UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

GILEAD SCIENCES, INC.
333 Lakeside Drive, Foster City, California 94404

and

GILEAD SCIENCES IRELAND UC
IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland

Plaintiffs,

v.

MERITAIN HEALTH, INC.

PROACT INC.

RX VALET, LLC

ADVANCED PHARMACY, LLC

AQUA ENTERPRISE INC d/b/a AFFORDABLE RX MEDS

GREGORY SANTULLI

FETIH ECZANESI

CANARX SERVICES, INC.

CRX INTERNATIONAL, INC.

CANARX GROUP, INC.

GILES ROBERT HOWARD

JOHN HOWARD

ELECTRX AND HEALTH SOLUTIONS, LLC
Serve on: URS Agents Inc., 3458 Lakeshore Drive, Tallahassee FL, 32312

FIRST AMENDED COMPLAINT

Case No. 24-cv-3566-JRR

JEFFREY DINSMORE Serve on: 32332 Cross Bow Street, Beverly Hills, MI, 48025 SCRIPTSOURCING, LLC Serve on: 3301 Bonita Beach, Rd., Suite 106, Bonita Springs, FL 34134; 6080 Falls Road, Suite 201, Baltimore, MD, 21209 GARY BECKER Serve on: 10927 Falls Road, Lutherville, MD, 21093 Defendants.	

Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, "Gilead" or "Plaintiffs"), by and through their counsel, Patterson Belknap Webb & Tyler LLP and Kramon & Graham, P.A, for their Complaint against Defendants Meritain Health, Inc. ("Meritain Health"), ProAct Inc. ("ProAct"), Rx Valet, LLC ("Rx Valet"), Advanced Pharmacy, LLC ("Advanced Pharmacy"), Aqua Enterprise Inc d/b/a Affordable Rx Meds ("Affordable Rx Meds"), Gregory Santulli ("Santulli"), Fetih Eczanesi, CanaRx Services Inc., CRX International Inc., CanaRx Group Inc. (together with CanaRx Services, Inc. and CRX International Inc., "CanaRx"), Giles Robert Howard ("Bob Howard"), John Howard, ElectRx and Health Solutions LLC ("ElectRx"), Jeffrey Dinsmore ("Dinsmore"), ScriptSourcing LLC ("ScriptSourcing"), and Gary Becker ("Becker") (collectively, "Defendants") allege as follows:

SUMMARY OF THE ACTION

1. Gilead brings this action under the Lanham Act and state law to put an immediate stop to Defendants' schemes to force, trick, or push American patients, who have commercial health insurance, to fill their U.S. prescriptions with non-FDA-approved, illegally imported medicines bearing Gilead trademarks from foreign countries. As discovery to date has shown, there is an industry dedicated to unlawfully filling U.S. patients' prescriptions with foreign medicines, which constitutes a strict-liability crime under U.S. law and violates the laws of the countries from which the drugs are imported. In this amended pleading, Gilead has named Defendants who are leading the industry in causing infringing, illegally imported Gilead-branded medicines to be mailed to the homes of U.S. patients – and continue to do so, despite knowing that this Court has enjoined their peers and business partners in the illegal-importation industry; despite having received formal FDA Warning Letters directly telling them their business model violates federal law and endangers American patients; and/or despite being directly involved in

delivering foreign-made counterfeit medicine to an American patient who was told he was receiving a perfectly safe imported brand-name drug, and who suffered grievous physical harm from taking the entirely fake medicine that was mailed to his doorstep.

2. Defendants' scheme opens the closed U.S. supply chain to unsecured, unregulated, and unmonitored drugs. This not only puts U.S. patients in danger, but also violates Gilead's trademark rights by causing American patients to receive infringing, misbranded, and improperly shipped foreign Gilead-branded medicine. These foreign versions of Gilead's medicines are not intended for sale in the United States, do not comply with FDA requirements, have materially different labels and Patient Information documents, and are diverted and transported in a way that violates Gilead's quality-control standards.

3. U.S. patients should have their prescriptions filled by authentic, FDA-approved medicines meant for the U.S. market and manufactured and distributed in accordance with U.S. law and Gilead's quality control regime. This is not a case about drug shortages: authentic U.S. Gilead medicines are widely available at virtually every pharmacy in the nation. Rather, this is a case about U.S. patients receiving infringing, non-FDA-approved, and unsecurely shipped medicine from foreign countries, all so that the insurers and their "international mail order partners" can pad their bottom lines.

4. As this Court knows, Gilead's original complaint in this action stated claims against a group of Defendants that were involved in the importation of a Gilead-branded prescription HIV medicine from Turkey to a patient in Maryland. That Turkish product, which infringed multiple Gilead trademarks, materially differed from the products that Gilead authorizes for sale in the United States and was not subject to the quality controls that Gilead has in place for U.S. medicines. As pleaded in that complaint, however, and as confirmed over the

course of expedited discovery and a two-day preliminary injunction hearing, the original Defendants' acts of infringement were not limited to the importation of Turkish medicine to a single patient. Rather, the Turkish medicine was just one example of a sprawling (and growing) scheme, which includes numerous players and involves thousands of bottles of infringing Gilead medicine substituted for the U.S. medicine that insured U.S. patients should receive.

5. This case presents a quintessential example of gray-market trademark infringement: Defendants are importing, or arranging for and facilitating the importation of, goods bearing Gilead's trademarks that are intended for sale and use in markets outside of the United States, without Gilead's consent. It is black-letter law that importing and selling into U.S. commerce non-FDA-approved bottles of Gilead prescription medication, labelled differently than their U.S. counterparts and shipped halfway around the world without Gilead's controls and through an illicit, unregulated and unmonitored supply chain, violates Gilead's trademark rights.

6. Importing diverted prescription medicine not only places Gilead's reputation at risk: it places the public at risk by circumventing the United States's closed, secure, and highly regulated pharmaceutical supply chain, which is the global "gold standard." Importing diverted prescription medicines is neither safe nor reliable and threatens the immense trust and goodwill Gilead's trademarks embody.

7. Defendants have opened illicit, unregulated, and unmonitored supply chains directly from essentially anonymous foreign sources to the doorsteps of U.S. patients in gross violation of federal law. This creates a serious risk that counterfeit pharmaceuticals will make their way to U.S. patients, and renders Gilead unable to enforce the procedures it uses to protect U.S. patients from unsafe products purporting to be Gilead drugs. Indeed, Congress outlawed

third-party importation of foreign pharmaceuticals in the 1980s in response to a rash of counterfeit drugs entering the U.S. supply chain disguised as "foreign imports." Defendants' scheme to line their pockets by illegally importing drugs is an invitation to foreign counterfeiters who are eager to sell their fake drugs in U.S. commerce disguised as "legitimate" foreign product.

8. On one end of this importation scheme lie the entities that help administer health insurance benefits, such as Defendants Meritain and ProAct, which provide the financial motivation (via payments for the infringing international products) and practical support (via the complex administrative ecosystems through which insurance claims are processed, approved, and paid) necessary for insured patients to receive international medicine. They are the drivers of the scheme and create the ecosystem in which large-scale provision of international medicine to U.S. patients is possible. On the other end lie the insured patients, who carry the physical risk from their insurers' efforts to discard U.S. regulatory protections but do not pay for or actively seek out international medicine. In between, a host of shady businesses exist for the sole purpose of managing "international sourcing programs." These entities directly manage the unlawful business of identifying and paying foreign sources of prescription drugs who are willing to ship those drugs across international borders, as well as foreign doctors or healthcare providers to provide prescriptions for U.S. patients whom they have never met and whom they do not treat. They serve as the middleman between the patient to the gray-market prescription drug underworld, allowing the health insurance entities to keep their hands clean and shielding the patient from the sordid reality that they are receiving illegally provided drugs that are not subject to regulatory oversight.

9. Rx Valet, for example, serves this role for some health plans; it obtains the patient's prescription, provides "customer service support" to the patient about the orders associated with those prescriptions, orders and pays for the international drug on the patient's behalf, and bills the health plan, PBM, or third-party administrator for the drug (and for their own fee, of course). Because the drugs that Rx Valet advertises and procures for U.S. patients infringe Gilead's trademarks, Rx Valet directly infringes Gilead's trademarks through its international sourcing program.

10. But Rx Valet is not the only entity providing this "middleman" international sourcing service. As documents produced in the course of expedited discovery made clear, new Defendants CanaRx, ElectRx, and ScriptSourcing provide the same "international sourcing program" services as Rx Valet—including to the *very health insurance administration entities* sued in this case, Meritain Health and ProAct. In their programs, each of these entities advertises and arranges for the delivery of infringing international Gilead-branded medicines to U.S. patients.

11. CanaRx, ElectRx, and ScriptSourcing are all well aware of this lawsuit and Gilead's claims herein. They are aware that this Court enjoined the original Defendants from advertising or importing international Gilead-branded products to the United States. Nevertheless, each of these Defendants has continued to advertise and import Gilead-branded products from foreign sources to U.S. patients. Gilead therefore exercises its rights as a U.S. manufacturer and trademark owner in this amended complaint to stop Defendants from selling infringing, materially different, and illegally imported medicines that violate Gilead's quality-control efforts, are likely to confuse U.S. consumers, and tarnish the value of Gilead's marks – and, most importantly, threaten patient health and safety.

THE PARTIES

12. Plaintiff Gilead Sciences, Inc. is a public corporation organized under the laws of the State of Delaware, with more than 18,000 employees. Its principal place of business is 333 Lakeside Drive, Foster City, California 94404. Gilead Sciences, Inc. develops and markets a large portfolio of lifesaving prescription medicines, including drugs for the treatment or prevention of HIV. Gilead Sciences, Inc. is the owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and Patient Information documents of Gilead-branded medicines.

13. Plaintiff Gilead Sciences Ireland UC is a private unlimited company organized under the laws of Ireland, with its principal place of business at IDA Business & Technology Park, Carrigtohill, County Cork, Ireland. Gilead Sciences, Inc. is the ultimate parent of Gilead Sciences Ireland UC. Gilead Sciences Ireland UC is the owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and Patient Information documents of certain Gilead-branded medicines.

14. Defendant Meritain Health, Inc. ("Meritain"), a New York corporation, is a health insurer and plan administrator with its principal place of business in Amherst, New York.

15. Defendant ProAct, Inc. ("ProAct"), a New York corporation, is a pharmacy benefit manager ("PBM") with its principal place of business in East Syracuse, New York.

16. Defendant Rx Valet, LLC ("Rx Valet"), a Georgia limited liability company, is an alternative funding program ("AFP") with its principal place of business in Lawrenceville, Georgia.

17. Defendant Advanced Pharmacy, LLC ("Advanced Pharmacy"), a Georgia limited liability company, is a pharmacy with its principal place of business in Lawrenceville, Georgia.

18. Defendant Aqua Enterprise Inc d/b/a Affordable Rx Meds ("Affordable Rx Meds"), a Florida corporation, is a prescription referral service and self-described "international mail order pharmacy" with its principal place of business in Sunrise, Florida.

19. Defendant Gregory Santulli is an individual residing in Lawrenceville, Georgia. Santulli is the founder and CEO of Rx Valet and is also the President of Advanced Pharmacy.

20. Defendant Fetih Eczanesi is a Turkish retail pharmacy located in Istanbul, Turkey.

21. Defendant CanaRx Services Inc. ("CanaRx Services") is a self-described "international prescription service provider" based in Windsor, Ontario, Canada.

22. Defendant CRX International, Inc. ("CRX") is a self-described "international prescription service provider" with a registered address in Christ Church, Barbados.

23. Defendant CanaRx Group Inc. ("CanaRx Group"; collectively with CanaRx Services and CRX, "CanaRx") is a Barbados corporation with a registered address in Christ Church, Barbados.

24. Defendant Bob Howard is an individual residing in Ontario, Canada. He is the president and a director of CanaRx Services.

25. Defendant John Howard is an individual residing in Ontario, Canada. He is the treasurer and a director of CanaRx Services.

26. Defendant ElectRx and Health Solutions, LLC ("ElectRx") is a limited liability company based in Michigan. ElectRx describes itself as a "pharmacy benefits strategist."

27. Defendant Jeffrey Dinsmore is an individual residing in Beverly Hills, Michigan. He is the member, managing partner, and authorized agent of ElectRx.

28. Defendant ScriptSourcing, LLC ("ScriptSourcing") is a limited liability company registered in Maryland, with a mailing address in Bonita Springs, Florida. ScriptSourcing describes itself as a company that "partner[s] with select benefits consultants, PBMs, and TPAs in an effort to provide the most competitive pricing for expensive specialty and name brand medications."

29. Defendant Gary Becker is an individual residing in Lutherville, Maryland. Becker is ScriptSourcing's founder, CEO, sole member, and registered agent.

JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 1121(a), 28 U.S.C. §§ 1331, 1338, and 1367, and general principles of ancillary and pendent jurisdiction.

