegally Imported International Medicines Bypass Gilead's International Shipping Temperature Controls

All U.S. Gilead-branded medications must be stored within certain temperature ranges, which are listed on their FDA-approved labelling. Potter Decl., Ex. 1 at ¶ 22. At the highest end, several U.S. Gilead-branded drugs may be stored at temperatures of up to 86 degrees Fahrenheit (30 degrees Celsius); other U.S. Gilead-branded drugs have lower maximum storage temperatures. *Id.*

International shipping routes routinely exceed 86 degrees Fahrenheit. *Id.* at ¶ 24. Therefore, when Gilead ships U.S.-intended product like BIKTARVY® from an international manufacturing site into the United States, it implements strict quality controls concerning the temperature of the medication. *Id.* These procedures include shipping the medications in sealed, temperature-controlled and temperature-monitored containers. *Id.* If the monitor for a particular shipment shows that the medication was exposed to temperatures exceeding its maximum range, a "quality event" is triggered, and Gilead's quality-assurance team will investigate. *Id.* Any medications affected by that quality event will not be released unless and until Gilead's quality assurance team concludes that the medication remains safe and effective. *Id.*

Defendants, on the other hand, take Gilead-branded drugs from countries around the world and ship them to American homes, completing skirting Gilead's quality-control procedures for temperature control and monitoring. This uncontrolled international shipping, which Gilead is unable to monitor, violates and undermines Gilead's established quality-control procedures for international shipment of its medications, and puts the quality of the medications

at risk. *See Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *12. The illegally imported international Gilead-branded medications are therefore infringing as a matter of law. *See Shell Oil*, 928 F. 2d at 107-08; *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *13 (finding international Gilead-branded medicines infringing under the quality-control doctrine in light of "the lack of quality/safety event trigger capacity for safe temperature ranges during distributions").

b. Illegally Imported Medicines Subvert Gilead's Ability to Issue Targeted Recalls

Defendants' scheme to illegally import international Gilead-branded medications also bypasses and actively undermines Gilead's ability to issue effective recalls for those products. Potter Decl., Ex. 1 at ¶¶ 28-31. Gilead has substantial quality-assurance protocols related to the issuance of a targeted recall in the event of a quality concern about any released lot of Gilead-branded medication. *Id.* at ¶ 28. Gilead's protocols provide that any such recalls will occur in the geographic market into which Gilead distributed the affected lot, and that recall notices will be provided to the distributors and other entities to which Gilead knows the affected lot was distributed. *Id*. at ¶ 30. Thus, if there were a quality concern with a lot of BIKTARVY® manufactured for sale in a foreign country, Gilead would issue a targeted recall only in that country. *Id.*

Issuing such a recall notice outside the country for which the medication was manufactured – for example, in the United States – would be doubly problematic. First, it would confuse American pharmacies and distributors, who might erroneously believe the recall applied to them, or who would question why they were receiving an obviously inapplicable recall notice for a non-FDA-approved version of the drug. *Id.* at ¶¶ 30-31. Second, receiving obviously inapplicable recall notices would have the proverbial "boy who cried wolf" effect, making it less

likely that Americans would pay attention in the future to any recall notices that are actually applicable to U.S. medications. *Id.*

For these reasons, courts have routinely found that diversion of international products circumvent and subvert manufacturers' targeted recall procedures and renders the diverted product infringing under the quality-control doctrine. *See Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 245 (2d Cir. 2009) (holding sale of product that interfered with plaintiff's ability to issue targeted recall infringing, and finding it irrelevant (a) whether the manufacturer had in fact ever issued such a recall and (b) whether consumers or distributors knew of the manufacturer's recall procedures or how they were being undermined); *Abbott Labs.*, 2015 WL 10906060, at *7; *Thorne Rsch., Inc. v. Davachi*, No. 2:24-cv-02356-DCN, 2024 WL 4607943, at *6-8 (D.S.C. Oct. 29, 2024). This Court has already found that "Gilead's inability to isolate data to deploy targeted recalls" renders international Gilead-branded medicines infringing under the quality-control doctrine. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *12-13.

c. Illegally Imported International Medicines Bypass Gilead's U.S. Pedigree and Tracing Controls

In the United States, Gilead-branded medications are always accompanied by what is known in the industry as a "pedigree," also known as a T3 or DSCSA document. Potter Decl. Ex. 1 at ¶ 25. Pedigrees are required for all prescription drugs in the United States under the federal Drug Supply Chain Safety Act ("DSCSA"), 21 U.S.C. § 360eee-1(b)(1). The FDA has referred to pedigrees as an anti-counterfeiting measure.[7]

[7] Potter Decl., Ex. 103 (United States Food & Drug Admin., *Drug Supply Chain Security Act (DSCSA)*, https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.).

