UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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| JANSSEN SCIENCES IRELAND UNLIMITED COMPANY, JANSSEN PRODUCTS, LP, and JOHNSON & JOHNSON | : | Case No. _____ |
| Plaintiffs, | : | |
| v. | : | |
| SAFE CHAIN SOLUTIONS, LLC; PROPHARMA DISTRIBUTION LLC; SCRIPTS WHOLESALE INC. STEVEN DIAMANTSTEIN, LEVI ELLIS, CHARLES BOYD, PATRICK BOYD, I CARE PHARMACY 14, INC, and EDWARD GENDIN, | : | |
| Defendants. | : | |

**COMPLAINT**

Plaintiffs Janssen Sciences Ireland Unlimited Company, Janssen Products, LP, and Johnson & Johnson (collectively "Janssen"), by and through their counsel, Patterson Belknap Webb & Tyler LLP, for their complaint against Defendants Safe Chain Solutions, LLC ("Safe Chain"); Patrick Boyd and Charles Boyd (together with Safe Chain, the "Safe Chain Defendants"); ProPharma Distribution LLC ("ProPharma"); Levi Ellis (together with ProPharma the "ProPharma Defendants"); Scripts Wholesale Inc. ("Scripts"); Steven Diamantstein, (together with Scripts, the "Scripts Defendants"); I Care Pharmacy 14, Inc. ("I Care"); and Edward Gendin (together with I Care, the "I Care Defendants") allege as follows:

**SUMMARY OF THE ACTION**

1. In this action, Janssen seeks to put an immediate and permanent stop to Defendants' dangerous sale of counterfeit HIV medication in New York City and across the United States.

2. Janssen has recently received a series of complaints from patients distressed to find that their prescribed bottles of SYMTUZA®, a lifesaving HIV medication that combines a complete multidrug HIV regimen in a single pill, contained the wrong pills inside the bottles.

3. Extensive investigation by Janssen confirmed that these bottles were counterfeits. The state-of-the-art process controls at Janssen's packaging plant make it impossible for genuine SYMTUZA® bottles to contain anything but SYMTUZA® pills. Furthermore, the bottles bore other indications of counterfeiting, including fake labels, falsified instructions for use, and counterfeit supply-chain pedigrees.

4. Patients who have been prescribed SYMTUZA® depend on the medication's complete multidrug regimen to control their viral loads and ultimately protect them from terminal disease. But the pills found inside the counterfeit bottles were different drugs that do not adequately control these patients' viral loads and thus place them at serious risk of disease progression.

5. Due to the rapidly mutating nature of HIV, missing all or part of a medication regimen can place patients at risk of developing drug resistance, which may persist even after the proper drug regimen is restored. As a result, counterfeit SYMTUZA® puts patients at risk of suffering permanent harm from disruption in treatment.

6. Beyond these serious microbiological consequences, finding the wrong pill in a bottle of HIV medication can lead some members of the HIV-positive community to lose trust in the healthcare system and stop treatment altogether. Indeed, one of the patients who received a counterfeit SYMTUZA® bottle and reported it to Janssen could not be located for

follow-up monitoring, with their healthcare provider reporting that the patient had fallen out of care following the counterfeiting incident.

7. Defendants have distributed counterfeit SYMTUZA® and other counterfeit Janssen HIV medications on a large scale.

8. The Safe Chain, Scripts, and ProPharma Defendants (together, the "Wholesaler Defendants") are pharmaceutical wholesalers that have distributed large quantities of counterfeit Janssen HIV medication. Several of the complaints of counterfeit SYMTUZA® with the wrong pills in the bottles could be traced to sales by Scripts or Safe Chain. ProPharma disclosed to Janssen that it was in possession of hundreds of bottles of Janssen HIV medication that proved to be counterfeit. And recently unsealed documents in *Gilead et al., v. Safe Chain Solutions LLC*, No. 21-cv-4106 (E.D.N.Y.) (the "Gilead Action") reveal that the counterfeits Janssen was notified about represent only a small fraction of the Wholesaler Defendants' counterfeiting activities.

9. Meanwhile, Janssen has continued to receive complaints of counterfeit SYMTUZA® including separate incidents in New York City in late December 2021 and January 2022. One of these complaints concerned a bottle dispensed by Defendant I Care, a Manhattan pharmacy that is not involved in the Gilead litigation.

10. Immediately after the counterfeit was discovered, I Care abruptly closed its doors in an obvious effort to stay one step ahead of the law. Janssen's investigation subsequently revealed that I Care, beginning in April 2021, had arisen from nowhere to become one of the largest sellers of Janssen HIV medication in New York City by the time it was discovered selling counterfeits in late December 2021. Then, days after I Care shut down, a Queens pharmacy abruptly took over I Care's HIV business.

11. This evidence indicates that I Care is connected to a criminal counterfeiting ring that continues to actively dispense dangerous counterfeit HIV medication in New York City. It also suggests that I Care has acted in concert with others whose identities remain unknown to Janssen.

12. Janssen brings this action to put a stop to Defendants' distribution of counterfeit HIV medication and to protect HIV-positive patients in New York City and throughout the country from the perils of these dangerous counterfeits.