31. This Court has personal jurisdiction over all Defendants pursuant to Maryland's Long Arm Statute, Md. Code Ann., Cts. & Jud. Proc. § 6-103, and consistent with the due process clause of the Fourteenth Amendment of the U.S. Constitution because: Defendants (i) transact business in Maryland; (ii) contract to supply goods, food, services, or manufactured products in Maryland; (iii) caused tortious injury in Maryland by an act or omission in Maryland; and (iv) caused tortious injury in Maryland by an act or omission outside of Maryland, and regularly do or solicit business, engage in other persistent course of conduct in Maryland, or derive substantial revenue from goods, food, services, or manufactured products used or consumed in Maryland. Defendants have knowingly and intentionally directed conduct toward Maryland and purposefully availed themselves of Maryland's market and laws by, *inter alia*, shipping or arranging to be shipped an infringing foreign Gilead medicine to a patient located in Maryland. Defendants' conduct alleged herein was knowingly and intentionally

directed toward Maryland, and Defendants purposefully availed themselves of Maryland's market and laws.

32. The effects of Defendants' conduct in Maryland were not only foreseeable; they were foreseen and intended.

33. This Court further has personal jurisdiction over Gregory Santulli pursuant to Maryland's Long Arm Statute, Md. Code Ann., Cts. & Jud. Proc. § 6-103, and consistent with the due process clause of the Fourteenth Amendment of the U.S. Constitution, because Santulli was an active and moving force behind Rx Valet's importation of infringing Gilead products to Maryland. This Court also has personal jurisdiction over Gregory Santulli because Santulli personally signs all contracts between Rx Valet and employer-sponsored health plans to provide infringing, international prescription drugs to Maryland patients, and because Santulli personally approves payments from Rx Valet and Advanced Pharmacy's bank accounts for infringing, international prescription drugs sent to Maryland patients.

34. This Court further has personal jurisdiction over Bob Howard and John Howard pursuant to Maryland's Long Arm Statute, Md. Code Ann., Cts. & Jud. Proc. § 6-103, and consistent with the due process clause of the Fourteenth Amendment of the U.S. Constitution, because they are active and moving forces behind CanaRx's importation of infringing Gilead products to Maryland.

35. This Court further has personal jurisdiction over Jeffrey Dinsmore pursuant to Maryland's Long Arm Statute, Md. Code Ann., Cts. & Jud. Proc. § 6-103, and consistent with the due process clause of the Fourteenth Amendment of the U.S. Constitution, because Dismore is an active and moving forces behind ElectRx's importation of infringing Gilead products to Maryland.

36. This Court has personal jurisdiction over Defendants ScriptSourcing and Gary Becker pursuant to Md. Code Ann., Cts. & Jud. Proc. § 6-102, and consistent with the due process clause of the Fourteenth Amendment of the U.S. Constitution, because Becker – ScriptSourcing's sole member – is domiciled in Maryland. Additionally, this Court has personal jurisdiction over Becker because he is an active and moving forces behind ScriptSourcing's importation of infringing Gilead products to Maryland.

37. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b)(2) because Defendants sold, or caused to be sold, infringing Gilead-branded products in this District, and/or conspired to operate a scheme to sell infringing Gilead-branded products to a patient in this District. Accordingly, a substantial part of the events giving rise to Gilead's claims occurred in this District.

38. This is an action for damages in excess of $75,000.00, exclusive of interest, costs, and attorneys' fees.

FACTUAL ALLEGATIONS

I. GILEAD'S TRADEMARKED MEDICATIONS

39. For more than three decades, Gilead has strived to create a healthier world for all by delivering innovative therapeutics that aim to prevent, treat, or cure life-threatening diseases. Gilead relentlessly pursues advancements in science with the goal of bringing treatments that improve care in areas of unmet medical needs to patients around the world.

40. Gilead has transformed care for people living with serious diseases, including by developing pioneering medicines such as the world's first single-tablet regimen to treat HIV, the first prophylactic medicine to prevent HIV infection, and four hepatitis C therapies.

41. For example, BIKTARVY®, developed by Gilead and first approved by the U.S. Food and Drug Administration ("FDA") in 2018, is a medicine for the treatment of HIV-1 infection. BIKTARVY® has a demonstrated long-term efficacy and safety profile, few drug interactions and side effects, and a high barrier to developing drug resistance. Although BIKTARVY® does not cure HIV, when taken every day as prescribed, it can lower the amount of virus in a patient's blood to undetectable levels.

42. The Gilead medicines sold in the U.S., including BIKTARVY®, are prescription drugs that have been approved for sale by the FDA.

43. Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC are the collective owners of a number of well-established and famous registered trademarks (the "Gilead Marks") that appear on its genuine medicines. Gilead also owns and uses distinctive packaging (the "Gilead Trade Dress") to distinguish its medications in the marketplace. A non-exhaustive list of Gilead Marks is set forth in **Exhibit A** hereto, which is incorporated by reference. Some Gilead Marks – such as "GILEAD" and the leaf-and-shield mark ( ) – appear on all Gilead medications, both in the U.S. and around the world.

44. In the U.S., these Gilead Marks convey to American consumers that the medicine is a legitimate, high-quality Gilead product that has been approved by the FDA, safely manufactured in an FDA-approved facility, and transported in accordance with Gilead's quality-control protections.

45. Other Gilead Marks are specific to a given medicine, such as BIKTARVY® and DESCOVY®. These marks appear on the labels and Patient Information documents of their corresponding Gilead-branded medicines.

46. Gilead currently uses and plans to continue using the Gilead Marks and the Gilead Trade Dress in commerce in connection with its sale of medicines. Gilead prominently displays the Gilead Marks in its advertising and promotional materials.

47. Gilead has engaged and continues to engage in activities designed to promote the business goodwill associated with its trademarks, and to expand the use and reputation of its trademarks, trade dress, and other intellectual property throughout the U.S. The Gilead Marks and Gilead Trade Dress symbolize the business goodwill of Gilead and are invaluable assets to Gilead.

II. THE "JOHN DOE" WHISTLEBLOWER REPORT AND GILEAD'S INVESTIGATION

48. "John Doe" is a patient residing in Maryland. John Doe has expressed, through his doctor, his strong desire to remain anonymous in order to preserve his privacy in his health-care matters. Gilead has not obtained any personally identifying information about John Doe.

49. John Doe has been taking BIKTARVY® as prescribed by his doctor since at least 2021. For most of that time, John Doe obtained authentic U.S. BIKTARVY® – i.e., FDA-approved BIKTARVY® manufactured, packaged, and labeled for sale in the U.S. – from chain retail pharmacies in Maryland.

50. In January 2024, John Doe switched to a new health insurer, which was administered by Meritain Health, a third-party administrator of employer-sponsored health plans. John Doe's pharmacy benefit coverage with his Meritain-administered health insurance plan was managed by ProAct, a pharmacy benefit manager, or PBM.

51. In January or February 2024, John Doe asked his doctor to send his BIKTARVY® prescription to ProAct's in-house mail-order pharmacy.

52. ProAct's in-house pharmacy refused to fill John Doe's prescription for BIKTARVY®. Instead, ProAct instructed John Doe to contact one of ProAct's "partners," Rx Valet, who would fill his prescription for free, with no copay.

53. Rx Valet instructed John Doe to have his doctor send his BIKTARVY® prescription to Advanced Pharmacy, a mail-order pharmacy based in Georgia. Rx Valet advertises Advanced Pharmacy as Rx Valet's pharmacy, and Gregory Santulli, the founder and CEO of Rx Valet, is also the President of Advanced Pharmacy. Advanced Pharmacy has a very minimal online presence, and exists for the purpose of selling and facilitating the sale of infringing and illegally imported medications.

54. Believing he was following his health insurer's instructions to obtain coverage for his BIKTARVY® prescription, John Doe instructed his doctor to send his BIKTARVY® prescription to Advanced Pharmacy. The doctor did so, just days after the prescription had been sent to (but not fulfilled by) ProAct's in-house pharmacy.

55. Weeks after his prescription was transferred to Advanced Pharmacy, John Doe received a three-month supply of BIKTARVY® – three bottles of 30 tablets each – delivered to his home in Maryland through an international courier, such as DHL or FedEx.

56. After receiving the BIKTARVY®, John Doe was immediately concerned that it might not be authentic Gilead product or safe to consume. Although the medication bore the name BIKTARVY®, the name GILEAD, and Gilead's leaf-and-shield trademark ( ), it did not look like the U.S. BIKTARVY® John Doe had been taking for years. U.S. BIKTARVY® is dispensed in bottles without any exterior packaging, but this medication was packaged in cartons containing the bottles. And, most saliently, the packaging, labeling, and Patient Information

documents were entirely in Turkish, not English. Photos of the BIKTARVY® received by John Doe are attached as **Exhibit B**.

57. The cartons containing the Turkish-language BIKTARVY® had a patient sticker applied to them with the company name Affordable Rx Meds. John Doe had never spoken with anyone at, or sent anything to, Affordable Rx Meds, and had never heard of the company before.

58. John Doe checked the tracking information for the package containing the Turkish-language BIKTARVY® and saw that the package originated in Istanbul and passed through several European countries before arriving in Maryland.

59. Unbeknownst to John Doe, the bottles of BIKTARVY® he received in the mail had been shipped to him directly by Fetih Eczanesi, a small retail pharmacy in Istanbul.

60. John Doe did not seek out Turkish BIKTARVY® or any other international version of BIKTARVY®. He never met with a Turkish doctor, obtained a Turkish prescription for BIKTARVY®, or communicated with a Turkish pharmacy. None of the entities that communicated with John Doe about his BIKTARVY® prescription in early 2024 informed him that his free BIKTARVY® would be imported from a Turkish pharmacy, would be labeled entirely in Turkish, or was manufactured on a Turkish assembly line that was not approved or inspected by the FDA.

61. On February 20, 2024, the Maryland clinic at which John Doe was a patient submitted a quality complaint to Gilead. The clinic explained that John Doe wished to remain anonymous, but had given permission for the clinic to share the details of the incident. This clinic explained John Doe had received a three-month supply of Turkish-language BIKTARVY® in the mail. The clinic and John Doe were both uncertain whether this Turkish-language BIKTARVY® was authentic Gilead product.

62. After receiving the clinic's quality complaint, Gilead promptly notified the FDA and launched an investigation.

63. At Gilead's request, on February 28, 2024, the clinic shipped the Turkish BIKTARVY® that John Doe had received to Gilead's Quality Assurance Department. Upon analysis, the sample appeared to be consistent with authentic Turkish BIKTARVY® – *i.e.*, BIKTARVY® manufactured, packaged, and labeled for sale in Turkey, in compliance with Turkish laws and regulations.

64. Each of Gilead's Turkish BIKTARVY® products is labeled with a unique serial number and a QR code that allows the product to be traced through a Turkish governmental track-and-trace system. Through that system, Gilead determined that the three Turkish BIKTARVY® products were last sold to Defendant Fetih Eczanesi, a Turkish retail pharmacy.

65. Until at least November 2024, after reporting the Turkish BIKTARVY® products and providing them to his healthcare provider, John Doe continued to receive 90-day supply shipments of Turkish BIKTARVY® at his home. He has not taken any action to trigger these shipments. John Doe discarded those cartons and bottles unopened.

III. THE PROCEEDINGS AGAINST THE ORIGINALLY NAMED DEFENDANTS

66. On December 10, 2024, Gilead filed its initial complaint against Defendants Meritain Health, ProAct, RxValet, Advanced Pharmacy, Gregory Santulli, Affordable Rx Meds, and Fetih Eczanesi: i.e., the entities that Gilead had identified as involved in supplying John Doe with Turkish BIKTARVY®. On the same day, Gilead sought a temporary restraining order against those Defendants, as well as an order permitting Gilead to seek expedited discovery from those Defendants and certain categories of non-parties in connection with Gilead's motion seeking a preliminary injunction.

67. Gilead proceeded to seek and obtain discovery from the originally named Defendants. Documents produced in discovery confirmed the existence of business relationships between those Defendants and CanaRx, ScriptSourcing, and ElectRx related to the importation of prescription drugs from foreign sources to U.S. patients, including the following:

a. ProAct "partnered" with CanaRx to provide a ProAct-branded international sourcing program to its health care clients.

b. Meritain processed invoices for infringing international prescription medicines from CanaRx, ScriptSourcing, and ElectRx.

c. Meritain [redacted]

d. Rx Valet ordered infringing international Gilead medicine from [redacted], to be delivered to U.S. patients.

68. During the expedited discovery period, Gilead also served non-party subpoenas on ScriptSourcing and ElectRx. In response to Gilead's non-party subpoena, ScriptSourcing refused to produce any information about the international Gilead medicine that it had arranged to import to U.S. patients. ElectRx provided some information about its importation of international Gilead medicine, but it meticulously redacted all information about the foreign sources from which it obtained Gilead-branded drugs or the U.S. locations of patients who received those drugs.

