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. Serve On: CT Corporation System, Resident Agent 1200 South Pine Island Road Plantation, FL 33324 PROACT INC. Serve On: David J. Schryver, Resident Agent 6333 Route 298, East Syracuse, NY 13057 RX VALET, LLC Serve on: Gregory Santulli, 2365 Bellefonte Avenue, Lawrenceville, GA 30043 ADVANCED PHARMACY, LLC Serve on: Gregory Santulli, 1580 Atkinson Road, Lawrenceville, GA 30043 AQUA ENTERPRISE INC d/b/a AFFORDABLE RX MEDS Serve on: Anwar Ladhani, 1117 Sawgrass Corporate Parkway, Sunrise, FL 33323 GREGORY SANTULLI 2365 Bellefonte Avenue, Lawrenceville, GA 30043 FETIH ECZANESI Defendants.	**COMPLAINT** Case No.

Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, "Gilead" or "Plaintiffs"), by and through their counsel, Patterson Belknap Webb & Tyler LLP and Zuckerman Spaeder LLP, 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"), and Fetih Eczanesi (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' scheme to force American patients, who have commercial health insurance, to fill their U.S. prescriptions with non-FDA-approved, illegally imported medicines from Turkey and other foreign countries. Gilead learned of Defendants' scheme from a Maryland patient who was concerned he had received inauthentic Gilead HIV medication after his insurance company arranged for his medication to come in the mail, but the bottles and Patient Information documents that arrived at his home looked strikingly different from the Gilead-branded medicine he had been taking for years – most saliently, because the bottles and Patient Information documents were entirely in Turkish.

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 non-English labels and Patient Information documents, and are diverted and transported in a way that violates Gilead's quality-control standards.

3. American 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. 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 health insurance companies strongarming patients into filling their prescriptions with 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. Moreover, Defendants have opened an illicit, unregulated, and unmonitored supply chain directly from essentially anonymous Turkish pharmacies to the doorsteps of U.S. patients in gross violation of federal law. 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." Today, American patients are protected by our closed, secure, and highly regulated pharmaceutical supply chain, which is the global "gold standard." Defendants' scheme to line their pockets by illegally importing drugs from Turkey – a known epicenter of pharmaceutical counterfeiting – is an invitation to foreign counterfeiters who would love nothing more than to sell their fake drugs in U.S. commerce disguised as "legitimate" foreign product.

5. The Gilead-branded drugs that Defendants are illegally importing treat serious diseases like HIV. Unsafe or ineffective medicines put patients' lives at risk.

6. Defendants here are a health insurer and its pharmacy benefit manager ("PBM"); an Alternative Funding Program ("AFP") that works with health insurers and PBMs to

implement policies and programs to reduce the cost of prescription drug benefits; two "international mail order" companies used to fill U.S. prescriptions with illegally imported drugs; and a Turkish pharmacy that ships Turkish drugs to American patients. Because health insurance companies are participants in the scheme, Defendants give themselves a veneer of legality and authenticity, which they employ to abuse their patients' trust. Defendants promise to arrange for patients to get Gilead-branded prescription medicine delivered right to their door, and either require or push the patient to send their prescription to a "mail-order pharmacy," including by promising the patient that any copay will be waived. But this is a bait-and-switch. What shows up to the patient's home is illegally imported, unapproved foreign product, shipped directly from Turkey, India, or another foreign country.

7. Under black-letter law, it is an act of trademark infringement to import and sell into U.S. commerce foreign products that are materially different from the manufacturer's U.S. versions of those products, or that are shipped or sold in violation of the manufacturer's quality-control efforts. This is not a close case: non-FDA-approved bottles of prescription medication, labeled entirely in Turkish and shipped halfway around the world without temperature controls and through an illicit, unregulated and unmonitored supply chain, are quintessential examples of infringing "materially different" products.

8. Gilead brings this action to protect U.S. patients. The FDA has issued official Warning Letters to companies like Defendants that illegally import foreign medications, citing them for selling non-FDA-approved drugs in this country and imperiling the health and safety of American patients. The Department of Justice has prosecuted "international mail order pharmacies" that, for example, have sold counterfeit cancer medication into U.S. commerce by claiming they were safely importing drugs from Canada, when in fact their fake drugs had no

active ingredients in them whatsoever. And yet Defendants continue their brazen scheme, openly advertising their efforts to put illegally imported drugs into the hands of insured U.S. patients, enriching themselves at patients' expense. Gilead therefore exercises its rights as a U.S. manufacturer and trademark owner 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

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

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

15. Defendant Aqua Enterprise Inc d/b/a Affordable Rx Meds ("Affordable Rx Meds"), a Florida corporation, is a prescription referral service with its principal place of business in Sunrise, Florida.

