STATE OF MARYLAND, Plaintiff, v. ALVOGEN, INC.; AMNEAL PHARMACEUTICALS LLC; APOTEX CORP.; HIKMA PHARMACEUTICALS USA INC. F/K/A WEST-WARD PHARMACEUTICALS CORP.; MYLAN INC.; SUN PHARMACEUTICAL INDUSTRIES, INC. ; ZYDUS PHARMACEUTICALS (USA) INC., Defendants.	)	IN THE CIRCUIT COURT OF FREDERICK COUNTY, MARYLAND Case No. C-10-CV-26-000630

COMPLAINT

Plaintiff, the State of Maryland, by and through its Attorney General, brings this action against Defendants Alvogen, Inc., Amneal Pharmaceuticals LLC, Apotex Corp., Hikma Pharmaceuticals USA INC. f/k/a West-Ward Pharmaceuticals Corp., Mylan Inc., Sun Pharmaceutical Industries, Inc., and Zydus Pharmaceuticals (USA) Inc. (collectively, "Defendants") pursuant to the Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 *et seq*. (the "Act") of the State of Maryland and alleges as follows:

I. JURISDICTION AND STATUTORY AUTHORITY

1. This civil action is authorized by, *inter alia*, Md. Code Ann., Com. Law §§ 13-402(b), 13-406, and 13-410.

2. This Court's subject-matter jurisdiction is conferred by Md. Code Ann, Cts. & Jud. Proc. § 1-501.

3. This Court has personal jurisdiction over the Defendants under Md. Code Ann., Cts. & Jud. Proc. § 6-103(a) & (b)(1)-(4) because Defendants and their agents have engaged in the

conduct of marketing and selling opioids in Maryland and caused tortious injury in Maryland by opioid-related acts and omissions in and outside of Maryland.

II. VENUE

4. Frederick County is an appropriate venue under Md. Code Ann., Cts. & Jud. Proc. § 6-201 because each Defendant regularly marketed and/or sold opioids in Frederick County.

III. DEFENDANTS

5. Defendants, acting by themselves and/or through agents and subsidiaries, manufactured opioids and then distributed, marketed, and/or sold them throughout the United States, including throughout Maryland and Frederick County.

6. Defendant **Alvogen, Inc.** ("Alvogen") is a corporation organized under the laws of Delaware and has its principal place of business in New Jersey, at 44 Whippany Road, Suite 300, Morristown, New Jersey. Defendant Alvogen conducts business in the State of Maryland.

7. Defendant **Amneal Pharmaceuticals LLC** ("Amneal") is a corporation organized under the laws of Delaware and has its principal place of business in New Jersey, at 400 Crossing Boulevard, Bridgewater, New Jersey. Defendant Amneal conducts business in the State of Maryland.

8. Defendant **Apotex Corp.** ("Apotex") is a corporation organized under the laws of Delaware and has its principal place of business in Florida, at 2400 North Commerce Parkway, Suite 400, Weston, Florida. Defendant Apotex conducts business in the State of Maryland.

9. Defendant **Hikma Pharmaceuticals USA INC. f/k/a West-Ward Pharmaceuticals Corp.** ("Hikma") is a corporation organized under the laws of Delaware and has its principal place of business in New Jersey, at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey. Defendant Hikma conducts business in the State of Maryland.

10. Defendant **Mylan Inc.** ("Mylan") is a corporation organized under the laws of Delaware and has its principal place of business in Pennsylvania, at 1000 Mylan Boulevard, Canonsburg, Pennsylvania. Defendant Mylan conducts business in the State of Maryland.

11. Defendant **Sun Pharmaceutical Industries, Inc.** ("Sun") is a corporation organized under the laws of Delaware and has its principal place of business in New Jersey, at 2 Independence Way, Princeton, New Jersey. Defendant Sun conducts business in the State of Maryland.

12. Defendant **Zydus Pharmaceuticals (USA) Inc.** ("Zydus") is a corporation organized under the laws of New Jersey and has its principal place of business in New Jersey, at 73 Route 31 North, Pennington, New Jersey. Defendant Zydus conducts business in the State of Maryland.

13. Whenever this Complaint alleges that a Defendant did any act, it means that the Defendant:

a. Performed or participated in the act; or

b. Its subsidiaries, officers, successors in interest, agents, partners, trustees, or employees performed or participated in the act on behalf of and under the authority of that Defendant.

IV. FACTUAL BACKGROUND

A. The Opioid Crisis

14. There is broad scientific consensus that the opioid crisis was caused by the overprescription, overdistribution, and over-dispensing of opioids and other controlled substances that resulted from illegal marketing activities of manufacturers, distributors, dispensers, and others in the pharmaceutical industry who sought to profit from a vastly expanded market for these drugs.