69. On June 24, 2025, this Court entered a preliminary injunction enjoining the originally named Defendants – Meritain, ProAct, Rx Valet, Advanced Pharmacy, Affordable Rx Meds, Santulli, and Fetih Eczanesi – from continuing to import or knowingly facilitate the importation of international Gilead prescription medicines. Among other findings, the Court

concluded that Gilead was likely to succeed on its trademark infringement claims based on the importation of international Gilead medicines, which materially differ from U.S. Gilead medicines.

IV. FOREIGN VERSIONS OF GILEAD'S MEDICATION ARE NOT FDA-APPROVED, AND THEIR IMPORTATION IS ILLEGAL

70. It is illegal under the U.S. Food, Drug, and Cosmetics Act ("FDCA") for anyone other than the manufacturer to import or facilitate the importation of prescription medications into the U.S. (subject to very limited exceptions not applicable here). 21 U.S.C. § 331(t). This is true even if the drugs being imported are FDA-approved. But here, the drugs Defendants are importing to the U.S. are not FDA-approved.

71. No international Gilead-branded medicines are intended for sale in the United States, and no international Gilead-branded medicines are regulated or approved by the FDA for use in the United States.

72. All U.S. versions of Gilead-branded drugs are FDA-approved and conform with all FDA requirements. International versions of Gilead-branded medicines are intended for sale outside of the U.S. and are not FDA-approved. No version of any Gilead-branded medicine meant for the international market meets all of the FDA manufacturing, packaging, and labeling requirements for versions of that medicine intended for the U.S. market. Rather, international Gilead-branded medicines meet the different regulatory requirements of the foreign markets in which they are intended for sale.

73. As a result, the importation or distribution of any international Gilead-branded medicine constitutes the sale of an "unapproved new drug" in the U.S. 21 U.S.C. § 355. Among other things, that makes the drugs "misbranded" under the FDCA. 21 U.S.C. § 353. The sale of misbranded prescription drugs is a strict-liability federal crime. 21 U.S.C. §§ 331(a), 333(a).

74. The FDA has issued two Warning Letters to companies that import or facilitate the importation of foreign prescription medications: Defendant CanaRx Services and Defendant ElectRx.[1] In those Warning Letters, the FDA states that the imported foreign medications are not FDA-approved, constitute "unapproved new drugs," and pose a serious threat to patient safety. Both Warning Letters give as examples of these illegally imported "unapproved new drugs" foreign versions of Gilead-branded medicine.

75. Congress tightened prohibitions on the importation of prescription drugs in the 1980s in response to a high-profile wave of counterfeit medications that made their way into the U.S. pharmaceutical supply chain disguised as "authentic" imported medicine and were sold to American patients, including counterfeit birth-control pills.

76. The Department of Health and Human Services has described the current U.S. prescription medication supply chain as "a 'closed' system" that "provides the American public with multiple levels of protection against receiving unsafe, ineffective, or poor-quality medications…. The result has been a level of safety for drug products that is widely recognized as the world's 'gold standard.'" Entities that illegally import foreign drugs into the U.S. create holes in this closed system and "increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system."[2]

77. All illegal importation of foreign medication breaches the secure U.S. supply chain and creates an unacceptable risk of counterfeit drugs reaching American patients. Foreign

[1] FDA Warning Letter (Mar. 2, 2023), at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023; FDA Warning Letter (Feb. 26, 2019), at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/canarx-services-inc-554740-02262019.

[2] HHS Task Force on Drug Importation, *Report on Prescription Drug Importation* (2004).

pharmaceutical counterfeiters are always looking for opportunities to penetrate the closed, highly regulated U.S. pharmaceutical supply chain and sell their fake drugs to American consumers. Defendants have opened the door for them.

78. Turkey and India are global hotspots for the manufacture and distribution of counterfeit pharmaceuticals, so the illegal importation of purported pharmaceutical products from those countries presents a particularly serious risk to U.S. patients.

79. Indeed, on February 6, 2025, Turkish police officers raided five locations linked to an organized crime group in Istanbul responsible for manufacturing and distributing counterfeit medicines. Among the counterfeit medicines this group produced was the Gilead-branded medicine TRODELVY®, which is a prescription drug for the treatment of advanced breast or urothelial cancer. Turkish police seized at least 300 empty counterfeit cartons bearing counterfeit Gilead marks during the raid.

80. In May 2025, Gilead identified a Turkish seller offering Turkish-language BIKTARVY® on social media. The original posting featured images that were indistinguishable from genuine Turkish BIKTARVY®. When Gilead's investigator contacted the seller, however, the seller provided additional images of the product that proved it was counterfeit, including a counterfeit seal that did not match Gilead's genuine seals and an expiry date that did not match the featured lot number. The seller claimed to have 40-50 boxes of Turkish BIKTARVY® available and stated that it would be willing to ship them overseas, including to the United States. This incident demonstrates what Gilead has emphasized in this litigation: that the grey market for Gilead pharmaceuticals contains counterfeit products, and the introduction of products from outside the secure U.S. supply chain places U.S. patients at unacceptable risk.

81. Turkey and India are not the only international sources of counterfeit pharmaceuticals, however. The Department of Justice has criminally prosecuted "international mail order pharmacies" that sold counterfeit cancer medication into U.S. commerce by claiming they were safely importing drugs from Canada. In reality, these fake drugs had no active ingredients in them whatsoever.

V. DEFENDANTS' IMPORTATION SCHEME

82. Defendants have all conspired to execute a scheme whereby American patients who have commercial health insurance expect to and should have their prescriptions filled by, and their insurance cover the cost of, authentic, FDA-approved U.S. medications, are instead required, tricked, or pushed into filling their prescriptions with illegally imported, non-FDA-approved foreign medications, including international Gilead-branded medicines.

83. All of the Defendants knew, and certainly had every reason to know, that imported international versions of Gilead-branded medicines are not FDA-approved and have numerous material differences as compared to authentic U.S. product. None of the Defendants warns the U.S. patients who use their services that they are receiving materially different, non-FDA-approved foreign medicines shipped through an unsecured, unregulated supply line. Indeed, all of the Defendants actively attempt to deceive patients into believing they are receiving the same safe, securely supplied medicines that they would receive from a U.S. retail pharmacy.

84. Because the international Gilead-branded medicines are materially different from their U.S. counterparts, the importation and distribution of these international Gilead-branded medicines violates and undermines Gilead's established quality-control procedures. Therefore, when used in U.S. commerce, international Gilead-branded medicines constitute infringing

goods that violate Gilead's U.S. trademarks, and their advertising, sale, importation, or distribution in the U.S. is an act of trademark infringement.

a. Rx Valet

85. Defendant Rx Valet is an "Alternative Funding Program" based in Georgia, which purports to provide services to health plans and PBMs that will reduce the cost of providing prescription-drug benefits to their insured patients.

86. Rx Valet advertises that it provides health plans "International Sourcing" of prescription drugs, which it also refers to as "International Pharmacy." Rx Valet advertises that it "utilize[s] a network of affiliated pharmacies from around the world" to provide "the lowest pricing for name-brand medications." It asserts that the medicines are "the exact same quality as if they were dispensed in the U.S." and that international importation is a "safe, convenient way to save big on the Rx Valet medications you know and trust."

87. Rx Valet encourages health plans to contract with it to provide "international sourcing" services for their U.S. members. Rx Valet has specifically cited the possible savings to plans by supplying internationally sourced Gilead medicines, including BIKTARVY®, to members, rather than providing U.S. Gilead medicines. Rx Valet also specifically recommends that health insurers make it "mandatory" for their members to obtain prescription drugs through Rx Valet.

88. Rx Valet obtains patient information directly from PBMs, TPAs, and/or health insurers, and contacts those patients to encourage them to obtain prescription medications through Rx Valet. Rx Valet uses its connection with the patients' insurers to encourage patients to trust it; indeed, sometimes Rx Valet's employees represent to patients that they are calling from a patient's PBM, rather than saying that they are calling from Rx Valet.

89. For example, Rx Valet told John Doe that, to obtain BIKTARVY® through his insurance prescription benefit for a $0 copay, he would have to direct his doctor to send his prescription to Advanced Pharmacy. Rx Valet gave this instruction knowing and intending that the prescription would be filled by an international pharmacy supplying international medication, not by a U.S. pharmacy supplying U.S. medication.

90. Rx Valet places orders for international prescription medicine, including for Gilead medicines, with "international mail order pharmacies," which are unlicensed referral services that obtain medicines from undisclosed foreign sources. Rx Valet does not know the identities of the entities shipping medicine to U.S. patients when it places orders, nor does it know how those entities obtained the medicine.

91. Rx Valet's web site openly advertises that it will sell or source the following international Gilead-branded medicines: AMBISOME®, BIKTARVY®, DESCOVY®, GENVOYA®, SOVALDI®, STRIBILD®, TRUVADA®, and VOSEVI®.

92. Rx Valet has regularly worked with U.S. patients, U.S. health plans, and PBMs to fill patients' prescriptions with infringing, non-FDA-approved international Gilead-branded medicines. Rx Valet reaps enormous illicit financial awards for its infringement. Rx Valet's infringement is intentional, knowing, and willful.

b. Advanced Pharmacy

93. Defendant Advanced Pharmacy is a mail-order pharmacy based in South Carolina.

94. Advanced Pharmacy's President, Defendant Gregory Santulli, is also the CEO and founder of Rx Valet.

95. Advanced Pharmacy advertises itself as Rx Valet's "mail order home delivery pharmacy." Advanced Pharmacy's information appears on the "contact us" page of Rx Valet's website, rxvalet.com.

96. Advanced Pharmacy acts as a "front" for Rx Valet's international sourcing program, creating a crucial link between the legitimate system by which U.S. healthcare providers transmit prescriptions to licensed U.S. pharmacies, and the unlawful network of unlicensed entities that arrange for drugs to be illegally shipped from foreign sources to U.S. patients. Because Advanced Pharmacy is a licensed U.S. pharmacy, it has access to the electronic prescription networks through which U.S. healthcare providers transmit patient prescriptions. When healthcare providers submit an electronic prescription to Advanced Pharmacy, they are under the impression that the prescription will be fulfilled by a domestic pharmacy that is subject to federal and state regulations related to pharmacy operation and pharmaceutical supply chains, including the Drug Supply Chain Security Act (DSCSA).

97. Instead, Advanced Pharmacy turns around and provides Rx Valet with access to those electronic prescriptions, pursuant to an agreement under which Advanced Pharmacy agreed to provide "management services" to Rx Valet in exchange for Rx Valet paying Advanced Pharmacy a minimum of $10,000 per month. Advanced Pharmacy does not provide any "management services" related to the operation of Rx Valet as a business entity; rather, in exchange for that steep monthly payment, Advanced Pharmacy provides Rx Valet with an access point into the U.S. e-prescription network, which provides Rx Valet's international sourcing program with a veneer of legitimacy.

98. The vast majority of Advanced Pharmacy's business is referred to it by Rx Valet. Advanced Pharmacy knows and intends that Rx Valet will access the e-prescriptions submitted

to it in order to send copies of those prescriptions to sketchy, unlicensed "international mail-order pharmacies," which arrange for international versions of prescription medicine – including Gilead medicines – to be delivered to U.S. patients. Indeed, if Rx Valet obtains a copy of a legitimate e-prescription via its access to Advanced Pharmacy's back-end database, and sends that prescription to an "international mail-order pharmacy," Advanced Pharmacy will refrain from filling that prescription with authentic domestic medicine.

99. For example, after Advanced Pharmacy received John Doe's BIKTARVY® prescription, Advanced Pharmacy did not dispense U.S. BIKTARVY® to him, even though U.S. BIKTARVY® was and is readily available. Instead, Advanced Pharmacy kept the BIKTARVY® prescription in its database where it was accessible to Rx Valet, with the understanding and intention that Rx Valet would refer the prescription to an "international mail order pharmacy" and that John Doe would receive international BIKTARVY® instead of U.S. BIKTARVY®. Advanced Pharmacy itself would not have been legally permitted to dispense Turkish BIKTARVY® to John Doe.

100. Advanced Pharmacy also places orders for Gilead medicines with unlicensed "international mail order pharmacy" entities, with the intention and knowledge that these entities will procure products that purport to be international Gilead medicines from foreign sources, to be delivered directly to U.S. patients. Advanced Pharmacy also pays for these international prescription medicines.

101. Advanced Pharmacy's infringement of Gilead's trademark rights is intentional, knowing, and willful. Advanced Pharmacy reaps enormous illicit profits for its infringement.

c. Gregory Santulli

102. Gregory Santulli is the founder, owner, and CEO of Rx Valet, and is also the sole member and President of Advanced Pharmacy.

103. As the founder and CEO of Rx Valet and the President of Advanced Pharmacy, Santulli is intimately involved in Rx Valet and Advanced Pharmacy's efforts to import international prescription drugs. Santulli directs, approves, and supervises both companies' advertising, sales, and importation of infringing international Gilead-branded medicines; indeed, he describes himself as a "very active" CEO. He controls both companies and is an active and moving force behind both companies' infringement. Santulli directly financially benefits from his companies' infringement.