16. 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.

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

JURISDICTION AND VENUE

18. 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.

19. This Court has personal jurisdiction over 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' conduct alleged herein was knowingly and intentionally directed toward Maryland, and Defendants purposefully availed themselves of Maryland's market and laws. The effects of Defendants' conduct in Maryland were not only foreseeable; they were foreseen and intended.

20. 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.

21. 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

22. 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.

23. 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.

24. For example, BIKTARVY®, developed by Gilead and first approved by the 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.

25. The Gilead medicines sold in the U.S., including BIKTARVY®, are prescription drugs that have been approved for sale by the U.S. Food and Drug Administration ("FDA").

26. 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 list of the Gilead Marks is set forth in **Exhibit A** hereto, which is incorporated by reference.

27. 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. 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.

28. 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.

29. 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.

30. 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 WHISTLEBLOWER REPORT AND GILEAD'S INVESTIGATION

31. "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.

32. 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.

33. In January 2024, John Doe switched his health insurer to Meritain. John Doe's pharmacy benefit coverage with his Meritain health insurance plan was managed by ProAct, a pharmacy benefit manager, or PBM.

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

35. 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.

36. 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.

37. 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.

38. 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.

39. 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**.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

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

46. 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.

47. 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.

48. Throughout 2024, after reporting the Turkish BIKTARVY® products and providing them to his healthcare provider, John Doe has 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 has discarded those cartons and bottles unopened.

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

49. 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.

50. Turkish BIKTARVY®, like all international Gilead-branded medicines, is not intended for sale in the U.S., and is not regulated or approved by the FDA for use in the U.S.

51. 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 international version of any Gilead-branded medicine meets all of the FDA manufacturing, packaging, and labeling requirements for that medicine. Rather, international Gilead-branded medicines meet the different regulatory requirements of the foreign markets in which they are intended for sale.

52. As a result, the importation or distribution of any international Gilead-branded medicine, like Turkish BIKTARVY®, 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).

53. The FDA has issued two Warning Letters to companies that, like Defendants, import or facilitate the importation of foreign prescription medications.[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.

54. 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.

55. 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

[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.

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]

56. All illegal importation of foreign medication breaches the secure U.S. supply chain and creates an unacceptable risk of counterfeit drugs reaching American patients. But Defendants have created an extreme threat by importing from Turkey, which is widely recognized as a global epicenter for the manufacture and distribution of counterfeit pharmaceuticals, including specifically Gilead-branded pharmaceuticals.

57. Foreign 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.

IV. DEFENDANTS' IMPORTATION SCHEME

58. Defendants have all conspired to execute a scheme whereby American patients, who have commercial health insurance and are entitled to have their prescriptions filled by 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.

59. 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

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

receiving the same safe, securely supplied medicines that they would receive from a U.S. retail pharmacy.

60. 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. Recidivist Infringers Rx Valet, Advanced Pharmacy, and Gregory Santulli

61. 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-drugs benefits to their insured patients.

62. 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."

63. Rx Valet coordinated directly with John Doe and told him 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.

64. 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®.

65. Rx Valet has regularly worked and continues to regularly work with American 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.

66. Defendant Advanced Pharmacy is a mail-order pharmacy based in Georgia.

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

68. 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.

69. Advanced Pharmacy is not a legitimate pharmacy. It exists only to sell and arrange for the sale of unlawful and infringing imported foreign drugs and medical devices.

70. After it 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 provided the BIKTARVY® prescription to Affordable Rx Meds, with the understanding and intention that Affordable Rx Meds would refer the prescription to one of its foreign "contracted pharmacies," which would unlawfully provide international BIKTARVY® instead of U.S. BIKTARVY®.

71. Advanced Pharmacy regularly accepts prescriptions for Gilead-branded medicines – most or all of which of which are referred by Rx Valet – and arranges for those prescriptions to be unlawfully filled with international Gilead medicines from foreign pharmacies.

72. Advanced Pharmacy advertises that it will sell or source the following international Gilead-branded medicines: AMBISOME®, BIKTARVY®, DESCOVY®, GENVOYA®, SOVALDI®, STRIBILD®, TRUVADA®, and VOSEVI®.

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

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

75. 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. He controls both companies and is an active and moving force behind both companies' infringement. Santulli directly financially benefits from his companies' infringement.