Among other things, pedigrees provide a tracing of every distributor or pharmacy that has ever taken possession of that particular bottle of medication, beginning with the first sale from Gilead to one of its U.S. authorized distributors. Potter Decl., Ex. 1 at ¶¶ 20, 25-26. Gilead creates the original pedigree for every bottle of Gilead-branded medicine it sells in the United States, and then the pedigrees travel with the bottle and are updated each time the bottles change hands, providing a full chain of custody for that specific bottle of medication back to the manufacturer. *Id.*

Gilead relies heavily on pedigrees for its quality-control efforts in the United States. *Id.* Pedigrees are critical elements of Gilead's efforts to establish a safe, secure, and controlled U.S. distribution chain for its medications. *Id.* When Gilead receives a quality complaint or inquiry about a bottle of Gilead-branded medication in the United States, Gilead's quality team always attempts to obtain the pedigree for that bottle to determine its route through the distribution stream. *Id.* Gilead uses pedigrees to identify and combat potentially adulterated and/or counterfeit versions of its medications in the United States. *Id.* For example, Gilead relied heavily on pedigrees to identify counterfeit BIKTARVY® and other Gilead-branded HIV medication in the U.S. distribution chain, which led to Gilead filing a major anti-counterfeiting action. *Id.*; *see Gilead Scis., Inc. v. Safe Chain Sols. LLC*, 753 F.Supp.3d 173, 179-80, (E.D.N.Y. Aug. 29, 2024), *adopted*, 2024 WL 4432341 (E.D.N.Y. Oct. 7, 2024).

International Gilead-branded medications are not accompanied by pedigrees. Potter Decl, Ex. 1 at ¶ 27. By importing international Gilead-branded medications into the United States, Defendants have made it impossible for Gilead to use pedigrees to trace the distribution of these illegally imported medications in the event of suspected or actual quality incident. *Id.* This Court has already found that lack of pedigrees renders international Gilead-branded

medications infringing under the quality-control doctrine. *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *12-13.

d. Illegally Imported Medicines Disrupt Gilead's Carefully Secured U.S. Supply Chain and Put American Patients at Risk of Counterfeits

Finally, as described *supra* at pp. 11-12, Defendants' illegal importation disrupts Gilead's highly secure supply chain and makes it likely that counterfeits disguised as "imported product" will enter the U.S. supply chain. Gilead goes above and beyond the FDA's already stringent requirements for maintaining a strictly controlled, traceable, secure supply chain for its medications. Potter Decl, Ex. 1 at ¶¶ 20-21. Defendants are actively working to undermine and subvert Gilead's secure supply chain by creating an illegal, untraceable, and unsecured supply chain from foreign countries directly to U.S. patients. This breach in Gilead's supply chain, and the attendant risk that American patients will receive fake and potentially dangerous versions of Gilead's life-saving medications, violates and undermines Gilead's quality control procedures and violates Gilead's "right to control the quality of the goods manufactured and sold under its trademark." *Shell Oil*, 928 F. 2d at 107; *see also Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *10, n. 13.

B. The Defendants Are Directly and Strictly Liable Under the Lanham Act

Defendants are all directly and strictly liable under the Lanham Act for their roles in their scheme to sell, import, and distribute infringing international Gilead-branded medications into the United States. Gilead's claims against each Defendant therefore meet and exceed the "likely to succeed" standard for injunctive relief.