104. Santulli personally signs contracts with health insurance companies that provide for Rx Valet to arrange for U.S. insured patients to receive international medicine, including international Gilead medicine. Some of these contracts are with companies whose employees reside in Maryland (including, but not limited to, John Doe).

105. Santulli also personally signed the contract pursuant to which Rx Valet maintains its access to e-prescriptions submitted by U.S. healthcare providers to Advanced Pharmacy.

106. In 2016, Santulli and Advanced Pharmacy were named as defendants in a federal lawsuit brought by a U.S. manufacturer of medical devices, alleging that they sold unlawfully imported medical devices that were materially different from the U.S. versions of those medical devices. The court in that case found that the imported international medical devices were infringing under the material-differences and quality-control doctrines, issued a Temporary Restraining Order prohibiting the defendants' sale of the infringing international devices, and

then converted the TRO into a preliminary injunction. Advanced Pharmacy and Santulli settled, and the preliminary injunction against them was converted into a permanent injunction.

107. Santulli intentionally, knowingly, and willfully violated Gilead's trademarks.

d. Affordable Rx Meds

108. Defendant Affordable Rx Meds is a self-described "prescription referral service" and "international mail-order pharmacy" based in Florida. It is not a pharmacy and does not have a pharmacy license; instead, it takes U.S. patients' prescriptions, passes them on to its "contracted pharmacies" in foreign countries, and arranges for the foreign source to ship the prescription drugs directly to U.S. patients.

109. As a matter of Turkish law, Turkish pharmacies cannot fill prescriptions written by a doctor who is not licensed to practice medicine within Turkey, and Turkish doctors cannot simply re-write an American doctor's prescription without seeing the patient. And, based on information available to Gilead, none of the patients whose prescriptions Affordable Rx Meds "refers" ever sees a Turkish doctor or consents to their prescription being re-written by a Turkish doctor. Affordable Rx Meds' "prescription referral service" is unlawful on its face.

110. Affordable Rx Meds serves as a U.S.-based front for international pharmacies that illegally ship prescription drugs from foreign countries to U.S. patients based on prescriptions written by U.S. healthcare providers. For example, the Turkish BIKTARVY® cartons shipped to John Doe were labeled with a sticker bearing the name "Affordable Rx Meds", the URL affordablerxmeds.com, and a U.S. phone number, rather than the name and contact information of the Turkish pharmacy that actually dispensed the drug.

111. Although Affordable Rx Meds is not a pharmacy, it designed this sticker to mimic legitimate pharmacy patient labels familiar to any U.S. patient – the labels applied by the

pharmacy to the outside of the bottle that identify the patient's name, the dispensing pharmacy, the drug dosage, etc. The purpose and intent of the Affordable Rx Meds sticker is to give the false appearance of the drug being dispensed by a U.S. pharmacy, and to conceal the fact that the product was shipped from a pharmacy in Turkey and to conceal the identity of that pharmacy.

112. Affordable Rx Meds publicly advertises that it supplies patients with prescription medications from "contracted pharmacies" in India, Turkey, the United Kingdom, and Mauritius, and that prescriptions are filled with medications "from the foreign jurisdiction in which [the contracted pharmacies] are located." It does not refer any prescriptions to U.S.-based pharmacies to be filled with legitimate U.S. medicines.

113. In reality, Affordable Rx does not even know the identity of the foreign entities that ultimately fill U.S. patients' prescriptions. Affordable Rx Meds sent John Doe's prescription for BIKTARVY® to a Turkish pharmaceutical wholesaler, with the intention and understanding that it would ship Turkish BIKTARVY® to John Doe in Maryland. Instead, however, the Turkish pharmaceutical wholesaler referred John Doe's prescription to a *different* Turkish entity – the pharmacy Fetih Eczanesi – to fill with BIKTARVY® that Fetih Eczanesi sourced. Until Gilead filed this lawsuit, Affordable Rx had never heard to Fetih Eczanesi, even though Fetih Eczanesi was shipping prescription medicines bearing Affordable Rx's name to U.S. patients.

114. Counterfeiters are often caught when a patient reports that their medication looks different from what they usually receive. However, Affordable Rx Meds directly advises patients to ignore their instincts and disregard any differences they notice. Affordable Rx Meds' "Frequently Asked Questions" website states:

> **Why do the pills I received look different from the ones I get from my local pharmacy?** If you have ordered the [*sic*] brand name medication and see variance from

> the brand name medication you have purchased locally do not be alarmed. Brand name medication sometimes varies in appearance and name from country to country.

Affordable Rx Meds has thus created an illicit supply chain and told American patients not to raise the alarm if they see something suspicious, which increases the risk of counterfeits entering the U.S. drug distribution system.

115. Affordable Rx Meds regularly solicits prescriptions for Gilead-branded medicines from U.S. patients and causes those prescriptions to be filled by pharmacies in other countries, including India, Turkey, and Mauritius, so that they can be filled with international Gilead-branded medicine. Affordable Rx Meds' web site openly advertises that it can provide U.S. patients with the following international Gilead-branded medicines: BIKTARVY®, DESCOVY®, GENVOYA®, STRIBILD®, and TRUVADA®.

116. Affordable Rx Meds has also arranged for U.S. orders for the Gilead-branded medicine BIKTARVY® to be filled by shipping a generic drug imported from India, called Taffic, directly to U.S. patients. The FDA has not approved Taffic for sale in the United States.

117. Affordable Rx Meds' infringement is intentional, knowing, and willful. Affordable Rx Meds reaps enormous illicit financial rewards for its acts of infringement

e. Fetih Eczanesi

118. Fetih Eczanesi is an Istanbul-based retail pharmacy that fills American patient's prescriptions with non-FDA-approved Turkish Gilead-branded medicines in violation of Turkish law. Fetih Eczanesi ships these Turkish medications directly to the American patients' homes.

119. Fetih Eczanesi ships Turkish Gilead-branded medicines in small plain packaging via international courier, where the shipping process takes days or weeks in non-climate-controlled conditions.

120. Fetih Eczanesi shipped three cartons of Turkish BIKTARVY® from Istanbul to John Doe in Maryland in an unmarked package with no special handling instructions or temperature controls. The package traveled from Turkey, through several European countries, to a central package processing center in Tennessee, to John Doe's home in Maryland.

121. Fetih Eczanesi regularly ships Turkish Gilead-branded drugs directly to U.S. patients in unmarked packages that do not identify their contents. All Gilead-branded drugs that Fetih Eczanesi sources in Turkey, such as the Turkish BIKTARVY® that it supplied to John Doe, are labeled in Turkish with Patient Information documents in Turkish.

122. In addition to violating U.S. law as described above, Fetih Eczanesi's practice of mailing Turkish prescription drugs to U.S. patients violates Turkish law, which prohibits pharmacies from shipping drugs outside of the country. Turkish law also prohibits pharmacies from dispensing prescription drugs without a physical prescription from a Turkish doctor.

123. Given that Turkish pharmacies, like Fetih Eczanesi, are knowingly violating the law by participating in Defendants' scheme and shipping medication to America, it is highly likely that such pharmacies will seek to increase their illicit profits by also shipping counterfeit versions of those medications, which are widely available in Turkey.

124. Fetih Eczanesi's infringement of Gilead's trademarks is intentional, knowing, and willful. Fetih Eczanesi reaps enormous illicit financial rewards for its acts of infringement.

f. CanaRx

125. CanaRx Services is a self-described "international prescription service provider."

126. CanaRx Group is described in its audited financial statements as a company that "operates an international prescription supply program designed for large employee groups in the United States." CanaRx Group is a subsidiary of 1646237 Ontario Inc., an Ontario entity with

the same registered headquarters as CanaRx Services. The directors and officers of 1646237 Ontario Inc. are the same as the directors of CanaRx Services: Bob Howard (president), John Howard (treasurer), and Robert King (secretary).

127. CRX is described in its audited financial statements as a company that "operates an international prescription supply program designed for large employee groups in the United States." CRX is a subsidiary of 2266578 Ontario Inc., an Ontario entity with the same registered headquarters as CanaRx Services. The directors of 2266578 Ontario Inc. are the same as the directors and officers of CanaRx Services: Bob Howard, John Howard, and Robert King.

128. CanaRx Services, CanaRX Group, and CRX each promote, advertise, and facilitate the provision of internationally sourced medicines to insured U.S. patients, using Gilead's trademarked brand names.

a. CanaRx Services: As described *supra* at paragraphs 66-67, Defendant ProAct publicly "partners" with "CanaRx," which it describes as an "international mail-order pharmacy." ProAct has a Memorandum of Understanding with CanaRx Services about this partnership. ProAct coordinates directly with CanaRx Services employees about this joint international mail-order pharmacy program, including by updating the formulary that governs which brand-name medicines ProAct's clients will pay for CanaRx to ship illegally to U.S. patients. The ProAct-CanaRx formulary includes Gilead medicines. Additionally, marketing materials provided by CanaRx Services state that "CANARX Services Inc. administers the $0 copay international mail-order prescription option" for insured U.S. patients.

b. CanaRx Group: As part of the CanaRx Services "international mail-order pharmacy" program, insured patients are required to "enroll" in "CanaRx" by entering an agreement with CanaRx Group. CanaRx Group's enrollment form states that enrolled patients can obtain "FREE Brand Name Medications", including BIKTARVY® and GENVOYA®, from international sources. Both CanaRx Services and CanaRx Group enter into "business associate agreements" with health plan entities, the goal of which is to allow the health plans to provide medical information about their members' use of prescription drugs that can be obtained from foreign sources without running afoul of HIPAA.

c. CRX International: CRX, like CanaRx Services, operates an "international mail-order pharmacy program" through which infringing international medicines – including Gilead-branded medicines – are illegally shipped to insured U.S. patients and paid for by the patients' health insurance plan. The CRX program utilizes a slightly different logo and enrollment form than the CanaRx Services program, but it is managed by the same CanaRx Services employees. CRX also relies on a "related party" – either CanaRx Services or CanaRx Group – to provide call center services to U.S. patients who obtain infringing international prescription medicines through CRX's program, and to purchase those infringing medicines from the foreign sources that ship them to U.S. patients.

129. CanaRx [redacted]

[redacted]

130. CanaRx's entire business model is providing insured U.S. patients with international prescription medicine, in direct violation of U.S. law. CanaRx agrees with PBMs and health insurers—including insurers based in the state of Maryland—to provide purported "international prescription services" to their patients. Pursuant to these entities' agreements to provide coverage for prescription medicine procured through a CanaRx program, patients are pressured to order their prescription drugs through CanaRx (an unlicensed entity that will arrange for them to receive international prescription medicine) rather than through a licensed U.S. pharmacy. For example, as CanaRx states in its enrollment forms, some health plans [redacted], if they ask their insurance to cover authentic domestic medicine from a licensed U.S. pharmacy, rather than obtaining the medicine through CanaRx.

131. Once CanaRx has contracted with a PBM or health insurer for insured patients to obtain international prescription medicines through CanaRx, CanaRx provides "member enrollment forms" for the insurance provider to distribute to patients, along with advertising materials touting the benefits of international sourcing, and lists of brand-name prescription drugs that CanaRx will import for patients (its "formulary").

132. The CanaRx member enrollment forms provide the patient's insurance and prescription information. In small print, these "member enrollment forms" also purport to release CanaRx *and* the patient's plan holder from "any and all liability, claims, and causes of action with respect to errors or omissions by the company or agency responsible for

transporting" medication to the patient – including the foreign entities selected by CanaRx and tasked with illegally shipping prescription medicine to the patient.

133. CanaRx asks U.S. patients to provide it with copies of their prescriptions. When CanaRx receives its copy of a U.S. patient's prescription, it transfers the prescription to a foreign healthcare provider, who "re-issues" the prescription in their local jurisdiction. This foreign healthcare provider does not examine or have any relationship with the patient. CanaRx then refers the prescription to a foreign entity with which it is contracted, which will ship medicine directly to a U.S. patient.

134. Although CanaRx publicly states that it partners only with pharmacies in Canada, the United Kingdom, and Australia, pharmacies in those jurisdictions do not ship only medicines packaged and intended for distribution in those countries. Rather, Canadian, British, and/or Australian pharmacies often purchase gray-market prescription medicines from other countries – sometimes from unauthorized sellers with no pedigree that could establish the authenticity of the product – and resell those medicines to U.S. patients, since they are unable to dispense them to patients in their own jurisdictions.

135. Indeed, CanaRx's contracted Canadian pharmacies violate local laws and regulations by participating in CanaRx's importation scheme. 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 Kirteekumar Rameshchandra Pandya, an Ontario pharmacist whose pharmacy, Comber Drugstore Ltd., had entered a contractual agreement with CanaRx to dispense prescription medicines to U.S. patients. OCP found that Pandya had engaged in professional misconduct and violated multiple Canadian pharmacy practice standards and laws through his dealings with CanaRx. OCP found that

Pandya 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.

136. In exchange for arranging for prescription drugs to be mailed to U.S. patients in violation of U.S. law (and, often, the laws of the jurisdictions where its partner pharmacies operate), CanaRx is paid a portion of the difference between the cost of the authentic U.S. medicine and the foreign medicine that it provides.