## THE PARTIES

### A. PLAINTIFFS

13. Plaintiff Johnson & Johnson is a public corporation organized under the laws of the State of New Jersey. Its principal place of business is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is a multinational holding company for companies with a primary focus of providing products and services related to human health and well-being. Johnson & Johnson is also the owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and instructional inserts of certain genuine HIV and other medications.

14. Plaintiff Janssen Products, LP ("JPLP") is a limited partnership organized under the laws of the State of New Jersey. Its principal place of business is 800 Ridgeview Dr, Horsham, PA 19044. Janssen Products, LP is an indirect subsidiary of Johnson & Johnson and markets lifesaving medications in the United States, including SYMTUZA®, PREZCOBIX®, PREZISTA®, and EDURANT®.

15. Plaintiff Janssen Sciences Ireland Unlimited Company ("Janssen Ireland") is a private unlimited company organized under the laws of Ireland. Its principal place of business is Airton Road, Dublin, Ireland D24WR89. Johnson & Johnson is the ultimate parent

of Janssen Ireland. Janssen Ireland is the owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and instructional inserts of certain genuine HIV and other medications, including SYMTUZA®, PREZCOBIX®, PREZISTA®, and INTELENCE®.

## B. DEFENDANTS

### 1. Safe Chain Defendants

16. Defendant Safe Chain Solutions, LLC ("Safe Chain") is a Delaware limited liability corporation with a principal place of business in Cambridge, Maryland.

17. Defendant Patrick Boyd is an individual residing in Maryland. Together with his brother Charles, Patrick Boyd is a founder, owner, and managing principal of Safe Chain. Patrick Boyd managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit HIV and other medications. Patrick Boyd directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

18. Defendant Charles Boyd is an individual residing in Maryland. Together with his brother Patrick, Charles Boyd is a founder, owner, and managing principal of Safe Chain. Charles Boyd serves as CEO of Safe Chain. Charles Boyd managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit HIV and other medications. Charles Boyd directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

### 2. ProPharma Defendants

19. Defendant ProPharma Distribution LLC ("ProPharma") is a Colorado limited-liability corporation with a principal place of business in Colorado.

20. Defendant Levi Ellis is an individual residing in Colorado. Ellis is the founder and owner of ProPharma. Ellis managed, supervised, ratified, and/or personally

participated in the trafficking of counterfeit HIV medications. Ellis directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

**3. Scripts Defendants**

21. Defendant Scripts Wholesale Inc. ("Scripts") is a New York corporation with a principal place of business in New York. Its principal is Defendant Steven Diamantstein. Scripts is a brick-and-mortar distributor that sells counterfeit HIV medication.

22. Defendant Steven Diamantstein is an individual residing in Brooklyn, New York. Diamanstein is the principal of Scripts. Diamanstein supervised, ratified, and/or personally participated in the trafficking of counterfeit HIV medications. Diamanstein directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

**4. I Care Pharmacy Defendants**

23. Defendant I Care Pharmacy 14, Inc. ("I Care") is a New York corporation with a listed corporate address in Queens, New York. Its principal is Defendant Edward Gendin. Until just recently, I Care Pharmacy 14, Inc. operated a brick-and-mortar pharmacy at 223 W 14th Street, New York, New York 10011. This location was abruptly abandoned upon being found with counterfeits.

24. Defendant Edward Gendin is an individual residing Hewlett, New York. Gendin is the principal of I Care Pharmacy 14, Inc. Gendin supervised, ratified, and/or personally participated in the trafficking of counterfeit HIV medications. Gendin directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

## JURISDICTION AND VENUE

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

26. The Court has personal jurisdiction over each of the Defendants because each of the Defendants has sufficient minimum contacts with New York and with this District so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

27. The Scripts Defendants and the I Care Defendants are located in this District and their principals reside in this District. The Scripts Defendants and the I Care Defendants each sold counterfeit Janssen HIV medication in New York City.

28. The Safe Chain Defendants sold counterfeit Janssen HIV medication to pharmacies in New York City. The Safe Chain Defendants have previously consented to personal jurisdiction and venue in this District.

29. ProPharma, through its principal Ellis, advertises that it sells pharmaceutical products throughout the United States, maintains active licensure in New York as an out-of-state pharmaceutical wholesaler for the purpose of selling pharmaceutical products in New York, and has sold counterfeit HIV products into New York, including, Janssen believes, Janssen HIV medication. The ProPharma Defendants have previously consented to personal jurisdiction and venue in this District.

30. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b) because, as alleged above, multiple Defendants are located in this District, multiple Defendants reside in this District, multiple Defendants have their principal place of business in this District, multiple Defendants sold counterfeit products into this District, multiple Defendants conspired to operate a counterfeiting enterprise that sold counterfeit products into this District, and because a substantial part of the events giving rise to Janssen's claims occurred in this District.

## FACTUAL ALLEGATIONS

### A. JANSSEN'S HIV MEDICATIONS

31. The Janssen HIV medications at issue in this case are groundbreaking treatments based on the protease inhibitor darunavir, which was developed by Janssen in the late 1990s and early 2000s to combat multi-resistant forms of HIV that could not be adequately treated with earlier HIV medications.

32. Like all antiretrovirals, darunavir should be administered in combination with other antiretroviral agents to achieve a complete combination antiretroviral therapy for HIV.