These practices generally have included, among others: (a) deceiving prescribers and patients about the benefits of opioids; (b) minimizing or omitting the extraordinary risks of addiction and death; (c) manipulating the addictive propensities of prescription opioids to get people hooked; (d) paying kickbacks, rebates, or providing other inducements; and (e) failing to fulfill legal duties to safeguard the health of members of the public who ultimately consumed these drugs.

15. Beginning in the mid-1990s, opioid manufacturers pursued aggressive sales strategies to increase sales of their prescription opioids, a plan that resulted in a dramatic rise in opioid prescriptions in the State of Maryland. This contributed to a sharp increase in the use of drugs such as illegal fentanyl and heroin, which are sometimes used by themselves and other times used in combination with prescription opioids.

16. The rise in opioid prescriptions caused a devastating rise in opioid abuse, dependence, addiction, and overdose deaths in the State of Maryland. Illicit fentanyl and heroin use exacerbated opioid abuse, dependence, addiction, and overdose deaths in the State of Maryland.

17. Prescription opioids continue to kill numerous people across the State of Maryland every year. Many more suffer from negative health consequences short of death and countless others have had their lives ruined by a friend or family member's addiction or death. Every community in the State of Maryland suffers from the opioid crisis of addiction and death.

B. Defendants' Unfair, Abusive, and Deceptive Marketing Practices

Alvogen

18. Since at least 2012, Alvogen has manufactured and sold generic opioids, focused on oxycodone products. Alvogen's market share sharply accelerated in the years after it entered

the opioids market, as it focused on filling the gap left by larger companies that ceased or reduced the manufacture of oxycodone products.

19. As a manufacturer and distributor of controlled substances, Alvogen had an obligation to design and maintain effective controls against diversion, including obligations to design and operate a system to disclose suspicious orders of controlled substances and to report such orders to DEA and certain State regulators when discovered.

20. Alvogen was aware of these obligations and their importance, and that its opioid products were vulnerable to diversion. However, for years Alvogen disclaimed that it had any regulatory responsibility to implement a Suspicious Order Monitoring system ("SOMs"), and for over a decade lacked any formal SOMs program.

21. As a result, Alvogen was responsible for significant diversion of its opioids products over a period of many years, that it could have prevented had it maintained an effective SOMs program.

Amneal

22. Since at least 2008, Amneal has manufactured, marketed, and sold generic oxycodone, hydrocodone, and oxymorphone products.

23. As a manufacturer and distributor of controlled substances, Amneal had an obligation to design and maintain effective controls against diversion, including obligations to design and operate a system to disclose suspicious orders of controlled substances and to report such orders to DEA and certain State regulators when discovered.

24. Amneal was aware of these obligations and their importance, and that its opioid products were vulnerable to diversion. However, Amneal lacked a formal SOMs program for much of the time it has manufactured opioids products, and when one was eventually implemented – and

primarily overseen by Amneal's sales department, who had a conflicting interest in maximizing Amneal's sales – it was perfunctory and was not adequately followed.

25. As a result, Amneal was responsible for significant diversion of its opioids products, that it could have prevented had it maintained an effective SOMs program.

Apotex

26. Starting in 2009, and between 2012 and 2023 through its corporate ownership of Aveva Drug Delivery Systems, Apotex manufactured and sold generic opioids, including a generic fentanyl patch product.

27. As a manufacturer and distributor of controlled substances, Apotex had an obligation to design and maintain effective controls against diversion, including obligations to design and operate a system to disclose suspicious orders of controlled substances and to report such orders to DEA and certain State regulators when discovered.

28. Apotex was aware of these obligations and their importance, and that its opioid products were vulnerable to diversion. However, Apotex lacked a formal SOMs program for much of the time it manufactured opioids products, and when one was implemented, it was perfunctory and was not adequately followed.

29. As a result, Apotex was responsible for significant diversion of its opioids products, that it could have prevented had it maintained an effective SOMs program.

Hikma

30. Since at least 2006, Hikma has manufactured and sold a wide range of generic opioids products, including generic oxycodone, hydromorphine, oxymorphine, morphine, meperidine, and levorphanol products.

31. As a manufacturer and distributor of controlled substances, Hikma had an obligation to design and maintain effective controls against diversion, including obligations to design and operate a system to disclose suspicious orders of controlled substances and to report such orders to DEA and certain State regulators when discovered.

32. Hikma was aware of these obligations and their importance, and that its opioid products were vulnerable to diversion. Hikma was aware of deficiencies in its SOMs program as early as 2006, but for years, Hikma failed to remedy these deficiencies, internally recognizing its SOMs program as inadequate as recently as 2021. Moreover, Hikma failed to even effectively implement the inadequate program that it did maintain.

33. As a result, Hikma was responsible for significant diversion of its opioids products, that it could have prevented had it maintained an effective SOMs program.

Mylan

34. Since at least 2005, Mylan has manufactured, marketed, and sold a wide range of generic opioids products, including fentanyl patches, and oxycodone and hydrocodone products.