137. CanaRx's business model relies entirely on cooperation and facilitation by health insurance entities, including plans, pharmacy benefit managers, and third-party administrators. CanaRx relies on these entities to, at minimum, (1) advertise CanaRx to their members; (2) agree to provide health insurance coverage prescription drugs sourced 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. For this reason, CanaRx publicly advertises directly to health plans.

138. CanaRx advertises the availability of Gilead-branded medicines, including GENVOYA®, BIKTARVY®, ODEFSEY®, and VIREAD®, to patients and health insurance companies. CanaRx continues to advertise these Gilead medicines, and to provide international Gilead medicines to U.S. patients, even though it received notice from ProAct about Gilead's claims in this case and this Court's temporary restraining order barring the sale of infringing Gilead medicines to U.S. patients in January 2025.

139. Since December 2021, through its partnership with ProAct alone, CanaRx has arranged for [redacted]

140. CanaRx knows that its importation activities violate U.S. law, infringe Gilead's trademark rights, and place U.S. patients at risk. On February 26, 2019, the FDA issued a Warning Letter addressed to CanaRx Services, explaining that importation of foreign prescription medication violates several provisions of the federal FDCA. The Warning Letter also identified CRX International as an entity whose importation activities violate the FDCA. In the Warning Letter, the FDA explicitly identified differences between international and U.S. prescription medicines, including the fact that foreign prescription medicines do not have FDA-approved labels and lack "adequate warnings" about the drugs' use. The Warning Letter also stated that CanaRx's importation creates a risk that counterfeit or contaminated prescription medicines may be introduced into the U.S. supply chain.

141. The FDA Warning Letter also specifically noted that CanaRx distributes a disclaimer to U.S. patients acknowledging that the medicine it provides differs from the same medicine intended for sale in the United States: "[d]epending on your country, our medications may appear different in size, shape or color." The FDA explained that the disclaimer "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." The FDA also called it "particularly concerning" that – just as Gilead has pleaded here – patients are likely to trust the legitimacy of a product provided through their insurance benefits, even if they might otherwise view a product obtained outside of authorized, legal distribution channels with

skepticism (particularly if it looked different from the drug obtained through authorized, legal channels).

142. Despite the FDA's warnings, CanaRx's websites continue to provide false reassurance to patients that they can and should take international prescription medicine that is different from prescription medicine intended for sale in the United States. For example, CanaRx says: "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. For example, a drug may be a capsule in the U.S. but a tablet in another country."

143. In response to the FDA warning letter, CanaRx ceased selling and advertising the specific prescription medicines identified as "examples" of the prescription drugs that CanaRx illegally imports. However, CanaRx did not discontinue its illegal and infringing importation business, and continues to arrange for infringing international Gilead-branded medicines to be delivered to U.S. patients.

144. Moreover, after ProAct gave CanaRx notice of this Court's December 13, 2024 Temporary Restraining Order, CanaRx Services sent a letter in response, admitting that CanaRx provides international Gilead-branded medicines to U.S. patients, but nevertheless asserting [redacted]

145. CanaRx's infringement of Gilead's trademarks is intentional, knowing, and willful. CanaRx reaps enormous illicit financial rewards for its acts of infringement.

g. Bob Howard and John Howard

146. CanaRx is a family business currently operated by two brothers: Bob and John Howard. Their father, Gregory Anthony Howard ("Tony Howard") founded CanaRx Services,

Inc. and served as its director, president, and CEO from the company's inception until his death in December 2020. Since January 2021, Bob has served as the president of CanaRx Services, and John has served as the treasurer of CanaRx Services. Bob and John Howard are also two of the three directors of CanaRx Services.

147. Bob Howard became a director and treasurer of CanaRx Services Inc. in 2006. He served in those roles until January 2021, when he became the president of CanaRx Services, Inc.

148. In January 2021, John Howard took Bob's place as treasurer of CanaRx Services. He also became a director of CanaRx Services.

149. Bob and John Howard are also directors and officers of 1646237 Ontario Inc., the corporate entity that is the sole shareholder of CanaRx Group. Bob Howard is the president of 1646237 Ontario Inc., and John Howard is its treasurer.

150. Bob and John Howard are also directors and officers of 2266578 Ontario Inc., the corporate entity that is the sole shareholder of CRX International Inc. Bob Howard is the president of 2266578 Ontario Inc., and John Howard is its treasurer.

151. Bob and John Howard have 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.

152. John Howard regularly exchanges emails with ProAct employees regarding the CanaRx international prescription drug program, including in connection with the sale of international BIKTARVY®. He also personally participates in "quarterly touch base" meetings with ProAct regarding the CanaRx importation program.

153. 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. 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. In reality, of course, when CanaRx arranges for international Gilead medicine to be shipped to U.S. patients, that medicine does not have information, warnings, and instructions that the FDA has determined to be required for the medicine to be safely dispensed to U.S. patients.

154. John Howard is listed as the individual contact for CanaRx Services in the 2024-2025 issue of *The Self-Insurers' Directory*, which describes itself as "[t]he *definitive* resource for self-insurance/captive industry solution providers." His contact information was provided directly by CanaRx Services, with the intention that he would personally coordinate with any employer-sponsored health plans who might consult the directory to identify so-called cost containment plans.

155. Both Bob and John Howard received notice of this Court's December 13, 2024 temporary restraining order against ProAct. John Howard signed the response letter, on behalf of "CanaRx Services, Inc., and the affiliated Canarx companies," addressing ProAct's notification of this Court's temporary restraining order enjoining ProAct, and anyone acting in concert or participation with ProAct, from importing international Gilead medicines to the United States. John Howard's response stated that the Court's order, as well as Gilead's claims in this [redacted] He did not address the infringing nature of the international product that was provided to those consumers, nor did he acknowledge

CanaRx's business relationships with or reliance on health insurance entities to facilitate and pay for infringing international medicines.

156. Bob and John Howard are active and moving forces behind all three CanaRx entities' acts of infringement. They direct, manage, and operate CanaRx's business of importing infringing Gilead medicines into the United States.

157. Bob and John Howard's continued infringement of Gilead's trademarks is intentional, knowing, and willful.

h. ElectRx and Health Solutions, LLC

158. 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 patients insured by more than 400 health plans.

159. Between June 2022 and December 2024 alone, ElectRx arranged for [redacted] In its response to Gilead's non-party subpoena, ElectRx strategically refused to identify the U.S. locations to which these bottles were shipped; however, given the size and nationwide scope of ElectRx's operation, upon information and belief, ElectRx caused infringing international Gilead-branded medicine to be shipped to patients in Maryland, among other states.

160. ElectRx publicly advertises its provision of infringing international Gilead medicines, including international GENVOYA®, BIKTARVY®, DESCOVY®, COMPLERA®, EMTRIVA®, ODEFSEY®, STRIBILD®, and VEMLIDY®, to patients and health insurance

companies. ElectRx has continued to advertise these Gilead medicines, and to provide international Gilead medicines to U.S. patients even after receiving notice about Gilead's claims in this case and this Court's temporary restraining order barring the sale of infringing Gilead medicines to U.S. patients. Indeed, ElectRx published a "partial list of medications available through the ElectRx Personal Importation Program" in September 2025, and that list included ODEFSEY® and STRIBILD®.

161. ElectRx also distributes documents encouraging health plans to engage it for a "Specialty Drug Solution," which involves importing prescription medicines to U.S. patients rather than obtaining them from domestic pharmacies. ElectRx's materials specifically cite a Gilead medicine (TRUVADA®) as one that it can help health plans obtain from international pharmacies for their members.

162. ElectRx's business model relies on cooperation and facilitation by health insurance entities, including plans, pharmacy benefit managers, and third-party administrators.

[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.

163. ElectRx publicly states that it partners only with pharmacies from Canada, New Zealand, England, and Australia. However, pharmacies in those jurisdictions do not ship only medicines packaged and intended for distribution in those countries. Rather, Canadian, New Zealand, British, and/or Australian pharmacies often purchase gray-market prescription medicines from other countries – sometimes from unauthorized sellers with no pedigree that could establish the authenticity of the product – and resell those medicines to U.S. patients, since they are unable to dispense them to patients in their own jurisdictions.

164. ElectRx knows that its importation activities violate U.S. law, infringe Gilead's trademark rights, and place U.S. patients at risk. On March 2, 2023, the FDA issued a Warning Letter to ElectRx, explaining that importation of foreign prescription medication violates the FDCA. In that Warning Letter, the FDA explicitly identified differences between international and U.S. prescription medicines, including the fact that foreign prescription medicines do not have FDA-approved labels and lack "adequate warnings" about the drugs' use. The Warning Letter also stated that ElectRx's importation creates a risk that counterfeit or contaminated prescription medicines may be introduced into the U.S. supply chain, and noted that the fact that ElectRx partners with U.S. insurers creates a false sense of security in U.S. patients that the foreign medicines provided through the ElectRx program are reliable.

165. The FDA Warning Letter noted that international prescription drugs that ElectRx provides to U.S. patients were accompanied by a disclaimer that "You may have noticed that the medication which has been shipped to you is different in name or presentation to that which you may have received in the past. IF YOU HAVE ORDERED A BRANDED DRUG the name may appear different to the one you are used to. The reason for this is that you have been supplied internationally branded product and for various reasons drug companies market their products

under different names and packaging in different countries." The FDA explained that the disclaimer "demonstrates 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." The FDA also called it "particularly concerning" that – just as Gilead has pleaded here – patients are likely to trust the legitimacy of a product provided through their insurance benefits, even if they might view a product obtained outside of authorized, legal distribution channels with skepticism (particularly if it looked different from the drug obtained through authorized, legal channels).

166. On December 18, 2024, ElectRx was notified of Gilead's claims in this litigation when it was served with a non-party subpoena. However, despite the FDA's warning letter and Gilead's pursuit of litigation against importers of infringing products, ElectRx did not discontinue its illegal and infringing importation business, and continues to advertise and arrange for infringing Gilead-branded medicines to be delivered to U.S. patients.

167. ElectRx's infringement of Gilead's trademarks is intentional, knowing, and willful. ElectRx reaps enormous illicit financial rewards for its acts of infringement.

i. Jeffrey Dinsmore

168. Jeffrey Dinsmore is the member, managing partner, and authorized agent of ElectRx.

169. Dinsmore personally coordinates and signs ElectRx's agreements with health plans regarding importation of infringing prescription medicines. He is the main point of contact for health insurance plans, PBMs, or TPAs who contact ElectRx regarding its international importation program.

170. Dinsmore also personally signed a "Statement of Assurance" to a health insurance plan regarding the ElectRx international prescription drug importation program, representing, *inter alia*, that "Prescription drug products shipped through the supply chain meet or exceed all safety concerns of the Food and Drug Administration (FDA)." This is, of course, false: international versions of Gilead medicines do not contain all of the FDA-mandated safety information on their packaging or accompanying information documents.

171. ElectRx is not Dinsmore's only company that illegally imports international prescription medicine. Dinsmore is also an officer and director of Canusa Health, Inc., a Canadian entity that appears to import prescription medicines from Canada to the United States. Dinsmore also serves as president, manager, and authorized agent of Canusa Health, LLC, a Michigan entity.

172. Dinsmore is an active and moving force behind ElectRx's acts of infringement. His continued infringement of Gilead's trademarks is intentional, knowing, and willful.

j. ScriptSourcing

173. ScriptSourcing purports to partner with "benefit consultants, PBMs, and TPAs" to provide "alternative medication sourcing options." ScriptSourcing's "alternative medication sourcing" refers to the practice of illegally importing brand-name prescription medicine from foreign countries to U.S. patients.

174. Among the international prescription medicines that ScriptSourcing has imported are infringing Gilead-branded products, including international GENVOYA®.

175. ScriptSourcing also advertises the availability of infringing international Gilead medicines to patients and health insurance companies. A "Specialty Medication List" on ScriptSourcing's website, for example, includes Gilead medicines on the list of "zero copay

medications" available, including BIKTARVY®, GENVOYA®, ODEFSEY®, STRIBILD®, and VEMLIDY®. ScriptSourcing continues to advertise these Gilead medicines, and to provide international Gilead medicines to U.S. patients, even after receiving notice about Gilead's claims in this case and this Court's temporary restraining order barring the sale of infringing Gilead medicines to U.S. patients.

176. ScriptSourcing has also partnered with Defendant CanaRx to advertise and provide infringing international prescription medicines, including Gilead medicines, to insured U.S. patients.

177. ScriptSourcing's business model relies entirely on cooperation and facilitation by health insurance entities, including plans, pharmacy benefit managers, and third-party administrators. It provides international medicines obtained from foreign sources only for insured U.S. patients whose health insurance is paying ScriptSourcing to obtain those medicines.