1. Defendants Are Willful Infringers, But Because They Are Strictly Liable, Willfulness Is Not Required

Defendants' scheme to import infringing Gilead-branded medications is, of course, no accident: each of them openly advertises its illegal importation of infringing products. Even at this early stage of the case, the evidence is overwhelming that Defendants are willful infringers. For present purposes, however, the Court need not make any determinations as to willfulness. Trademark infringement is a strict-liability offense, and so Gilead is likely to succeed on its claims regardless of each Defendant's knowledge or intent. *See, e.g.*, *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 25 (2d Cir. 2004) ("[I]t is well established that wrongful intent is not a prerequisite to an action for trademark infringement . . . and that good faith is no defense." (citations and internal quotations omitted)); *Hard Rock Café Licensing Corp. v. Concession Servs., Inc.*, 955 F.2d 1143, 1152 n.6 (7th Cir. 1992) ("Sellers bear strict liability for violations of the Lanham Act."); *Taubman Co. v. Webfeats*, 319 F.3d 770, 775 (6th Cir. 2003); *R/C Theatres Mgmt. Corp. v. Metro Movies, LLC*, 44 F. Supp. 3d 626, 636 (D. Md. 2014); *Philip Morris USA Inc. v. Shalabi*, 352 F. Supp. 2d 1067, 1073-74 (C.D. Cal. 2004); *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *7-8.

2. Defendants Are Directly Liable

Defendants are directly liable for trademark infringement under the Lanham Act where they "use in commerce" an infringing mark, including the "sale, offering for sale, distribution, or advertising" of materially different goods bearing the plaintiff's registered trademark. 15 U.S.C. §§ 1114(1)(a), 1125(a); s*ee, e.g.*, *Original Appalachian Artworks*, 816 F.2d at 71-73; *Nestle*, 982 F.2d at 637-38. The definition of "use in commerce" is broad, *see* 15 U.S.C. § 1127, and does not require that the defendant actually take title or physical possession of the infringing product. *See, e.g., Polo Fashions, Inc. v. BDB, Inc.*, No. 82-315-14, 1983 WL 44362, at *1 n.1 (D.S.C.

Aug. 23, 1983) (holding defendant liable despite his claims that he was "merely a broker" for the infringing goods; noting that "Section 1114 is broad and clearly covers varying levels of involvement," and so "[b]rokers do not escape liability for trademark infringement by claiming a less than dominant role in the infringing transaction"); *Philip Morris U.S.A, Inc. v. U.S. Sun Star Trading, Inc.*, CV 08-0068 (KAM) (JO), 2010 WL 2133937, at *5 (E.D.N.Y. Mar. 11, 2010) (finding U.S.-based defendant liable for "arranging for [the infringing goods'] transport into the United States" from overseas even though defendant never received the infringing goods); *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *20-21 (finding Gilead likely to succeed on its direct-liability Lanham Act claims against defendant Rx Valet, which advertised the availability of international Gilead-branded products and facilitated their delivery to the United States, but did not take title to those products).

Here, Defendants CanaRx, ElectRx, and ScriptSourcing are all directly liable for their role in the trafficking of infringing international Gilead-branded medications in the United States. Each of them advertised, brokered, and offered for sale infringing international Gilead-branded medicines, and they all did so using Gilead's registered trademarks without Gilead's permission. Thus, they are all directly liable for their acts of infringement. 15 U.S.C. §§ 1114(1)(a), 1125(a).

For their part, the individual Defendants – Bob and John Howard, Jeffrey Dinsmore, and Gary Becker – are directly liable as agents, operators, and owners of CanaRx, ElectRx, and ScriptSourcing, respectively. Where a corporation or other business entity commits trademark infringement, corporate owners and officers who participated in the infringement are personally and directly liable for that infringement alongside the corporation. Specifically, "under the Lanham Act, a corporate officer may be held personally liable for trademark infringement . . . if