35. Mylan's products, particularly its fentanyl patches, were prone to abuse and diversion. Users could readily extract dangerous amounts of fentanyl from Mylan's patches using a number of means that were not possible with different patch designs.

36. Mylan engaged in this promotion of its opioid products, including its fentanyl patches, directly to doctors, deceptively claiming that its products were safer than alternatives, despite the truth being the exact opposite. The result of this was dangerous overprescribing and diversion of its opioids into the illegal drug market.

Sun

37. Since at least 2009, Sun has manufactured and sold generic opioids, including oxycodone and hydrocodone products. Sun's market share significantly increased between 2012 and 2016, filling the void left by larger opioid manufacturers that left or decreased their involvement in the opioids market.

38. As a manufacturer and distributor of controlled substances, Sun had an obligation to design and maintain effective controls against diversion, including obligations to design and operate a system to disclose suspicious orders of controlled substances and to report such orders to DEA and certain State regulators when discovered.

39. Sun was aware of these obligations and their importance, and that its opioid products were vulnerable to diversion. However, for years Sun failed to monitor and report suspicious orders placed by its customers.

40. As a result, Sun was responsible for significant diversion of its opioids products over a period of many years, that it could have prevented had it maintained an effective SOMs program.

Zydus

41. From at least 2013 through 2019, Zydus manufactured and sold generic opioids, including oxycodone and morphine products. Zydus entered the market to fill the void left by larger opioid manufacturers that left or decreased their involvement in the opioids market.

42. As a manufacturer and distributor of controlled substances, Zydus had an obligation to design and maintain effective controls against diversion, including obligations to design and operate a system to disclose suspicious orders of controlled substances and to report such orders to DEA and certain State regulators when discovered.

43. Zydus was aware of these obligations and their importance, and that its opioid products were vulnerable to diversion. However, for years Zydus failed to monitor and report suspicious orders placed by its customers.

44. As a result, Zydus was responsible for significant diversion of its opioids products over a period of many years, that it could have prevented had it maintained an effective SOMs program.

CAUSE OF ACTION
(Violations of the Maryland Consumer Protection Act)
(All Defendants)

45. Plaintiff incorporates and adopts by reference the allegations contained in paragraphs 1 through 44.

46. The opioids Defendants manufactured, which were sold in Maryland, are consumer goods pursuant to § 13-101(d)(1) of the Consumer Protection Act because they are used for personal, family, or household purposes.

47. Each Defendant acted as a merchant as defined by § 13-101(g)(1) of the CPA.

48. Each Defendant, in the course of manufacturing, selling, and/or marketing opioid-containing prescription drugs, engaged in unfair, abusive, or deceptive acts and practices that are generally prohibited by §§ 13-301 and 13-303 of the Consumer Protection Act.

49. Defendants' unfair, abusive, or deceptive acts and practices include, but are not limited to, the following:

a. Failing to exercise effective controls and procedures to guard against diversion of opioids in the State of Maryland;

b. Misrepresenting the risks and benefits of their opioid products and opioids generally in the State of Maryland;

c. Falsely representing that the opioids they manufactured were safe and effective for customers' consumption and that they had undertaken adequate steps to ensure customer safety; and

d. Failed to state material facts the omission of which deceived or tended to deceive consumers and constitute deceptive trade practices.

50. Defendants made false or misleading oral or written statements or other representations that had the capacity, tendency, or effect of deceiving or misleading consumers and constitute deceptive trade practices prohibited by Com. Law § 13-303 as defined in Com. Law § 13-301(1) of the CPA.

51. Defendants failed to state material facts the omission of which deceived or tended to deceive consumers and constitute deceptive trade practices prohibited by Com. Law § 13-303 as defined in Com. Law § 13-301(3) of the CPA.

52. Defendants' practices were unfair because they caused substantial injury to consumers, who were placed at risk of or left with addictions they could not overcome and the risk of or fact of death from those addictions, which could not have been reasonably avoided by those consumers, and which did not provide any offsetting benefits.

REQUEST FOR RELIEF

53. Plaintiff respectfully requests that the Court enter an Order:

a. Issuing a permanent injunction prohibiting Defendants, and Defendants' officers, agents, servants, employees, attorneys and any other person in active concert or participation with Defendants, from engaging in unfair, abusive, or deceptive acts and practices in violation of the Consumer Protection Act;

b. Issuing a permanent injunction mandating that Defendants take affirmative steps to remedy the effects of that conduct, including by making payments to the State of Maryland's Opioid Restitution Fund;

c. Ordering Defendants to disgorge all ill-gotten gains;

d. Imposing civil penalties for each violation of the Consumer Protection Act; and

e. Awarding the costs of this action.

54. Plaintiff further requests that this Court grant all other relief to which the Plaintiff is entitled.

Respectfully submitted,

OFFICE OF THE ATTORNEY GENERAL
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