178. ScriptSourcing's international sourcing program has a dangerous track record. ScriptSourcing arranged for a prescription drug product to be imported and delivered to an insured U.S. patient. That product turned out to be counterfeit, illustrating the danger of relying on products shipped informally across international borders – skirting regulatory safeguards and the manufacturer's quality controls. As a result of taking this counterfeit medicine, the patient was seriously injured and hospitalized. This is precisely the risk that Congress intended to ameliorate by outlawing rampant importation of prescription drugs to the United States – but ScriptSourcing did not rethink its illegal business practices after almost killing a patient.

179. On December 24, 2024, ScriptSourcing was placed on notice of this litigation when it was served with a non-party subpoena by Gilead. Additionally, on January 3, 2025, ProAct specifically notified ScriptSourcing of the December 13, 2024 Temporary Restraining

Order entered by this Court enjoining ProAct from facilitating the importation of international Gilead medicines from any foreign location. Nevertheless, ScriptSourcing has continued to willfully advertise and cause infringing Gilead-branded medicines to be delivered to U.S. patients.

180. ScriptSourcing's infringement of Gilead's trademarks is intentional, knowing, and willful. ScriptSourcing reaps enormous illicit financial rewards for its acts of infringement.

k. Gary Becker

181. Gary Becker is the founder, CEO, member, and registered agent of ScriptSourcing, LLC.

182. Becker first founded an insurance brokerage, Becker Benefit Group Inc., in Maryland. In 2015, Becker registered "ScriptSourcing" as a trade name used by 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[.]"

183. Becker publicly touts ScriptSourcing's international sourcing program in interviews and on social media. In a June 2025 interview published in *The Self-Insurer*, Becker falsely stated that the FDA allows prescription medicine to be shipped to U.S. patients from foreign sources, and bragged, "There are no consequences for doing this. There's no fine or jail time."

184. Becker personally coordinates ScriptSourcing's agreements with health plans regarding importation of infringing prescription medicines and personally signs contractual agreements related to ScriptSourcing's importation services. He is the main point of contact for health insurance plans, PBMs, or TPAs who contact ScriptSourcing regarding its international importation program.

185. In addition to ScriptSourcing, LLC, Becker is a member of multiple other healthcare-related corporate entities, including ScriptSourcing affiliate ScriptSourcing Rare Disease Fund, LLC.

186. Becker is an active and moving force behind ScriptSourcing's acts of infringement. His continued infringement of Gilead's trademarks is intentional, knowing, and willful.

l. ProAct

187. Defendant ProAct is a PBM that manages prescription drug benefits on behalf of health plans.

188. ProAct began managing John Doe's prescription benefits in January 2024. Although John Doe sent his BIKTARVY® prescription to ProAct's in-house mail-order pharmacy, ProAct instead directed John Doe to contact Rx Valet about how to fill his prescription, and informed John Doe that Rx Valet would help him obtain his BIKTARVY® for free, with no copay.

189. ProAct knew and intended that, by advising John Doe to obtain his BIKTARVY® through Rx Valet, it was steering him toward a pharmacy that would fill his prescription with infringing international Gilead-branded drugs.

190. In fact, ProAct openly advertises that patients should fill any "new-to-you" medications "domestically" through its in-house mail order pharmacy. However, ProAct directs "treatment-experienced" patients to fill prescriptions through a ProAct "international mail order partner" – i.e., Rx Valet, CanaRx, or another company that illegally fills U.S. prescriptions with infringing international medications.

191. When ProAct learned that John Doe, who was filling his first prescription for BIKTARVY® after joining the Meritain/ProAct health plan, had been taking BIKTARVY® for years, it required, tricked, or pushed John Doe to fill his prescription with infringing international BIKTARVY® instead of U.S. BIKTARVY®.

192. ProAct has had a special partnership with CanaRx since 2010, which it describes as a [redacted] ProAct touts that its partnership with CanaRx provides [redacted]. ProAct and CanaRx also [redacted] in exchange for surrendering the security of U.S. prescription drug regulations and the manufacturer's U.S. quality control efforts. ProAct's "[redacted]" international pharmacy program with CanaRx also offers [redacted].

193. As explained above, the FDA issued a Warning Letter to CanaRx in 2019, notifying CanaRx that importing foreign drugs constituted the sale of "unapproved new drugs" in the U.S. and posed a serious threat to patient safety. That Warning Letter was reported on the front page of the *New York Times* and is referenced on CanaRx's website. And yet ProAct continues to "partner" with CanaRx and companies like it, including Rx Valet, to this day.

194. Even after receiving CanaRx's January 16, 2025 letter stating that CanaRx would continue to supply infringing Gilead medicines to U.S. patients, *including ProAct patients*, ProAct has continued to partner with CanaRx. As a result, CanaRx's co-branded website with ProAct, which is specifically provided to ProAct members in advertising materials endorsed by

ProAct, continued to advertise the availability of international Gilead medicines like BIKTARVY® after this Court had enjoined ProAct or anyone acting in concert or participation with ProAct from doing so.

195. ProAct publicly advertises its "international mail-order program" – referring to its partnership with CanaRx – which allows patients to receive "brand-name maintenance medications" for a $0 copay.

196. In a public video available on YouTube, ProAct calls its international mail-order program "convenient and safe" and says, "You should know that these medications are being sourced from some of the same Tier 1 countries and manufacturing facilities that supply your local retail pharmacies in the United States." The video tells patients that "switching over to ProAct's international mail order program is easy," and walks patients through the process of checking to see if their particular medication is part of the "program." The video concludes: "Save hundreds if not thousands of dollars a year on your maintenance medications with this convenient and safe program!"

197. ProAct regularly requires, tricks, or pushes patients to fill their U.S. prescriptions for Gilead-branded medicines with infringing foreign versions of those medicines. ProAct receives patient information and prescriptions in its capacity as a pharmacy benefits manager, coordinates the filling of the prescription with foreign medicine, and arranges for the infringing foreign medicine to be paid for from the health plan's funds.

198. ProAct knowingly induces others, including its "international mail order partners" and patients, to infringe Gilead's marks by advertising, offering for sale, and otherwise using in U.S. commerce materially different Gilead-branded medicines. ProAct also continued to provide its services as a PBM to others that it knew to be engaged in infringing behavior, including

negotiating which international drugs would be covered by health insurers, approving the cost of infringing international Gilead-branded medicines, and approving and paying for, or arranging for the payment for, the infringing medicines.

199. ProAct could stop or limit the other Defendants' infringement at any time by ceasing its practice of forcing or otherwise referring patients to its "international mail order partners," by instructing patients that they only offer services that lawfully fill their prescriptions with FDA-approved U.S. medicine, by refusing to provide patient eligibility and/or prescription history data to international mail-order programs, and by refusing to pay invoices for infringing product. ProAct has not done so, and continues to directly financially benefit from the infringement, including by persuading health insurance plans to engage its PBM services based on its willingness to skirt the law and facilitate international importation programs.

200. ProAct's infringement of Gilead's trademarks is intentional, knowing, and willful. ProAct reaps enormous illicit financial rewards for its acts of infringement.

m. Meritain

201. Defendant Meritain administers health insurance benefits for self-funded employers' plans, including John Doe's health plan. The services that it offers as an administrator include payment-processing services (such as the payment of invoices submitted by a client's vendors) and the maintenance of a patient eligibility feed.

202. Meritain has routinely and knowingly paid for and processed invoices for internationally sourced prescription medicine, including Gilead medicine. In internal communications, Meritain's employees have acknowledged that Meritain is "supporting" international sourcing programs by processing these invoices. For example, Meritain processed and paid for a client invoice from ScriptSourcing for GENVOYA®, even though the invoice

stated on its face that the GENVOYA® was obtained through an International Prescription Program. The invoice also contained other indicia that the GENVOYA® was meant for a foreign market, rather than the United States, such as a price far below the standard price for U.S. GENVOYA®. Meritain employees acknowledged internally that the invoice was for international GENVOYA®.

203. Meritain has also paid invoices from CanaRx for international prescription medicines, including Gilead-branded medicines. When it paid those invoices, Meritain was well aware that CanaRx has no business other than the illegal importation of foreign prescription medicines to U.S. patients.

204. Meritain has also paid invoices for international prescription drugs obtained through ElectRx. Meritain acknowledged that ElectRx's business was the importation of international prescription drugs from foreign sources to U.S. patients, but agreed to connect directly with its clients' PBMs and process ElectRx invoices submitted by those PBMs.

205. Moreover, Meritain continues to provide payment-processing services when it knows – and has been warned by its internal analysts – that those services are being used to process payments for international prescription drugs.

206. Meritain also maintains and provides access to its health plan clients' patient eligibility feeds. These feeds provide up-to-date information about the individuals covered by a given plan and the scope of their coverage. This data is provided in a standard format that health insurance vendors can use to immediately confirm a patient's coverage and status. Meritain's patient eligibility feed serves as the single "source of truth" for any vendor who is part of the provision of benefit. Access to Meritain's eligibility feed is critical to the provision of any health insurance services; without it, there would be no way to verify, for example, whether a particular

patient is a current member of a particular plan or eligible for a particular benefit, such as coverage for a prescription medicine.

207. Meritain classifies all of its customers' PBMs, among other entities, as "direct vendors" to whom Meritain provides direct access to the patient eligibility data feed. Meritain has classified multiple entities as "direct vendors" despite knowing that these entities will use the "source of truth" data that Meritain provides to cause U.S. patients to receive non-FDA-approved international prescription medicines.

208. For example, Meritain classified ProAct as a "direct vendor" with access to its patient eligibility data feed, despite knowing that ProAct had an "international pharmacy program" through which patients were supplied with international prescription medicines (including Gilead-branded medicines). Meritain was aware of the techniques that ProAct and its "international pharmacy partners" used to force, trick, or push patients into receiving infringing foreign Gilead-branded medications, and allowed them to occur. Meritain was also aware of the FDA Warning Letter issued to CanaRx, and that ProAct uses CanaRx as one of its "partners," and still decided to utilize ProAct as its PBM.

209. In March 2023, a Meritain employee compiled a list of "[redacted]" that Meritain [redacted] This list includes "[redacted]", "[redacted]" and "[redacted]." By 2023, Meritain had known for years that CanaRx, ElectRx, and ScriptSourcing each ran international sourcing programs aimed at illegally importing foreign versions of prescription medicine to insured U.S. patients. Nevertheless [redacted].

210. On its website advertising its "international mail order program," ProAct informs patients that the "program" is not available to everyone, and instructs patients to "check your plan documents to see if this is available to you." Those "plan documents" are managed and effectuated by Meritain, the administrator of the insurance plan. It is ultimately Meritain's decision whether to administer health insurance plans that provide coverage for infringing, illegally imported foreign medications.

211. Meritain also knew that international prescription medicine is materially different from prescription medicine intended for sale in the United States, and that international medicine is not subject to manufacturers' U.S. quality control efforts. Indeed, Meritain published a public flyer noting some of the differences between international and U.S. prescription medicines.

212. As the administrator of John Doe's health plan and the provider of the patient data feed to ProAct, Meritain provided John Doe's patient and coverage information to ProAct, resulting in ProAct's referral of John Doe to Rx Valet's international sourcing program. Meritain also approved payment for the cost of the infringing imported BIKTARVY® that John Doe received.

213. Meritain continues to provide its services as a health insurance plan administrator to others that it knows to be engaged in infringing behavior, including by arranging for the payment for the infringing medicines, referring patients to entities that provide infringing international prescription drugs, and providing the patient data feed to entities that rely on it to confirm that a patient is eligible for coverage for infringing international prescription drugs.

214. Meritain knowingly induces others to infringe Gilead's marks, and also provides its services as a health insurance plan administrator to others that it knew to be engaged in infringing behavior, including by approving and paying for, or arranging for the payment for, the

infringing medicines, referring patients to entities that provided infringing international prescription drugs, and providing the data feed to entities that Meritain knew relied on that feed in order to pay for and deliver infringing medicines to U.S. patients.

215. Meritain could stop or limit the other Defendants' infringement at any time by instructing patients that its services can only be used to lawfully fill their prescriptions with FDA-approved U.S. medicines, refusing to provide TPA services like the patient data feed to health insurers and/or vendors that funnel U.S. patients to international sourcing programs, and by refusing to approve or arrange for payment of infringing product. Meritain has not done so, and continues to directly financially benefit from the infringement by touting its flexibility in working with outside vendors, including ones with widely advertised international sourcing programs.

216. Meritain chooses to facilitate international sourcing programs despite being well aware of the risks that obtaining prescription drugs internationally, outside of authorized and regulated supply channels, pose to U.S. patients. In February 2023, Meritain launched an advertisement that it internally referred to as the "international sourcing horror story," which discussed a real-life example of a U.S. patient receiving counterfeit medicine from ScriptSourcing's international sourcing program. The patient suffered grievous physical harm and was hospitalized. Nevertheless, Meritain not only continued to pay ScriptSourcing invoices for infringing international medicines of uncertain pedigrees, but in fact implemented ScriptSourcing's programs for clients who used Meritain's in-house PBM, Meritain Pharmacy Services (which Meritain employees operate).