the officer is a moving, active, conscious force behind the defendant corporation's infringement." *KatiRoll Co. v. Kati Junction, Inc.*, 33 F. Supp. 3d 359, 368 (S.D.N.Y. 2014). "A plaintiff may show that a corporate employee is [a] moving, active, conscious force behind the infringing activity by demonstrating that [he or she] direct[ed], control[led], ratifie[d], or participate[d] in the infringing activity." *Matsunoki Grp., Inc. v. Timberwork Or., Inc.*, No. 08-04078 (CW), 2009 WL 1033818, at *4 (N.D. Cal. Apr. 16, 2009); *see also Polo Fashions, Inc. v. Craftex, Inc*., 816 F.2d 145, 149 (4th Cir. 1987); *Microsoft Corp. v. Md. Micro.com, Inc*., No. JFM-01-3797, 2003 WL 21805213, at *4 (D. Md. July 15, 2003); *Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *8. Here, the record set forth above clearly establishes that these individual defendants are the owners and/or principals of entities whose business model is illegally importing prescription medications, including Gilead-branded medications, and that they both personally participated in that infringement and directed, controlled, and ratified the infringing activity.[8] *See supra* pp. 22-23; 25-26; 28.

3. The Defendants Are Also Contributorily and Vicariously Liable

Although the Court need not reach the issue in light of the Defendants' direct liability, the Defendants are also vicariously liable and contributorily liable for trademark infringement under the Lanham Act: they each partner with other direct infringers, including foreign pharmacies, to facilitate the importation of infringing Gilead-branded medications. *See generally* Dkt. No. 11 at 40, 44; *Rosetta Stone Ltd v. Google, Inc*., 676 F.3d 144, 163 (4th Cir. 2012); *Living Legends Awards for Service to Humanity, Inc. v. Human Symphony Found., Inc*., No. PX 16-3094, 2017

[8] In the alternative, each of the individual defendants is also, at minimum, vicariously liable for trademark infringement: as the owners, directors, and principals of their respective companies, they each financially benefitted from the infringement and failed to exercise their authority to stop or limit their infringing activity.

WL 3868586, at *4 (D. Md. Sept. 5, 2017) (citing *Goldstein v. Metro. Reg'l Info. Sys., Inc*., No. CV TDC-15-2400, 2016 WL 4257457 at *5 (D. Md. Aug. 11, 2016))

C. Gilead Is Suffering Irreparable Harm as a Result of Defendants' Activities

Because Gilead has demonstrated a likelihood of success on the merits on its Lanham Act claims, it is entitled to a rebuttable presumption of irreparable harm as a matter of law pursuant to the Trademark Modernization Act of 2020. 15 U.S.C. § 1116(a). And even before that statutory presumption was implemented, the Fourth Circuit recognized that "irreparable injury regularly follows from trademark infringement." *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.*, 43 F.3d 922, 939 (4th Cir. 1995); *see also, e.g.*, *Pizzeria Uno Corp. v. Temple*, 747 F.2d 1522, 1535 (4th Cir. 1984) (a trademark infringer "borrows the owner's reputation, whose quality no longer lies within his own control." (quoting *Yale Elec. Corp. v. Robertson*, 26 F.2d 972, 974 (2d Cir. 1928) (Hand, J.))); *see also Church of Scientology Int'l v. Elmira Mission*, 794 F.2d 38, 44 (2d Cir. 1986) ("[A]llowing defendants the opportunity to reduce the marks' reputational value and goodwill by its continued unauthorized use constitutes the irreparable harm that is requisite to the issuance of the preliminary injunction.").

The Defendants' illegal-importation scheme causes irreparable harm both to Gilead and to U.S. patients because the imported medications are not FDA-approved, do not provide FDA-approved labeling or Patient Information documents, and undermine and subvert Gilead's quality-control procedures. *See supra* pp. 35-44. Moreover, as set forth above, Defendants' illegal importation scheme is an invitation for foreign pharmaceutical counterfeiters to sell their fake medications into the United States disguised as diverted international product. *See supra* at pp. 43-44. The federal government has cited these concerns about public health and safety in connection with the laws that prohibit importation of prescription drugs, and the FDA

emphatically instructed CanaRx and ElectRx to cease and desist their illegal activities. *See* Potter Decl., Exs. 20; 21. And concern about counterfeit or adulterated medication is particularly potent here, given that Defendants blithely instruct American patients to simply *disregard* differences between the medication they expect and the medication they receive. *See* Potter Decl., Exs. 20; 21; 24; 25. Immediate injunctive relief is necessary to prevent both damage to Gilead's reputation and goodwill and to patient health and safety, none of which can be undone. *See Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *29 (finding "Gilead has resoundingly demonstrated" that it is likely to suffer irreparable harm from the continued importation and sale of international Gilead-branded medications).