33. PREZISTA® is the original darunavir medication – its only active ingredient is darunavir. To provide a complete treatment regimen against HIV, PREZISTA® must be administered with at least two other medications: (1) a "booster" for darunavir that inhibits a liver enzyme that would otherwise metabolize darunavir (usually ritonavir or cobicistat); and (2) at least one other antiretroviral agent from a different class of drugs, such as integrase inhibitors (INI) or nucleoside reverse transcriptase inhibitors (NRTI). Patients prescribed PREZISTA® must therefore take at least three drugs a day – PREZISTA® and two others – to complete their HIV treatment regimen.

34. PREZCOBIX® is a fixed-dose combination medication that combines darunavir with the CYP3A inhibitor cobicistat, which acts as a booster for darunavir and eliminates the need for separate administration of a booster. But PREZCOBIX® is not a complete HIV regimen. A person prescribed PREZCOBIX® as part of their HIV treatment regimen must take at least one other antiretroviral medication.

35. SYMTUZA® is a complete, single-tablet, once-a-day medication that contains an entire HIV combination therapy regimen in a single pill. SYMTUZA® contains the boosted darunavir combination found in PREZCOBIX® (darunavir and cobicistat), as well as

two other drugs (emtricitabine and tenofovir alafenamide) A patient prescribed SYMTUZA® receives their entire HIV combination treatment (i.e., "a complete regimen") in one daily pill.

36. EDURANT® and INTELENCE® are HIV medications that are also used to treat HIV as part of combination antiretroviral therapy.

37. Janssen's HIV medications do not cure HIV. But when as prescribed (and, except in the case of SYMTUZA®, in combination with other medications), they can lower the amount of virus in a patient's blood to undetectable levels.

## B. JANSSEN'S TRADEMARKS

38. Plaintiffs own several different registered, well-known trademarks that appear on the packaging of genuine Janssen HIV medications.

39. Janssen Sciences Ireland Unlimited Company owns the SYMTUZA®, PREZCOBIX®, PREZISTA®, INTELENCE®, and INTELENCE marks (the "Janssen Ireland Marks").

40. Johnson & Johnson owns the EDURANT®, JANSSEN®, and janssen marks (the "Johnson & Johnson Marks").

41. Janssen has used and is currently using the Janssen Ireland Marks and Johnson & Johnson Marks in commerce in connection with its sale of the above-described medications, and plans to continue such use in the future. Janssen prominently displays the Janssen Ireland Marks and Johnson & Johnson Marks in its advertising and promotional materials.

## C. DEFENDANTS' COUNTERFEIT JANSSEN MEDICATIONS

42. Janssen has recently learned that Defendants and others have been distributing counterfeit Janssen HIV medication in the United States.

43. Janssen learned of Defendants' counterfeits through three sources: (1) complaints of counterfeit Janssen HIV medication from pharmacists and patients, (2) the return of hundreds of bottles of counterfeit medicine by Defendant ProPharma, and (3) the disclosure of widespread distribution of purported Janssen product by known counterfeiters in litigation brought by another manufacturer of HIV medication, Gilead Sciences, Inc. ("Gilead").

**1. Complaints of Counterfeit Janssen HIV Medication**

44. Beginning in November 2020 and continuing to the present, Janssen has investigated a continual series of complaints concerning counterfeit Janssen HIV medication.

45. Janssen has conducted its own investigation into the complaints and has also cooperated in an investigation conducted by the Food and Drug Administration's Office of Criminal Investigations.

46. In the course of Janssen's investigation, Janssen has obtained several of the reported counterfeit bottles that contain the wrong medication and has confirmed through internal testing that the labels and instructions for use are, in many cases, also counterfeit.

47. Janssen also undertook an extensive process analysis to determine whether the mislabeling could have occurred through an error in the original manufacturing or packaging process. This analysis concluded that it was not possible that wrong pills could have been inadvertently placed in the bottle due to a manufacturing or bottling error.

48. Rather, the counterfeit bottles with the wrong pills inside are the work of criminal counterfeiters.

**a. Ascan and Quick Med Pharmacies**

49. In November 2020, Janssen received a complaint that a bottle labeled and sold as SYMTUZA® by Ascan Pharmacy in Queens, New York contained only PREZCOBIX® tablets.

50. The pharmacist reporting the counterfeit bottle sold at Ascan Pharmacy retained the counterfeit bottle and sent it to Janssen, who evaluated the sample for authenticity. Janssen's evaluation determined that the sample was counterfeit.

51. This conclusion was reached because the label did not contain the security features present on genuine labels of SYMTUZA®, the bottle did not contain a desiccant pouch (necessary to prevent moisture from degrading the medication), and the patient Instructions for Use was not the correct version for medication with the lot and serial number displayed on the label.

52. Janssen also confirmed that the tablets contained in the sample were PREZCOBIX®, not SYMTUZA®.

53. Janssen learned from the pharmacist that Ascan Pharmacy obtained the medication from Defendant Scripts. Janssen reported this information to the Food and Drug Administration's Office of Criminal Investigations.

54. Defendant Scripts has acknowledged that it was subject to an FDA OCI inquiry about counterfeit SYMTUZA® and has confirmed that Ascan purchased counterfeit SYMTUZA® from Scripts.