76. In 2016, Advanced Pharmacy and Santulli 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.

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

b. The "Prescription Referral Service" and the Turkish Pharmacy: Affordable Rx Meds and Fetih Eczanesi

78. Defendant Affordable Rx Meds is a self-described "prescription referral service" 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 pharmacies to ship the prescription drugs directly to U.S. patients.

79. Affordable Rx Meds does not publicly specify how, precisely, it "refers" a U.S. prescription written by an American doctor to be filled by a pharmacy in Turkey. 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.

80. Affordable Rx Meds sent John Doe's prescription for BIKTARVY® to Fetih Eczanesi, with the intention and understanding that the Turkish pharmacy would send Turkish BIKTARVY® to John Doe in Maryland.

81. Although Affordable Rx Meds is not a pharmacy, it 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 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.

82. 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.

83. 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.

84. Affordable Rx Meds' "Frequently Asked Questions" website states:

> **Why do the pills I received look different from the ones I 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.

85. Counterfeiters are often caught when a patient reports that their medication looks different from what they usually receive. Affordable Rx Meds directly advises patients to ignore their instincts and disregard any differences they notice. 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.

86. Affordable Rx Meds regularly solicits prescriptions for Gilead-branded medicines from U.S. patients and causes those prescriptions to be filled by its "contracted pharmacy"

partners in other countries, including India and Turkey, 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®.

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

88. Fetih Eczanesi is a retail pharmacy, licensed by the Turkish government, in Istanbul that partners with Defendants, including Affordable Rx Meds, to illegally fill American patient's prescriptions with non-FDA-approved Turkish Gilead-branded medicines. Fetih Eczanesi ships these Turkish medications directly to the American patients' homes.

89. Fetih Eczanesi, like all of the foreign pharmacies who participate in Defendants' scheme, 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.

90. 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.

91. 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.

92. 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.

93. 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.

94. 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.

c. The Health Insurers Who Force American Patients to Receive Non-FDA-Approved Foreign Drugs: ProAct and Meritain

95. Defendants' scheme begins with ProAct and Meritain, sophisticated American companies in the commercial health insurance business. ProAct and Meritain's insured patients are entitled to the same securely supplied, FDA-approved U.S. medications as every other American citizen. But ProAct and Meritain put their patients' health at risk by forcing or tricking them into filling their prescriptions for life-saving Gilead-branded medicines with non-FDA-approved medicine shipped through an illicit, unsecured, and unregulated supply line.

96. Defendant ProAct is a PBM that manages prescription drug benefits on behalf of health plans, including Meritain. ProAct acts as Meritain's agent and negotiates with other companies to fill their insured patients' pharmaceutical prescriptions at lower cost.

97. 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.

98. 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.

99. 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 or another company that illegally fills U.S. prescriptions with infringing international medications.

100. 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®.

101. ProAct publicly advertises its "international mail-order program," which allows patients to receive "brand-name maintenance medications" for a $0 copay.

102. 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!"

103. In addition to partnering with Rx Valet, as it did with John Doe, ProAct advertises its relationship with another "international mail order partner," CanaRx, which also advertises its unlawful services filling U.S. prescriptions with imported foreign drugs. The FDA issued a Warning Letter to CanaRx in 2018, 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.

104. ProAct regularly requires, tricks, and pushes patients to fill their U.S. prescriptions for Gilead-branded medicines with infringing foreign versions of those medicines. Acting as the agent for Meritain and other health insurers, ProAct receives patient information and prescriptions, 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.

105. 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 prices, approving the cost of infringing international Gilead-branded medicines, and approving and paying for, or arranging for the payment for, the infringing medicines.

106. 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 must lawfully fill their prescriptions with FDA-approved U.S. medicine, and by refusing to pay for infringing product. ProAct has not done so,

and continues to directly financially benefit from the infringement, both by pocketing the difference between the cost of the infringing foreign medication its patients receive and the authentic U.S. medication that they should receive, and by touting its ability to use "creative" and "innovative" techniques to lower drug costs for health insurance plans.

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

108. Defendant Meritain is a U.S. health insurer and administers health insurance benefits for self-funded employers' plans, including John Doe's health plan.

109. Meritain contracts with ProAct and uses ProAct as its agent to administer prescription benefits for its health plans. Meritain knew about ProAct's so-called "international pharmacy program," which ProAct extensively advertises, and knew that by using ProAct as its PBM, Meritain-insured patients would be required, tricked, or pushed into filling their prescriptions with infringing, non-FDA approved foreign medicines. Indeed, Meritain agreed to use ProAct as its PBM in large part to take advantage of ProAct's unlawful "international pharmacy program."