217. Meritain's infringement of Gilead's trademarks is intentional, knowing, and willful. Meritain reaps enormous illicit financial rewards for its acts of infringement.

VI. DIFFERENCES BETWEEN GILEAD'S U.S. AND INTERNATIONAL MEDICINES ARE MATERIAL

218. Gilead manufactures BIKTARVY® for sale in the U.S. only at FDA-approved facilities in Canada, Ireland, and Germany. BIKTARVY® intended for sale in the U.S. is manufactured, packaged and labeled in accordance with Gilead's FDA-approved U.S. New Drug Application for that product. Images of the FDA-approved bottle and label of BIKTARVY® distributed in the U.S are attached as **Exhibit C**. All bulk medicine that Gilead brings into the United States is packaged for the U.S. market within the United States.

219. Turkish BIKTARVY® is materially different from the FDA-approved BIKTARVY® that Gilead sells in the U.S., in many respects. For example:

220. First, Turkish BIKTARVY® – including the three cartons delivered to John Doe – is manufactured exclusively at a manufacturing site in Turkey, and the BIKTARVY® manufactured at that site is packaged and distributed for sale only within Turkey.

221. The manufacturing line on which Turkish BIKTARVY® is manufactured is regulated and approved by Turkish authorities. That Turkish manufacturing line is not approved by the FDA and not regulated by or inspected by the FDA – as is required by law for all medication sold in the U.S. – because none of the BIKTARVY® manufactured on that line is intended for sale in the U.S.

222. Second, Turkish BIKTARVY® is packaged entirely in the Turkish language in a carton, with the Patient Information document inserted loosely into that carton. U.S. BIKTARVY® is packaged entirely in the English language in bottles, with the Patient Information document folded and affixed to the outside of the bottle.

223. Third, Turkish BIKTARVY® is labeled entirely in Turkish, while U.S. BIKTARVY® – like all U.S. Gilead-branded medicines – is labeled entirely in English.

224. Fourth, the label and packaging for Turkish BIKTARVY® does not include a National Drug Code ("NDC"), which serves as a unique identifier for drugs in the U.S. and appears on U.S. BIKTARVY®.

225. Fifth, the label and packaging for Turkish BIKTARVY® does not bear the phrase "Rx only" (stylized as ℞only), which appears on U.S. BIKTARVY®. The ℞only symbol is required by FDA regulations to appear on prescription medication, and signals to U.S. consumers that the medication is an FDA-approved medication.

226. Sixth, the Patient Information document for Turkish BIKTARVY® is entirely in Turkish, whereas the Patient Information document for U.S. BIKTARVY® (which sets forth important information about the medication, including instructions for dosing and possible side effects) is entirely in English.

227. Seventh, the Patient Information document for Turkish BIKTARVY® contains different and less information than the Patient Information document for U.S. BIKTARVY. For example, the U.S. Patient Information document provides information about clinical studies of the drug that do not appear in the Turkish document. As another example, the Patient Information document for U.S. BIKTARVY® contains a prominent "black box" warning at the outset concerning cessation of the drug for patients co-infected with hepatitis B; the Patient Information document for Turkish BIKTARVY®, which comport with Turkish regulations, do not have any black-box warnings or any similarly prominent warnings.

228. Eighth, the Patient Information document that accompanies U.S. BIKTARVY® contains Gilead's U.S. 1-800 toll-free number, while the Patient Information document that accompanies Turkish BIKTARVY® does not. The toll-free number connects to a hotline that patients can call with questions or concerns, including to report potential quality problems.

229. Ninth, the Patient Information document that accompanies U.S. BIKTARVY® provides instructions on how to contact the FDA to report side effects or adverse events, and includes the statement: "This Patient Information has been approved by the U.S. Food and Drug Administration." None of this information is included in the Patient Information documents for any international version of any Gilead-branded medicine, including Turkish BIKTARVY®.

230. Tenth, Turkish BIKTARVY®'s label and accompanying Patient Information document lists only metric measurements, such as kilograms and degrees Celsius. Both the labeling and Patient Information documents for all U.S. Gilead-branded drugs, including U.S. BIKTARVY®, detail imperial units of measurements, such as pounds and degrees Fahrenheit.

231. The differences between U.S. and Turkish BIKTARVY® are illustrative of the differences between all U.S. and foreign Gilead medicines. The FDA-compliant packaging and labeling of every authentic U.S. Gilead-branded medicine is unique to the U.S. Likewise, every international version of every medication that Gilead manufactures has materially different labeling and packaging as compared to the U.S. version of that medication.

232. For example, the U.S. version of every Gilead-branded drug contains a patient information document that provides the Gilead toll-free 1-800 patient hotline, provides FDA contact information, and states "This Patient Information has been approved by the U.S. Food and Drug Administration." No foreign versions of Gilead-branded medicine have that information.

233. Additionally, the U.S. version of every Gilead-branded drug contains the NDC associated with that drug. The NDC is not only required by U.S. law to be present on prescription medicines; it is an important identifier that is used to bill prescription drugs to health insurers. NDCs are not present on foreign versions of Gilead medicines.

VII. GILEAD'S QUALITY-CONTROL EFFORTS FOR U.S. MEDICINE

234. Gilead implements strict, world-class quality controls for the manufacture, packaging, and distribution of its pharmaceutical products. To U.S. consumers, the Gilead Marks that appear on their medications indicate that the drugs have been manufactured and distributed according to Gilead's high-quality, fully FDA-compliant standards, ensuring that the medication that reaches them is genuine, high-quality, securely distributed Gilead medication. Through these established quality controls, Gilead protects its customers' expectations of safety and quality, as well as the value and goodwill associated with its trademarks. Defendants' conduct at issue in this case thwarts and nullifies the benefit of these quality control measures.

a. International Shipping Temperature Controls and Monitoring

235. For example, all Gilead-branded medicines have temperature storage requirements. BIKTARVY® has a maximum storage temperature of 86° Fahrenheit; some Gilead drugs have lower maximum temperature thresholds. Because international shipping temperatures routinely exceed 86° Fahrenheit, Gilead takes steps to ensure that any Gilead medicines that are shipped internationally into the U.S. are shipped in temperature-controlled and temperature-monitored containers. If the temperature monitors show that a Gilead medicine was subjected to temperatures outside its approved range during transport – for example, because it was exposed to temperatures above 86° Fahrenheit – Gilead treats that as a "quality event," which triggers an investigation by Gilead's Quality Assurance team. Any medicine that has experienced a temperature-related quality event will be released only if, after investigation, Gilead's Quality Assurance team concludes that the medicine remains safe and effective.

236. Defendants, on the other hand, import international Gilead-branded drugs through regular international parcel services such as FedEx. Defendants' international shipments of

foreign Gilead-branded medicines have no temperature controls or temperature monitoring and are completely outside Gilead's oversight, as they move halfway across the globe over the course of days or weeks or months.

237. This uncontrolled, unmonitored, and unregulated international shipping violates and undermines Gilead's established quality-control procedures for international shipment of its medicines, and puts the quality of the medications at risk.

b. Targeted Recalls

238. Another quality control measure that Gilead has in place – and which Defendants' conduct renders ineffective – relates to targeted recalls. In the event of a quality concern about any released lot of Gilead-branded medicine, Gilead has adopted protocols that govern the issuance of a targeted recall to ensure that patients who received medication from the affected lot are informed of the event and are able to obtain replacement medicine that is safe and effective.

239. Gilead's protocols provide that any recall of a Gilead-branded medicine due to a quality concern will occur in the geographic market into which Gilead distributed the affected lot. Gilead's protocols provide that the recall notices will be provided to the distributors and other entities that Gilead knows received the affected lot.

240. For example, if Gilead were to determine that there was a potential quality concern with a particular lot of Turkish BIKTARVY® and implement its recall protocol, Gilead would issue a recall notice within Turkey only, because all lots of Turkish BIKTARVY® are intended for distribution only within Turkey. Thus, in this example, Gilead's recall notice would not reach John Doe in Maryland.

241. The same is true for international Gilead medicine intended for sale any other country in the world. If Gilead determined that its recall protocol should be implemented for that

medicine, it would issue a recall notice in the country into which the medicine was sold, not in the United States.

242. Gilead does not seek FDA approval to issue targeted recall notices in the U.S. for medicine intended for distribution outside the U.S. because such recall notices would likely confuse American pharmacies and distributors, including by leading them to erroneously believe the recall applied to U.S. medicine. Additionally, even if Gilead were able to obtain FDA approval to issue recall notices in the U.S. based on quality concerns about non-U.S. medicine, repeatedly issuing inapplicable recall notices in the U.S. would likely dilute the effectiveness of recall notices that *do* apply to U.S. medicine.

c. Pedigrees

243. A third quality-control measure that Defendants' conduct undermines is the "pedigree," also known as a T3 or DSCSA document. The federal Drug Supply Chain Safety Act ("DSCSA") requires all prescription drugs in the U.S. to be accompanied by a pedigree. When Gilead sells or distributes a bottle of prescription drugs in the U.S., it is always accompanied by a Gilead-created pedigree.

244. Pedigrees provide a running list 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, thus providing a full chain of custody for that specific bottle of medication all the way back to the manufacturer.

245. Pedigrees are a critical component of Gilead's U.S. quality-control efforts. When Gilead receives a quality complaint or inquiry about a bottle of Gilead-branded medicine in the U.S., Gilead's quality team attempts to obtain the pedigree for that bottle to determine its route through the distribution stream. That allows Gilead to evaluate whether the Gilead-branded

medicine is authentic and whether it has been adulterated. If Gilead-branded medicine has been adulterated, the pedigree helps Gilead assess how and where in the distribution chain the adulteration occurred, which impacts the number of bottles that might be affected.

246. Pedigrees also allow Gilead to trace where potentially affected medicines were distributed. And if Gilead is unable to verify the transaction history on a pedigree or determines information has been falsified, that information allows Gilead to investigate the source of the incorrect information. Indeed, Gilead has heavily relied on pedigrees to identify and trace U.S-based counterfeiters of Gilead-branded medicines, which resulted in the filing of a major anti-counterfeiting litigation and related law-enforcement action in 2021.

247. International Gilead-branded medicines are not accompanied by pedigrees. The DSCSA does not apply to international medicines.

248. When international Gilead-branded medicines are imported into the U.S. directly from foreign sources to American patients, the international medicines lack any cross-border tracking that is subject to government regulation or manufacturer oversight. Gilead does not know that they have entered into the U.S. supply chain at all – they are "ghost medications." In the event of a suspected or actual quality event, it is impossible for Gilead to trace international medicine that has been shipped from a foreign pharmacy directly to a U.S. patient.

d. Gilead's Secure Supply Chain

249. Finally, Gilead maintains a highly secure U.S. supply chain to prevent the introduction of counterfeit, adulterated, or otherwise substandard Gilead-branded medicine to U.S consumers. Gilead's supply chain protections exceed the FDA's already stringent requirements for maintaining a strictly controlled, traceable, secure pharmaceutical supply chain.

250. Defendants' illegal importation of international medicines directly from foreign sources to U.S. patients undermines Gilead's secure supply chain. Defendants' supply line is illicit, unsecured, and untraceable. Foreign pharmacies, which can operate anonymously and are already breaking the law by participating in this scheme, can send anything in the unmarked packages directly to the homes of U.S. patients.

251. As the U.S. government has stated, any illegal importation of prescription medications creates an unacceptable risk of counterfeits entering the U.S. supply chain. By undermining Gilead's efforts to create a highly secure supply chain, Defendants are creating an enormous risk that counterfeit Gilead-branded medicine will be shipped to U.S. patients.

252. It should go without saying that counterfeit Gilead-branded drugs create significant health and safety risks for U.S. patients. At best, these drugs may be ineffective, meaning that patients will not receive treatment for their serious, life-threatening conditions; at worst, counterfeit drugs may be dangerous because they are not manufactured in accordance with Gilead's exacting standards or under the supervision of any regulatory body.

253. Diverted and counterfeit Gilead-branded drugs undermine the goodwill associated with the Gilead Marks by creating a question in consumers' minds about whether the existence of Gilead Marks on products are actually indicative of high-quality Gilead medications.

254. Defendants' scheme to import and encourage the importation of international Gilead-branded drugs thus violates and undermines Gilead's quality control efforts.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1))
(Against all Defendants)

255. Gilead incorporates by reference the paragraphs above as if fully set forth herein.

256. Gilead is the owner of all right, title and, interest in and to the Gilead Marks.

257. Defendants, without authorization, have imported, and/or distributed and/or facilitated the distribution, and/or sold and/or facilitated the sale, and/or paid for the importation, of international Gilead medicine featuring the Gilead Marks in the U.S. The products that Defendants import are materially different from the products Gilead sells in the U.S., and the importation and use of such products in U.S. commerce violates and undermines Gilead's established and non-pretextual quality-control procedures.