**b. Quick-Med Pharmacy**

55. In December 2020, Janssen received a complaint from Quick Med Pharmacy in Asbury Park, New Jersey that was nearly identical to the complaint from Ascan Pharmacy: PREZCOBIX® pills inside a bottle labeled SYMTUZA®.

56. Notably, the suspect bottles from Ascan and Quick-Med, reported by different pharmacies, purported to come from the same lot, and, importantly, bore the same serial number. This is a clear indicator of counterfeiting, because each authentic SYMTUZA® bottle is given a unique serial number.

57. The bottle labeled SYMTUZA® dispensed by Quick-Med Pharmacy was confirmed to be counterfeit.

58. Quick-Med Pharmacy provided Janssen with an invoice for the counterfeit SYMTUZA® showing that the product had been purchased from Defendant Safe Chain.

**c. Navarro Pharmacy**

59. In December 2020, Janssen received the first of several complaints arising out of Navarro / CVS Specialty Pharmacy ("Navarro") in Miami.

60. The complaint was nearly identical to the previous complaints from New York and New Jersey—PREZCOBIX® tablets in bottles sold as SYMTUZA®. That bottle purported to be from the same lot as the previous counterfeits, and also included the identical falsified serial number.

61. In 2021, Janssen would receive two additional complaints from Navarro. The first of these was identical to the previous three: PREZCOBIX® tablets in bottles sold as SYMTUZA®, with the same lot number, and the same replication of the identical serial number.

62. The second complaint was a bottle labeled as PREZCOBIX®. That bottle did not contain HIV medication at all, and was instead filled with high-dose tablets of SEROQUEL XR (400 mg), a powerful antipsychotic, which is not manufactured by Janssen.

**d. SRX Specialty Pharmacy**

63. In June 2021, Janssen received another complaint of a SYMTUZA® bottle containing PREZCOBIX®. That bottle was dispensed by SRX Specialty Pharmacy in Michigan.

64. Janssen's investigation into this complaint revealed that the patient had taken the incorrect PREZCOBIX® pills for nearly a month, potentially jeopardizing their health.

65. Janssen's analysis of this sample concluded that it was an authentic SYMTUZA® bottle containing PREZCOBIX® pills, and therefore a counterfeit product.

66. For this sample, the pharmacists provided Janssen with the supply-chain pedigree document for the counterfeit. The pedigree had been provided to the pharmacy by Defendant Safe Chain.

67. Janssen determined that the pedigree was counterfeit. The pedigree identified a purported direct sale from Janssen to Cintex Services LLC, which is not a Janssen authorized distributor and thus could not have purchased the product directly from Janssen.

**e. Recent Complaints from I Care Pharmacy and Morris Park Pharmacy**

68. On December 20 2021, Janssen received a complaint from a patient that Defendant I-Care dispensed to him a bottle of SYMTUZA® that actually contained PREZCOBIX® tablets.

69. Janssen confirmed that the tablets inside the bottle were PREZCOBIX®, not SYMTUZA®.

70. On January 14, 2022, Janssen received an additional complaint from New York City of another patient had received PREZCOBIX® in a SYMTUZA® bottle. This complaint related to a bottle dispensed at Morris Park Pharmacy in the Bronx.

71. As alleged below, Janssen's investigation of the I Care complaint indicates that I Care was part of a sophisticated counterfeiting operation that remains active. Janssen has not been able to confirm the supplier of the Morris Park Pharmacy counterfeit.

**2. ProPharma Inquiry and Return**

72. During the course of Janssen's investigations, Defendant ProPharma contacted Janssen in August 2021 to inquire about the legitimacy of Janssen HIV medication in its possession.

73. At the time of the inquiry, ProPharma stated that its inquiry was prompted by "due diligence." Janssen subsequently learned that that ProPharma reached out to Janssen only after Gilead conducted a Court-ordered seizure at ProPharma's warehouse. During that seizure ProPharma was found with hundreds of bottles of counterfeit Gilead-branded HIV medication.

74. ProPharma provided supply-chain pedigrees for some of the Janssen medication in its possession. Every single supply-chain pedigree provided by ProPharma was counterfeit. Specifically, ProPharma's pedigrees listed fraudulent sales that never occurred.

75. After being informed that the pedigrees were false, ProPharma returned 247 bottles of Janssen HIV medication to Janssen, representing 32 different lot numbers.

76. Janssen's investigation has revealed that in addition to bearing false pedigrees, most of the bottles received from ProPharma, including at least one sample from every one of the 32 lot numbers, bore counterfeit instructions for use.

### 3. Disclosure of the Widespread Distribution of Counterfeit HIV Medication by the Gilead Action

77. Recently unsealed documents from the Gilead Action reveal that the Wholesaler Defendants have distributed Gilead and Janssen HIV medication on a large scale throughout the country. These documents also demonstrate that the Wholesaler Defendants' sale of counterfeits was willful.

#### a. The Safe Chain Defendants

78. Documents filed in the Gilead Action indicate that the Safe Chain Defendants sold many millions of dollars' worth of counterfeit HIV medication, all of which was accompanied by counterfeit pedigrees and much of which had counterfeit instructions for use, counterfeit bottle caps, or the wrong pills inside the bottles.