110. As the administrator of John Doe's health plan, Meritain provided the patient information to ProAct, approved the coverage and cost of the infringing imported BIKTARVY® that John Doe received (including that John Doe would not be charged a copay), and approved the payment for the infringing imported BIKTARVY® and caused that payment to occur.

111. Meritain was aware of the techniques that ProAct and its "international pharmacy partners" used to force or trick 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.

112. On its website advertising its "international mail order program," ProAct warns 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 controlled and drafted by Meritain, the administrator of the insurance plan. It is ultimately Meritain's decision whether to provide coverage for infringing, illegally imported foreign medications.

113. Meritain knowingly induces others – including ProAct, its "international mail order partners," and patients – to infringe Gilead's marks by advertising, offering for sale, selling, and otherwise using in U.S. commerce materially different Gilead-branded medicines. Meritain also continued to provide its services as a health insurance plan administrator to others that it knew to be engaged in infringing behavior, including by agreeing to cover infringing, non-FDA-approved foreign medicines under its health plan, approving the cost of those infringing foreign medicines, and approving and paying for, or arranging for the payment for, the infringing medicines.

114. Meritain could stop or limit the other Defendants' infringement at any time by instructing patients that they must lawfully fill their prescriptions with FDA-approved U.S. medicines, refusing to cover international medicines under its health plan, and/or 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, both by pocketing the difference between the cost of the infringing foreign medicine its patients receive and the FDA-approved U.S. medicine they should receive, and by touting its ability to use "creative" and "innovative" techniques to lower drug costs for the self-funded employer health plans it administers.

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

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

116. 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**.

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

118. 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.

119. 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.

120. 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.

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

122. 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®.

123. Fifth, the label and packaging for Turkish BIKTARVY® does not bear the phrase "Rx only" (stylized as ), which appears on U.S. BIKTARVY®. The 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.

124. 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.

125. 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.

126. 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.

127. 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®.

128. 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.

129. 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.

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

130. 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

131. 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.

132. 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, as they move halfway across the globe over the course of days or weeks or months.

133. 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

134. 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.

135. 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.

136. 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.

137. Gilead does not seek FDA approval to issue targeted recall notices in the U.S. for products 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. product. 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. product, 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

138. 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.

139. 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.

140. 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.

141. 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.

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

143. When international Gilead-branded medicines, like Turkish BIKTARVY®, are imported into the U.S. directly from foreign pharmacies 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 use pedigrees to trace international medicine that has been shipped from a foreign pharmacy directly to a U.S. patient.

d. Gilead's Secure Supply Chain

144. 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.

145. Defendants' illegal importation of international medicines directly from foreign pharmacies 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.

146. 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. But here, the risk of counterfeit medication is especially dire, because Defendants' scheme involves importing Gilead-branded medicines from Turkey and India, both of which have been identified by the U.S. government as leading regions for pharmaceutical counterfeiting. 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.

147. 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.

148. 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.

149. 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)

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

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

152. 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.

153. 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.

154. 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.

155. 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.

156. 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.

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

158. 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.

159. 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.

160. 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)

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

162. 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.

163. 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.

164. For example, Defendants ProAct and Rx Valet publicly advertise the fact that they offer "international sourcing" for 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."

165. 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.

166. 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.

167. 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).

168. 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.

169. 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.

170. 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.

171. 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)

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

173. 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.

174. 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.

175. 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, and Fetih Eczanesi)

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

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

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

179. Defendant Rx Valet receives a payment for each international Gilead medication that it causes to be imported from a foreign country as part of its conspiracy with ProAct, Meritain, and health plans, reflecting the health plan's savings by relying on illegally imported medication.

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

181. Defendant Gregory Santulli, as an owner and principal of Rx Valet and Advanced Pharmacy, has personally profited as a result of those companies' profits from illegally imported Gilead medication.

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

183. 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)

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

185. 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.

186. 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)

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

188. 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 pharmacies 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.

189. 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.

190. Importing international Gilead medications directly from foreign pharmacies to U.S. patients violates federal law.

191. 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.

[*intentionally left blank*]

Dated: New York, New York
December 10, 2024

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EXHIBIT A – List of Gilead Marks

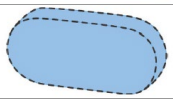
Trademark	Registration Number(s)	Registration Date
GILEAD	3,251,595	6/12/2007
	2,656,314	12/3/2002
GSI	3,890,252	12/14/2010
BIKTARVY	5,344,455	11/28/2017
DESCOVY	4,876,632	12/29/2015
DESCOVY FOR PREP	5,912,591	11/19/2019
AMBISOME	1,598,121	5/29/1990
9883	5,467,392	5/15/2018
	5,636,131	12/25/2018
7977	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