258. Defendants' actions have caused and/or are likely to cause confusion, mistake, or deception as to the source of origin, sponsorship or approval of the international Gilead medication in that patients in this judicial district and elsewhere in the U.S. are likely to believe Gilead authorizes and controls the sale and importation of international Gilead medications, or that Defendants are associated with or related to Gilead or are authorized by Gilead to sell international Gilead medications in the U.S.

259. Defendants' acts have injured and/or are likely to injure Gilead's image and reputation with consumers in this judicial district and elsewhere in the U.S. by creating confusion about, and/or dissatisfaction with, international Gilead-branded medicines.

260. Defendants' acts have injured and/or are likely to injure Gilead's reputation in this judicial district and elsewhere in the U.S. by causing customer dissatisfaction and a diminution of the value of the goodwill associated with the Gilead Marks.

261. Defendants' acts have been committed deliberately and willfully, with knowledge of Gilead's exclusive rights and goodwill in the Gilead Marks, and with knowledge of the infringing nature of the marks when used in connection with the international Gilead

medications. Defendants' acts have also been committed with bad faith and the intent to cause confusion, or to cause mistake and/or to deceive.

262. Defendants are directly, contributorily, and/or vicariously liable for the acts of infringement alleged herein.

263. As a result of Defendants' trademark infringement, Gilead has suffered and will continue to suffer substantial and irreparable injury, loss and damage to its rights in and to the Gilead Marks, and damage to the goodwill associated therewith, for which it has no adequate remedy at law.

264. If not restrained, Defendants will have unfairly derived and will continue to unfairly derive income, profits, and business opportunities as a result of their acts of infringement.

265. As the acts alleged herein constitute infringement of the Gilead Marks under 15 U.S.C. § 1114(1), and as Gilead has no adequate remedy at law, Gilead is entitled to injunctive relief as well as to Defendant's profits, Gilead's damages, and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

SECOND CLAIM FOR RELIEF
FEDERAL UNFAIR COMPETITION, 15 U.S.C. § 1125(a)
(Against all Defendants)

266. Gilead incorporates by reference paragraphs 1-149 as if fully set forth herein.

267. Defendants, without authorization, have imported, and/or distributed and/or facilitated the distribution, and/or sold and/or facilitated the sale, and/or paid for the importation, of international Gilead medications featuring the Gilead Marks in the U.S. These products are materially different from the products Gilead sells in the U.S., and the importation and use of

such products in U.S. commerce violates and undermines Gilead's established and non-pretextual quality-control procedures.

268. Defendants' actions have caused and/or are likely to cause confusion, mistake, or deception as to the source of origin, sponsorship or approval of the international Gilead medication in that patients in this judicial district and elsewhere in the U.S. are likely to believe Gilead authorizes and controls the sale and importation of international Gilead medications, or that Defendants are associated with or related to Gilead or are authorized by Gilead to sell international Gilead medications in the U.S.

269. For example, Defendants ProAct, Rx Valet, CanaRx, ElectRx, and ScriptSourcing publicly advertise the fact that they offer "international sourcing" for "brand-name" prescription medications. Defendant ProAct states that imported medications "are being sourced from some of the same Tier 1 countries and manufacturing facilities that supply your local retail pharmacies in the United States." Defendant Rx Valet states that the medications are "the exact same quality as if they were dispensed in the U.S." Defendant ElectRx states that it procures "the same brand name medications available in the U.S." for U.S. patients.

270. As an additional example, in its public advertisements, Defendant Rx Valet claims that "most" international medications that it sources from its "affiliated pharmacies" are "shipped from Canada," but in fact sourced Gilead-branded medicines from Turkey, India, and Mauritius. Rx Valet also knew that its patients were obtaining non-Canadian medicine from an affiliated pharmacy in Canada, including medicine from Israel.

271. Defendants' public statements induce participation in the scheme by providing false reassurance that the international medications provided to U.S. patients are the same as the medications that intended for distribution in the U.S. by U.S. retail pharmacies.

272. Defendants' acts constitute a false representation and a false designation of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

273. Defendants' acts have been committed with knowledge of Gilead's exclusive common law rights and goodwill in the Gilead Marks, as well as with bad faith and the intent to cause confusion or mistake, and/or to deceive.

274. Gilead has suffered and, if Defendants are not enjoined, will continue to suffer great and irreparable injury, loss, and damage to its rights in and to the Gilead Marks and to the goodwill associated therewith for which Gilead has no adequate remedy at law.

275. If not restrained, Defendants will have unfairly derived and will continue to unfairly derive income, profits, and business opportunities as a result of their acts of infringement.

276. As the acts alleged herein violate Section 43(a) of the Lanham Act, 15 U.S.C.§ 1125(a), and as Gilead has no adequate remedy at law, Gilead is entitled to injunctive relief and to Defendants' profits, Gilead's damages, and other remedies provided by 15 U.S.C. §§ 1116-1118, and to reasonable attorneys' fees and prejudgment interest pursuant to 15 U.S.C. § 1117.

THIRD CLAIM FOR RELIEF
UNFAIR COMPETITION UNDER STATE LAW
(Against all Defendants)

277. Gilead incorporates by reference paragraphs 1-149 as if fully set forth herein.

278. Defendants, without authorization, have imported into the United States, and/or distributed and/or facilitated the distribution, and/or sold and/or facilitated the sale, and/or paid for the importation, of international Gilead medications featuring the Gilead Marks in the U.S. These products are materially different from the products Gilead sells in the U.S., and the

importation and use of such products in U.S. commerce violates and undermines Gilead's established and non-pretextual quality-control procedures.

279. Defendants' actions have caused and/or are likely to cause confusion, mistake, or deception as to the source of origin, sponsorship or approval of the international Gilead medication in that patients are likely to believe Gilead authorizes and controls the sale and importation of international Gilead medications, or that Defendants are associated with or related to Gilead or are authorized by Gilead to sell international Gilead medications in the U.S.

280. Defendants' acts constitute an infringement of Gilead's trademark rights in violation of the common law of trademarks, and/or constitute common-law unfair competition, including under the common law of the State of Maryland and elsewhere.

FOURTH CLAIM FOR RELIEF
UNJUST ENRICHMENT
(Against Defendants Rx Valet, Advanced Pharmacy, Gregory Santulli, Affordable Rx Meds, Fetih Eczanesi, CanaRx Services, CanaRx Group, CRX International, Bob Howard, John Howard, ElectRx and Health Solutions, LLC, Jeffrey Dinsmore, ScriptSourcing, LLC, and Gary Becker)

281. Gilead incorporates by reference paragraphs 1-149 as if fully set forth herein.

282. Defendants intentionally used, without authorization or license, the Gilead Marks in their unlawful scheme to import international Gilead medication.

283. As a result of the importation of international Gilead medication, Defendants wrongfully derived a monetary benefit to which they were not legally entitled.

284. Defendants Rx Valet, CanaRx Services, Inc., CanaRx Group, Inc., CRX International, Inc., ElectRx and Health Solutions, LLC, and ScriptSourcing, LLC receive a payment for each international Gilead medication that they cause to be imported from a foreign country.

285. Defendants Fetih Eczanesi and Affordable Rx Meds are paid for each international Gilead product that they cause to be imported to the U.S. from a foreign country.

286. Defendant Advanced Pharmacy is paid a monthly fee for providing Rx Valet with access to prescriptions for Gilead products, which are then diverted and filled with international Gilead products rather than U.S. Gilead medicines.

287. The individual Defendants are the owners, officers, and principals of their respective companies, and thus have personally profited as a result of those companies' profits from illegally imported Gilead medication.

288. Defendants have no right to retain these unjust gains, which they had and have full knowledge and understanding were unjust, improper, and unlawful.

289. It would be inequitable to allow Defendants to keep the unjust monetary benefits that they have knowingly reaped from their importation of international Gilead medication.

FIFTH CLAIM FOR RELIEF
IMPORTATION OF GOODS BEARING INFRINGING MARKS, 15 U.S.C. § 1124
(Against all Defendants)

290. Gilead incorporates by reference paragraphs 1-149 as if fully set forth herein.

291. By illegally importing international Gilead medication from foreign countries with the intent of inducing patients into believing that the products are authorized for distribution in the United States, Defendants have violated 15 U.S.C. § 1124.

292. Gilead has been, and continues to be, damaged by Defendants' activities and conduct. Defendants have profited thereby and, unless their conduct is enjoined, Gilead's reputation and goodwill will continue to suffer irreparable injury that cannot adequately be calculated or compensated by money damages. Accordingly, Gilead is entitled to injunctive relief under 15 U.S.C. § 1116.

SIXTH CLAIM FOR RELIEF
CIVIL CONSPIRACY
(Against all Defendants)

293. Gilead incorporates by reference paragraphs 1-149 as if fully set forth herein.

294. Defendants have agreed with each other to import, and/or to distribute and/or facilitate the distribution of, and/or to sell and/or facilitate the sale, and/or to pay for the importation, of international Gilead medications featuring the Gilead Marks in the U.S. via direct shipping from foreign sources to U.S. patients. These international Gilead medications are materially different from the U.S. Gilead medications authorized by Gilead for sale in the U.S., and the importation of such products in U.S. commerce violates and undermines Gilead's established and non-pretextual quality-control procedures.

295. Defendants' actions have caused and/or are likely to cause confusion, mistake, or deception as to the source of origin, sponsorship or approval of the international Gilead medication in that patients are likely to believe Gilead authorizes and controls the sale and importation of international Gilead medications, or that Defendants are associated with or related to Gilead or are authorized by Gilead to sell international Gilead medications in the U.S.

296. Importing international Gilead medications directly from foreign sources to U.S. patients violates federal law.

297. Defendants' acts have injured or are likely to injure Gilead's image and reputation with consumers in this judicial district and elsewhere in the U.S. by creating confusion about, and/or dissatisfaction with, international Gilead-branded medicines, and have caused Gilead actual damages in the form of lost sales.

PRAYER FOR RELIEF

WHEREFORE, Gilead demands judgment against Defendants as follows:

A. An order preliminarily and permanently enjoining each and every one of the Defendants and their subsidiaries, parents, affiliates, agents, servants, employees, members, directors, officers, and attorneys, and those persons in active concert or participation with them:

(i) from importing, advertising the importation of, or otherwise facilitating the importation of product bearing a Gilead Mark;

(ii) from purchasing, selling, distributing, marketing, manufacturing, offering for sale, or otherwise using in United States commerce, any product bearing a Gilead Mark that was not intended for sale in the United States;

(iii) from falsely representing any or all of Defendants as being connected with Plaintiffs or sponsored by or associated with Plaintiffs with respect to the importation of international Gilead-branded medicine, or engaging in any act (including using the Gilead Marks or any marks confusingly similar to the Gilead Marks) which is likely to cause the trade, retailers and/or members of the purchasing public to believe that any or all of Defendants are associated with Plaintiffs with respect to the importation of international Gilead-branded medicine;

(iv) from destroying any records concerning the sale, offer for sale, distribution, advertisement, or receipt of any international product or product dispensed by a foreign pharmacy purporting to be Gilead medicine;

(v) from assisting, aiding, or abetting any other person or entity in engaging in or performing any of the activities referred to in subparagraphs (i) through (iv) above;

B. awarding to Gilead punitive damages from each Defendant in an amount to be ascertained at trial, but in no event less than $25 million;

C. awarding to Gilead statutory, actual damages, or threefold damages in an amount to be ascertained at trial, and costs and attorney's fees;

D. awarding to Gilead an accounting, and an award of: (i) all ill-gotten profits from Defendants' manufacture, sale, and/or distribution of the illegally imported medication; (ii) Gilead's lost profits; and (iii) Gilead's remedial costs;

E. awarding to Gilead pre-judgment and post-judgment interest;

F. awarding to Gilead reasonable attorneys' fees and other costs of suit; and

G. awarding such other and further relief as may be just, proper, and equitable.

Dated: New York, New York
September 30, 2025

/s/ Geoffrey Potter
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EXHIBIT A – List of Gilead Marks

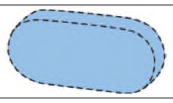
Trademark	Registration Number(s)	Registration Date
GILEAD	3,251,595	6/12/2007
	2,656,314	12/3/2002
GSI	3,890,252	12/14/2010
BIKTARVY	5,344,455	11/28/2017
DESCOVY	4,876,632	12/29/2015
DESCOVY FOR PREP	5,912,591	11/19/2019
AMBISOME	1,598,121	5/29/1990
9883	5,467,392	5/15/2018
	5,636,131	12/25/2018
7977	4,585,257	8/12/2014
TRUVADA	2,915,213	12/28/2004
SOVALDI	4,468,665	1/21/2014
STRIBILD	4,263,613	12/25/2012
	6,031,751	4/14/2020
VOSEVI	5,259,592	8/8/2017
	5,030,567	8/30/2016
	5,018,106	8/9/2016
	5,154,303	3/7/2017
	5,906,177	11/12/2019
GENVOYA	4,797,730	8/25/2015

EXHIBIT B – Photos of Turkish BIKTARVY® Received by John Doe

EXHIBIT C – Sample Photos of U.S. BIKTARVY® Label and Packaging