79. Business records filed by Safe Chain in the Gilead Action document that Safe Chain sold millions of dollars of Janssen HIV medication – not just SYMTUZA® but also four other products: PREZISTA® , PREZCOBIX® , EDURANT®, and INTELENCE®.

80. The public docket in the Gilead action also shows that concurrent with Janssen's investigation, Gilead confronted Safe Chain over its sale of counterfeit Gilead HIV medication.

81. On May 4, 2021, Safe Chain represented to Gilead that it had ceased buying Gilead medication from the supplier of the counterfeits and was now buying Gilead HIV medication solely from a new seller who sourced the product directly from a Gilead-authorized distributor, so that there was no question the product was legitimate. But just hours before Safe Chain was making those representations to Gilead, the man who introduced that supplier to Safe Chain told Safe Chain's owner, in writing, that "all of their shit is counterfeit."

82. Safe Chain's Director of Compliance stated in writing that the new supplier had provided a "fake pedigree," and directly warned Safe Chain's owners that the supplier was using a fraudulent email address meant to mimic the email address of one of Gilead's authorized suppliers..

83. Despite being warned by its Director of Compliance and directly told by its business partner that this supplier was selling counterfeit HIV medication, Safe Chain went on to purchase millions of dollars of counterfeit Gilead HIV medication from that supplier.

**b. The Scripts Defendants**

84. Documents filed in the Gilead Action indicate that the Scripts Defendants sold many millions of dollars' worth of counterfeit HIV medication, all of which was accompanied by counterfeit pedigrees and much of which had counterfeit instructions for use,

counterfeit bottle caps, or the wrong pills inside the bottles. These counterfeits included large quantities of Janssen HIV medication.

85. Documents from the Gilead Action reveal that in 2019, the principals of a Scripts distributor, Mainspring Distribution LLC ("Mainspring"), were indicted and subsequently convicted for running a "black market" pharmaceutical counterfeiting scheme that "specialized in expensive name-brand prescription drugs used to treat HIV." One of Mainspring's principals confessed that his operation would "re-label bottles of drugs for something more expensive, or a bottle of drugs would contain 'candy' instead of medication."

86. Scripts was informed of the Mainspring indictment. Even after being so informed, Scripts continued to sell counterfeit HIV medication that it had received from Mainspring – including counterfeit Janssen HIV medication.

87. When confronted about this decision during a deposition taken by Gilead, Script's owner, Defendant Steven Diamantstein, testified: "Well, I didn't know how much of that was illegal or not illegal . . . And at that point it's innocent until proven guilty, and I don't believe I had an obligation to let the drugs sit around."

**c. The ProPharma Defendants**

88. Documents filed in the Gilead Action indicate that the ProPharma Defendants sold many millions of dollars' worth of counterfeit HIV medication, all of which was accompanied by counterfeit pedigrees and much of which had counterfeit instructions for use, counterfeit bottle caps, or the wrong pills inside the bottles. These counterfeits included large quantities of Janssen HIV medication.

89. Documents from the Gilead Action show that ProPharma was part of the same counterfeiting network as Safe Chain and Scripts, including sharing the same fly-by-night

counterfeit suppliers. For example, the evidence in the Gilead Action shows that ProPharma began selling counterfeit HIV medications after being told by organizers of the counterfeiting ring that its "two major competitors" were already selling millions of dollars' worth of purported HIV medication weekly: "Safechain is moving about $5M a week and Scripps [*sic*] is around $8M."

## D. DEFENDANT I CARE'S INVOLVMENT IN COUNTERFEIT JANSSEN-BRANDED MEDICATIONS

90. Janssen's investigation into the complaint stemming from I Care Pharmacy revealed a pattern of activity that indicates a broader counterfeiting operation by that pharmacy and its owner.

91. I Care was incorporated by the same agent that incorporated entities for known members of the counterfeiting ring revealed by the Gilead Action.

92. Prior to April 2021, I Care had never ordered genuine Janssen HIV medication from a Janssen-authorized distributor. Then, from April to December 2021, I Care received 84 bottles of Janssen HIV medication from authorized distributors – placing I Care in the top 10% of pharmacies in New York City in volume of Janssen HIV medication received. This sudden increase in volume for a specialty medication is highly unusual.

93. Janssen has confirmed that no products bearing the lot number or serial number of the counterfeit product sold by I Care were ever shipped to the authorized distributor from whom I Care purchased medication, indicating that the counterfeit did not come from that distributor. Despite its large volume of authorized purchases, in other words, I Care was dispensing HIV medication it had obtained somewhere else.

94. This pattern – anomalously large purchases of authorized product by pharmacies that dispense counterfeits -- is consistent with a known practice among certain

pharmacies in New York City. These pharmacies knowingly dispense counterfeit medication, purchase equivalent quantities from authorized distributors to avoid detection by auditors and law enforcement, and then resell the medication purchased from authorized distributors at substantial profit.

95. I Care's behavior after the December 20, 2021 patient complaint evinces a clear effort to flee from the law, and thus further corroborates that I Care's sale of counterfeits was knowing and intentional.