The irreparable harm to Gilead is in no way lessened by the fact that the Defendants at issue here were not named in Gilead's original complaint. As the Fourth Circuit has acknowledged, trademark owners are often presented with a "conundrum" when they encounter infringement: they can "rush[] immediately into litigation" with "little or no evidence" (creating the risk that they "appear … as 'shooting from the hip'" and that they will "face a counterclaim for overly aggressive use of litigation"), or they can wait and risk a laches defense. *Sara Lee Corp. v. Kayser-Roth Corp.*, 81 F.3d 455, 462 (4th Cir. 1996); *see also Dmarcian, Inc. v. Dmarcian Europe BV*, Civ. Case No. 1:21-cv-00067-MR, 2021 WL 2144915, at *16 (W.D.N.C. May 26, 2021), *aff'd in relevant part*, 60 F.4th 119 (4th Cir. 2023) (granting preliminary injunction on Lanham Act claims and concluding that Plaintiff's 15-month delay in filing suit, during which time it had "attempt[ed] to protect itself in other ways," did not show a lack of diligence); *Fairbanks Cap. Corp. v. Kenney*, 303 F. Supp. 2d 583, 591 (D. Md. May 6, 2003) (finding no undue delay where plaintiff retained counsel, "who reasonably and in a

professionally appropriate manner investigated the strength of his client's claims before filing a complaint in this court").[9]

Here, Gilead obtained information about each of the newly named Defendants through party and non-party discovery while preparing for the preliminary injunction against the originally named defendants.[10] As noted above, CanaRx, ElectRx, and ScriptSourcing are all business partners and co-conspirators of the originally named defendants. Because CanaRx, ElectRx, and ScriptSourcing were made aware of this litigation and the injunctions this Court issued against the importation of Gilead-branded medications, there was reason to hope that those entities would, at minimum, cease illegally importing Gilead-branded products in light of this Court's orders. But in the weeks following the entry of the preliminary injunction, CanaRx, ElectRx, and ScriptSourcing continued to advertise illegally imported, infringing international Gilead-branded medicines. In fact, when ProAct served CanaRx with notice of this Court's TRO, CanaRx wrote a letter in response, admitting that CanaRx facilitated the "importation of medicines manufactured by Gilead Sciences, Inc." but nevertheless made the frivolous claim "that the litigation in general, and the temporary restraining order in particular, do not implicate

[9] Moreover, in the Fourth Circuit, a laches defense is "relative[ly] unavailab[le] … to preclude injunctive relief," because the public interest in avoiding confusion does not fade with time. See *Sara Lee Corp.*, 81 F.3d at 461-62 ("[I]n consideration of the public interest, estoppel by laches may not be invoked to deny injunctive relief if it is apparent that the infringing use is likely to cause confusion."); *Lyons P'ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789, 797 (4th Cir. 2001) ("[E]ven in equity under the Lanham Act, laches does not bar a claim for prospective injunctive relief.").

[10] Specifically, although CanaRx is outside this Court's subpoena power, Gilead filed and won a motion to compel requiring ProAct to produce documents concerning CanaRx, Dkt. Nos. 68; 69; 71; 87; Gilead issued a non-party subpoena to ElectRx, which produced thousands of pages of heavily redacted documents; and Gilead received information regarding ScriptSourcing from Meritain. Gilead also issued a non-party subpoena to ScriptSourcing, but ScriptSourcing refused to produce documents.

Canarx or its clients in any way." *See* Potter Decl., Ex. 53 at -502-03. Because the newly named Defendants have ignored this Court's findings and continue to willfully infringe Gilead's trademarks and endanger patients by illegally importing international Gilead-branded medications, Gilead now seeks direct injunctive relief against those Defendants.