96. Within days after Janssen discovered the counterfeit SYMTUZA® sold by I Care in late 2021, the pharmacy abruptly closed. A private investigator hired by Janssen visited I Care on several occasions in mid-January 2022 and found the pharmacy to be closed with the security gate locked during posted business hours, although, on one occasion, the security case was partially open and the pharmacy was occupied by menacing individuals.

97. The following week, on January 25, 2022, I Care's pharmacy license was discontinued.

98. Meanwhile, on January 6, 2022 – just days after Janssen received the complaint about I Care's counterfeit – Brooklyn Chem Corp. d/b/a Diamond Star, a different pharmacy located near I Care's corporate headquarters in Queens, registered I Care's name with the New York Division of Corporations as a "doing business as."

99. On January 28, 2022, just three days after I Care's pharmacy license was discontinued, Brooklyn Chem (using the Diamond Star name) abruptly began purchasing the same high volume of Janssen HIV medication that I Care had been purchasing, from the same distributor. This evidence suggests that I Care closed down its Manhattan location in response to the counterfeit complaint and transferred its business to Brooklyn Chem.

100. Defendant Edward Gendin is the sole owner of I Care and the corporate address of I Care is a former address of Mr. Gendin's in Queens. As the sole individual known to be associated with I Care, Mr. Gendin actively participated in its counterfeiting business.

## E. COUNTERFEIT HIV MEDICATIONS POSES A SEVERE RISK TO PUBLIC HEALTH

101. SYMTUZA®, PREZCOBIX®, and PREZISTA® come in thirty-tablet bottles, representing a one-month supply.

102. For patients treating an HIV infection, it is important that the patient take the Janssen medication as prescribed. If a patient does not take the medication as prescribed, the patient faces the risk that their viral load—*i.e.*, the amount of HIV in their blood—will increase. This viral rebound can have severe consequences: over time, it can weaken the patient's immune system and increase the possibility of infections; it can result in progression of the disease and lead to the development of AIDS; and it can make patients more likely to infect their sexual partners.

103. HIV is a rapidly mutating virus that can quickly develop permanent resistance to a single antiretroviral agent, or even an entire class of antiretrovirals. For this reason, the standard of care since the mid-1990s has been to treat HIV with a combination of antiretroviral agents from different classes.

104. The advent of single-dose tablets has allowed a full combination antiretroviral therapy to be combined into a single tablet, and SYMTUZA® is such a medication. It contains an entire antiretroviral combination therapy in one pill. But PREZCOBIX®, which has appeared in many confirmed counterfeit bottles of SYMTUZA®, is not.

105. PREZCOBIX® lacks two of the antiretroviral agents contained in SYMTUZA. It contains only one class of antiretroviral agent. Thus, a patient who takes

PREZCOBIX® believing it to be SYMTUZA® is receiving an incomplete HIV treatment regimen. This gap in treatment opens the door for the patient to develop drug resistance, which can persist even after a complete treatment regimen is restored.

106. In addition to the viral rebound and drug resistance risks, the dispensing of counterfeit medication to patients threatens trust in the healthcare system. The population living with HIV is diverse. But many individuals within the population face various psychosocial factors—such as low healthcare literacy, mental health comorbidities, substance abuse, and homelessness—that complicate the patient's relationship with HIV treatment. As a result, the treatment of HIV requires extensive patient outreach and education to build patient trust.

107. That fragile trust can be shattered when a patient receives a bottle of the wrong medication. Indeed, Janssen is aware of at least one patient who did not return to their healthcare provider after receiving a counterfeit HIV medication, and has apparently fallen out of care for their HIV.

108. These risks created by illegitimate medication may be even greater for the population prescribed one of Janssen's darunavir-based medications (*i.e.*, PREZISTA®, PREZCOBIX®, and SYMTUZA) than for the general population of patients undergoing HIV treatment.

109. Darunavir is a protease inhibitor with a particularly high genetic barrier to drug resistance. This characteristic of darunavir means that it is often prescribed to patients who either have already developed resistance to other antiretroviral agents or are at risk for doing so, based on treatment history or other psychosocial factors. In other words, a subset of persons living with HIV who are prescribed one of these three Janssen HIV drugs are generally at greater

risk for the adverse impacts of viral rebound, drug resistance, and falling out of care due to distrust in the healthcare system.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF
### FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1)(A)

110. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

111. In violation of 15 U.S.C. § 1114(1)(a), Defendants, independently and in conspiracy with others, used in commerce, without Janssen's consent, either a reproduction, counterfeit, copy or colorable imitation of the Janssen Ireland Marks and Johnson & Johnson Marks in connection with the sale, offering for sale, distribution, or advertising of counterfeit Janssen products; in connection with the sale, offering for sale, distribution, or advertising of Janssen products with altered and/or falsified pedigrees that are materially different from authentic Janssen products authorized for sale by Janssen in the United States and that are not subject to and subvert Janssen's quality-control measures; and in connection with which such use that is likely to cause confusion, or to cause mistake, or to deceive.

112. Defendants' actions constitute willful infringement of Janssen's exclusive rights in the Janssen Ireland Marks and the Johnson & Johnson Marks.

113. Defendants are directly, contributorily, and vicariously liable for their infringement.

114. As a direct and proximate result of Defendants' conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants are restrained from further infringement

of the Janssen Ireland Marks and Johnson & Johnson Marks, Janssen will continue to be irreparably harmed.

115. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

116. As a direct and proximate result of Defendants' conduct, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

**SECOND CLAIM FOR RELIEF**
**FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1)(B))**

117. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

118. In violation of 15 U.S.C. § 1114(1)(b), Defendants, independently and in conspiracy with one another, reproduced, counterfeited, copied, or colorably imitated the registered Janssen Ireland Marks and Johnson & Johnson Marks belonging to Janssen and applied such reproduction, counterfeit, copy or colorable imitation to labels, signs, prints, packages, wrappers, receptacles, or advertisements intended to be used in commerce upon or in connection with the offering for sale, distribution or advertising of counterfeit Janssen products; in connection with the sale, offering for sale, distribution, or advertising of Janssen products with altered and/or falsified pedigrees that are materially different from authentic Janssen products authorized for sale by Janssen in the United States and that are not subject to and subvert Janssen's quality-control measures; and in connection with such use that is likely to cause confusion, to cause mistake, or to deceive.

119. For example, and without limitation, the Defendants used counterfeit, reproduced, copied, or colorably imitated Janssen Ireland Marks and Johnson & Johnson Marks

on the labels of the counterfeit bottles of Janssen HIV medications they purchased, advertised, and sold, as well as on altered and/or falsified pedigrees for bottles of Janssen HIV medications.

120. Defendants' actions constitute willful infringement of Jansen's exclusive rights in the Janssen Ireland Marks and Johnson & Johnson Marks.

121. Defendants are directly, contributorily, and vicariously liable for their infringement.

122. As a direct and proximate result of Defendants' conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants are restrained from further infringement of the Janssen Ireland Marks and Johnson & Johnson Marks, Janssen will continue to be irreparably harmed.

123. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

124. As a direct and proximate result of Defendants' conduct, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

**THIRD CLAIM FOR RELIEF**
**FALSE DESCRIPTION AND DESIGNATION OF ORIGIN IN COMMERCE**

125. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

126. In violation of 15 U.S.C. § 1125(a)(1)(A), Defendants, independently and in conspiracy with one another, in connection with the counterfeit Janssen medication, and in connection with Janssen products with altered and/or falsified pedigrees that are materially different from authentic Janssen products authorized for sale by Janssen in the United States,

and/or that are not subject to and subvert Janssen's quality-control measures, used in commerce a slogan, trade dress, word, term, name, symbol, or device, or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which was or is likely to cause confusion or to cause mistake, or to deceive as to an affiliation, connection, or association with Janssen.

127. Defendants' actions constitute willful infringement of Janssen's exclusive rights in the Janssen Ireland Marks and Johnson & Johnson Marks.

128. Defendants are directly, contributorily, and vicariously liable for their infringement.

129. As a direct and proximate result of Defendants' conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants are restrained from further infringement of the Janssen Ireland Marks and Johnson & Johnson Marks, Janssen will continue to be irreparably harmed.

130. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

131. As a direct and proximate result of Defendants' conduct, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

## FOURTH CLAIM FOR RELIEF
## FEDERAL FALSE ADVERTISING

132. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

133. In violation of 15 U.S.C. § 1125(a)(1)(B), Defendants, independently and in conspiracy with one another, in connection with the sale of counterfeit Janssen medication, and in connection with the sale of Janssen products with altered and/or falsified pedigrees that are materially different from authentic Janssen products authorized for sale by Janssen in the United States and that are not subject to and subvert Janssen's quality-control measures, used a slogan, trade dress, word, term, name, symbol, or device, or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, and qualities of the counterfeit Janssen medication.

134. Defendants advertised, marketed, and promoted the counterfeit Janssen products, and the materially different Janssen products with altered and/or falsified pedigrees, to the public, and/or to specific segments of the public, using the Janssen Ireland Marks and Johnson & Johnson Marks, as well as other intellectual property belonging to Janssen.

135. Defendants' actions constitute willful infringement of Janssen's exclusive rights in the Janssen Ireland Marks and Johnson & Johnson Marks.

136. Defendants are directly, contributorily, and vicariously liable for their infringement.

137. As a direct and proximate result of Defendants' conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants' conduct is restrained, Janssen will continue to be irreparably harmed.

138. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

139. As a direct and proximate result of Defendants' conduct, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

**FIFTH CLAIM FOR RELIEF**
**FEDERAL DILUTION OF MARK**

140. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

141. The Janssen Ireland Marks and Johnson & Johnson Marks are famous and distinctive within the meaning of 15 U.S.C. § 1125(c).

142. Defendants are selling and/or have sold counterfeit, altered, and/or falsified products bearing the Janssen Ireland Marks and Johnson & Johnson Marks after such trademarks and trade dress became famous.

143. By selling these products, Defendants, independently and in conspiracy with one another, have diluted and are diluting the distinctive quality of a mark or trade name owned by Janssen in violation of 15 U.S.C. § 1125(c).

144. Defendants' actions constitute willful infringement of Jansen's exclusive rights in the Janssen Ireland Marks and Johnson & Johnson Marks.

145. Defendants are directly, contributorily, and vicariously liable for their infringement.

146. As a direct and proximate result of Defendants' conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants' conduct is restrained, Janssen will continue to be irreparably harmed.

147. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

148. As a direct and proximate result of Defendants' conduct, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

**SIXTH CLAIM FOR RELIEF**
**NEW YORK DILUTION OF MARK AND INJURY TO BUSINESS REPUTATION**

149. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

150. All of the Janssen Ireland Marks and Johnson & Johnson Marks are individually distinctive under New York General Business Law § 360-1.

151. By selling counterfeit, altered, and/or falsified products bearing the Janssen Marks and Trade Dress, Defendants, independently and in conspiracy with one another, have injured and are continuing to injure Janssen's business reputation and/or have diluted and are continuing to dilute the distinctive quality of a mark or trade name owned by Janssen, in violation of New York General Business Law § 360-1.

152. As a direct and proximate result of Defendants' conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants' conduct is restrained, Janssen will continue to be irreparably harmed.

153. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

154. As a direct and proximate result of Defendants' conduct, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

**SEVENTH CLAIM FOR RELIEF**
**NEW YORK DECEPTIVE BUSINESS PRACTICES**

155. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

156. In violation of New York General Business Law § 349, Defendants, independently and in conspiracy with one another, are selling, offering for sale, and/or distributing counterfeit, altered, and/or falsified products unlawfully bearing the Janssen Ireland Marks and Johnson & Johnson Marks.

157. As a direct and proximate result of Defendants' deceptive conduct, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants are restrained from further infringement of the Janssen Ireland Marks and Johnson & Johnson Marks, Janssen will continue to be irreparably harmed.

158. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

**EIGHTH CLAIM FOR RELIEF**
**COMMON-LAW UNFAIR COMPETITION**

159. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

160. In violation of the common law of the State of New York and elsewhere, Defendants, independently and in conspiracy with one another, have unfairly competed with Janssen by selling the counterfeit, altered, and/or falsified products.

161. As a direct and proximate result of Defendants' unfair competition, Janssen has suffered irreparable harm to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and their reputation in the industry. Unless Defendants' conduct is restrained, Janssen will continue to be irreparably harmed.

162. Janssen has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

163. As a direct and proximate result of Defendants' unfair competition, Janssen has suffered damages to the valuable Janssen Ireland Marks and Johnson & Johnson Marks and other damages in an amount to be proved at trial.

## NINTH CLAIM FOR RELIEF
## COMMON-LAW UNJUST ENRICHMENT

164. Janssen realleges and incorporates by reference paragraphs 1 through 109 of this Complaint as if fully set forth herein.

165. By selling the counterfeit, altered, and/or falsified products bearing Janssen's valuable trademarks independently and in conspiracy with one another, Defendants have been unjustly enriched at Janssen's expense in violation of the common law of New York and elsewhere.

166. Under principles of equity, Janssen is entitled to restitution and/or disgorgement of Defendants' ill-gotten gains.

## PRAYER FOR RELIEF

WHEREFORE, Jansen demands judgment against Defendants as follows:

A. 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 selling any Janssen medication, whether genuine or counterfeit;

(ii) from using any of the Janssen Ireland Marks and Johnson & Johnson Marks or any marks confusingly similar thereto in connection with the manufacture, sale, offer for sale, distribution, advertisement, or any other use of medication;

(iii) from using any logo, trade name, or trademark confusingly similar to any of the Janssen Ireland Marks and Johnson & Johnson Marks, which may be calculated to falsely represent or which has the effect of falsely representing that the services or products of Defendants or of others are sponsored by, authorized by, or in any way associated with Janssen;

(iv) from directly, contributorily, and vicariously infringing any of the Janssen Ireland Marks and Johnson & Johnson Marks;

(v) from otherwise unfairly competing with Janssen in the manufacture, sale, offering for sale, distribution, advertisement, or any other use of Janssen medications;

(vi) from falsely representing themselves as being connected with Janssen or sponsored by or associated with Janssen or engaging in any act which is likely to cause the trade, retailers, and/or members of the purchasing public to believe that Defendants, or any of them, are associated with Janssen;

(vii) from using any reproduction, counterfeit, copy, or colorable imitation of any of the Janssen Ireland Marks and Johnson & Johnson Marks in connection with the publicity, promotion, sale, or advertising of medications;

(viii) from affixing, applying, annexing or using in connection with the sale of any goods, a false description or representation including words or other symbols tending to falsely describe or represent such goods as being authentic Janssen medication and from offering such goods in commerce;

(ix) from diluting the Janssen Ireland Marks and Johnson & Johnson Marks;

(x) from destroying any records documenting the manufacture, sale, offer for sale, distribution, advertisement, or receipt of any product purporting to be Janssen medication; and

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

B. ordering that, within fifteen days after the entry and service of a preliminary or permanent injunction, Defendants serve and file a written report under oath setting forth in detail the manner and form in which they have complied with the injunction; and

C. ordering that all infringing material be turned over, seized, impounded, and/or destroyed; and

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

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

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

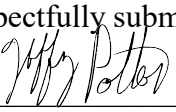
G. awarding Janssen restitution and/or a constructive trust for Defendants' unjust enrichment; and

H. awarding to Janssen pre-judgment and post-judgment interest; and

I. awarding such other and further relief to Janssen as may be just, proper, and equitable.

Dated: April 7, 2022

Respectfully submitted,



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