D. The Balance of Equities Tips Decisively in Gilead's Favor

Here, the equities emphatically support the issuance of a temporary restraining order. Federal law *already prohibits* the importation of prescription drugs destined for foreign markets into the United States, separate and apart from Gilead's trademark rights. *See supra* pp. 6-9; *see Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *31. As this Court has held, there can be no hardship to Defendants from an injunction prohibiting them from selling or facilitating the sale of imported international Gilead medications. *Id.* ("Defendants will not be heard to complain that they will suffer business hardship by this court's order that they comport their business practices with pre-existing law"); *NaturaLawn of Am., Inc. v. West Grp., LLC*, 484 F. Supp. 2d 392, 403 (D. Md. 2007) (concluding that balance of hardships weighed in plaintiff's favor where "defendants' hardships have been created by their own willful acts"). And as noted above, there is no shortage of authentic, FDA-approved Gilead-branded medications, which any American pharmacy can easily and quickly obtain from a Gilead-authorized supplier.

In contrast to the lack of harm to Defendants from the requested injunction, every sale of international Gilead product violates Gilead's trademarks and causes harm to its reputation and goodwill, while putting patients at risk. On these facts, the harm to Gilead weighs heavily in favor of the proposed injunctive relief.

E. An Injunction Is in the Public Interest

The public's interest in the injunction Gilead seeks is already a matter of public record. Congress and the FDA have determined that preventing the unregulated and unmonitored

importation of international prescription products is important to public health. *See supra* pp. 6-9. It is in the public interest to prevent the sale of unapproved and misbranded drugs in the United States. *See* Dkt. No. 274 at 7 ("[T]he court finds the public is better served by ensuring patients digest unadulterated medications subject to the rigors of United States standards."); *Rx Depot, Inc.*, 290 F. Supp. 2d at 1246-48 (preliminarily enjoining scheme to import prescription drugs from Canada and concluding that "Congress explicitly found that the unrestricted reimportation of U.S.-manufactured drugs created 'an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers'" (quoting Pub. L. 100-293, (HR 1207), § 2, 102 Stat. 95, 95 (Apr. 22, 1988)); *cf. Burger King Corp. v. Stephens*, No. 89-CV-7691, 1989 WL 147557, at *12-13 (E.D. Pa. Dec. 6, 1989) (granting preliminary injunction where trademark infringer failed to comply with regulatory health and safety standards and noting that "[f]ailure to maintain required quality standards constitutes an imminent threat to public health and safety"). The U.S.'s "closed" drug distribution network, which "provides the American public with multiple levels of protection against receiving unsafe, ineffective, or poor-quality medications," has resulted in "a level of safety for drug products that is widely recognized as the world's 'gold standard.'" Potter Decl., Ex. 17, at 11. Defendants' activities poke holes into this closed system, creating "weaknesses" that will "increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system." *Id.* CanaRx, ElectRx, and ScriptSourcing's public assertion that they import only from pharmacies in "Tier 1" countries, like Canada, is no defense. Indeed, Canadian entities have pleaded guilty in federal court for shipping counterfeit prescription drugs into the United States. Potter Decl., Ex. 19.

In addition to the public health implications of preventing the importation of international Gilead products, the public interest weighs in favor of injunctive relief because the misuse of Gilead's trademarks itself causes an injury to the public. Members of the public have a "strong interest in not being confused or deceptively 'attracted'" to the foreign drugs peddled by Defendants, which are not subject to the same regulatory standards that the federal government has imposed on products sold within the U.S. or the distribution safeguards and other quality control procedures Gilead has for its U.S. products. *See Fairbanks Cap. Corp.*, 303 F. Supp. 2d at 593; *Green*, 702 F. Supp. 3d at 424 ("Enforcement of the Lanham Act's trademark protections serves the public interest . . . ."); *Cytosport, Inc. v. Vital Pharms., Inc.*, 617 F. Supp. 2d 1051, 1081, (E.D. Cal. 2009), *aff'd*, 348 F. App'x 288 (9th Cir. 2009) ("When a trademark is said to have been infringed, what is actually infringed is the right of the public to be free of confusion and the synonymous right of the trademark owner to control his products' reputation") (internal citation omitted); *Int'l Kennel Club of Chicago, Inc. v. Mighty Star, Inc.*, 846 F.2d 1079, 1092 n.8 (7th Cir. 1988) ("[T]he relevant consideration in determining whether the public interest will be disserved by the grant of an injunction is the consumer's interest in not being deceived about the products they purchased.'" (alteration omitted)); *Green v. ABC Cos.*, 702 F. Supp. 3d 418, 424 (W.D.N.C. 2023) ("Enforcement of the Lanham Act's trademark protections serves the public interest"); *see also Gilead Scis., Inc.*, No. 1:24-CV-03566-JRR, 2025 WL 1745669, at *31.

II. THE COURT SHOULD AUTHORIZE EXPEDITED DISCOVERY

Gilead also respectfully seeks a limited expedited discovery order prior to any preliminary injunction hearing. Such discovery is critical to Gilead's ability to fully present its case at the requested preliminary injunction hearing. The expedited discovery that Gilead seeks

here is substantially similar to the expedited discovery that this Court ordered with regard to the originally named defendants.

Courts in this district have "adopted a reasonableness standard in reviewing expedited discovery requests, determining whether the request is supported by good cause considering the totality of the circumstances." *Savaria USA, Inc. v. Elevator Works, LLC*, No. RDB-24-1311, 2024 WL 2212914, at *12 (D. Md. May 16, 2024) (citing *Océ North Am., Inc. v. MCS Servs.*, No. WMN-10-CV-984, 2010 WL 11553001, at *1 (D. Md. June 22, 2010)). Expedited discovery requests must also be tailored to obtain information relevant to a preliminary injunction determination. *See Océ North Am., Inc.*, 2010 WL 11553001, at *1; *see also IOMAXIS, LLC v. Hurysch*, No. 20-3612 PJM, 2022 WL 180734, at *4 (D. Md. Jan. 20, 2022) (exercising court's "discretion under Rule 26 and direct[ing] the parties to engage in discovery on an expedited basis" because "Plaintiff's requested discovery is tailored to obtain information relevant to a determination of whether Defendants should be enjoined").

Gilead meets this two-part showing. First, based on the totality of the circumstances, good cause exists for an expedited discovery order in this matter. Expedited discovery is needed to facilitate a prompt resolution of Gilead's motion and to minimize further harm to Gilead. Further, expedited discovery will allow Gilead to prepare for, and the Court to conduct, a prompt but thorough preliminary injunction hearing. *See IOMAXIS, LLC*, 2022 WL 180734, at *5 (granting plaintiff's request for expedited discovery to obtain relevant information where a preliminary injunction was sought); *see also ClearOne Advantage, LLC v. Kersen*, Civ. No. JFB-23-03446, 2024 WL 278917 (D. Md. Jan. 25, 2024) (granting plaintiff's request for expedited discovery where a preliminary injunction motion was pending).

Second, the scope of discovery Gilead seeks to take before the preliminary injunction hearing is narrowly tailored to determine the scope and method of Defendants' illegal scheme to import Gilead's medications in the United States. It is only through immediate limited discovery that Gilead can determine behind-the-scenes interactions among Defendants and others that made the illegal importation scheme possible and what other persons and entities are involved in the illegal importations scheme, and assess the extent of the damage caused by Defendants. *See Courthouse News Serv. v. Harris*, No. ELH-22-548, 2022 WL 3577255, at *5-6 (D. Md. Aug. 18, 2022) (granting plaintiff's request for expedited discovery where the discovery was limited to facts relevant to the preliminary injunction motion). The limited discovery sought will also help Gilead understand the extent to which its medication is being illegally imported into the United States and how much of that importation is under Defendants' control. Without expedited discovery, Gilead will not be able to obtain this key information. *See id*. (discovery granted where other sources of information not available). In short, Gilead readily meets the reasonableness test used in this Court, and an expedited discovery order should be granted.

Finally, Gilead notes that its proposed expedited discovery order is based on the maximum 28-day timeframe (14 days plus a 14-day discretionary extension by the Court) to hold a preliminary injunction hearing after entry of a temporary restraining order under Federal Rule of Civil Procedure 65(b)(2). If the Defendants agree to an extended preliminary-injunction schedule, the parties can confer regarding discovery response times and make a proposal to the Court.

CONCLUSION

For the reasons stated above, the Court should grant Gilead's motion for a temporary restraining order (to be followed by a preliminary injunction) and an expedited discovery order,

and should award any other and further relief that the Court may deem just and proper. Proposed orders for the requested relief are being filed simultaneously herewith.

Dated: September 30, 2025

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