UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

SEIU LOCAL 4 HEALTH AND WELFARE FUND and SEIU HOME CARE AND CHILD CARE HEALTH FUND, Plaintiffs, v. TAKEDA PHARMACEUTICAL COMPANY LIMITED; MILLENNIUM PHARMACEUTICALS, INC. D/B/A TAKEDA ONCOLOGY GROUP; AMERISOURCEBERGEN CORPORATION, Defendants.	No.

COMPLAINT

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I. INTRODUCTION

1. Plaintiffs and the Class complain of a scheme perpetrated by all Defendants to manufacture, market and sell oversized vials of Velcade (bortezomib), which is approved for the treatment of patients with multiple myeloma (a cancer of the plasma cells) or for the treatment of patients with mantle cell lymphoma (a cancer of the lymph nodes) who have already received other treatments.

2. The scheme was perpetuated by the Velcade Distribution Enterprise defined as and comprised of: (i) Defendants Takeda Pharmaceutical Company Limited and Millennium Pharmaceuticals, Inc. d/b/a Takeda Oncology Group, which were responsible for all of the activities associated with manufacturing and selling Velcade in 3.5mg vials in the United States (and foregoing the more appropriate 1mg size vials sold outside the U.S.) ("Manufacturer Participants"); and (ii) Defendant AmerisourceBergen Corporation, which was responsible for managing the ordering, distribution, shipment, and monitoring of Velcade into the U.S. oncology marketplace, as well as accounts receivables on Velcade orders, knowing that a significant portion of the Velcade in the 3.5mg vials would go to waste. The Manufacturer and Distributor Participants worked together to restrict distribution of Velcade through the MilleniumDirect where only one size vial is made available.

3. The scheme to defraud implemented by the Velcade Distribution Enterprise caused Plaintiffs and the Class to suffer significant out-of-pocket losses as they bore the cost of the discarded portion of Velcade or "Wasted Velcade." Plaintiffs estimate that during the Class period over $1 billion has been spent by the Class on "Wasted Velcade."

4. Plaintiffs sue on their behalf and on behalf of all persons and entities which paid in whole or in part for Velcade, not for resale, during the period January 1, 2012, to the present ("Relevant Period"), for injunctive relief under Section 1 of the Sherman Antitrust Act, and to

recover their out-of-pocket losses, compensatory damages, punitive damages, and attorneys' fees and expenses under the Racketeer Influenced Corrupt Organizations Act ("RICO") and state antitrust laws, and for the disgorgement of profits under the common law of unjust enrichment.

II. JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and 18 U.S.C. § 1964(c), because this action alleges violation of the Racketeer Influenced Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

6. Plaintiffs also bring this action to obtain injunctive relief, costs of suit, and reasonable attorneys' fees arising from Defendants' violations of Section 1 of the Sherman Act (15 U.S.C. § 1). This Court thus also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337(a) and 1367.

7. Alternatively, this Court has jurisdiction over the subject matter presented by this Class Action Complaint because it is a class action arising under 28 U.S.C. § 1332(d), which, under the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No. 109-2, 119 Stat. 4 (2005), explicitly provides for the original jurisdiction of the Federal Courts of any class action in which any member of the plaintiff class is a citizen of a state different from any defendant, and where the amount in controversy exceeds the aggregate sum of $5,000,000, exclusive of interest and costs. Plaintiffs allege that the total claims of the individual members of the Plaintiff Class in this action are in excess of $5,000,000 in the aggregate, exclusive of interest and costs, as required by 28 U.S.C. § 1332(d)(2).

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(1) and 1391(b)(2) because Defendants reside in and conduct business in this judicial district, and

because a substantial part of the acts or omissions giving rise to the claims set forth herein occurred in and near this judicial district.

III. PARTIES

A. Plaintiffs

9. SEIU Local 4 Health and Welfare Fund is a Third-Party Payor which maintains its principal place of business in Chicago, Illinois. Plaintiff is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees. Plaintiff paid for Velcade on behalf of its members and beneficiaries during the Relevant Period and was damaged by the conduct alleged herein.

10. SEIU Home Care and Child Care Health Fund is a Third-Party Payor which maintains its principal place of business in Chicago, Illinois. Plaintiff is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees. Plaintiff paid for Velcade on behalf of its members and beneficiaries during the Relevant Period and was damaged by the conduct alleged herein.

B. Defendants

1. The Manufacturer Participants

11. Takeda Pharmaceutical Company Limited is a Delaware corporation with its principal place of business located at 40 Landsdowne Street, Cambridge, MA, USA 02139.

12. Millennium Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 40 Landsdowne Street, Cambridge, MA, USA 02139. Millennium Pharmaceuticals, Inc. does business as the Takeda Oncology Group.

2. The Distributor Participants

13. AmerisourceBergen Corporation is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, PA 19087. By agreement with the Manufacturer Participants, AmerisourceBergen agreed to distribute oversized vials of Velcade through its subsidiaries. These subsidiaries include, but may not be limited to (a) Integrated Commercialization Solutions, Inc. d/b/a MillenniumDirect, which is a California corporation with its principal place of business located at 3101 Gaylord Parkway, Frisco, TX 75034; and (b) AmerisourceBergen Specialty Group, Inc. (ABSG), which is a Delaware corporation with its principal place of business located at 3101 Gaylord Parkway, Frisco, TX 75034. Each of ICS and ABSG are considered business units of AmerisourceBergen.

IV. FACTS

A. Velcade Background

14. Velcade (bortezomib) is approved for the treatment of patients with multiple myeloma (a cancer of the plasma cells). Velcade is also approved for the treatment of patients with mantle cell lymphoma (a cancer of the lymph nodes) who have already received other treatments.

15. Velcade is administered by a healthcare professional as an injection into the patient's vein (intravenously, or IV) or under their skin (subcutaneously).

16. Velcade is only available in 3.5mg vials in the United States as depicted below:

Bortezomib (For Multiple Myeloma)

FY2014 net sales: ¥152.7 billion

VELCADE (bortezomib) is the only drug for treating multiple myeloma (MM) that has overall survival benefit data included in its prescribing information in the U.S. Approved in more than 90 countries around the world, it is indicated in Europe and the U.S. as a first-line treatment for MM patients that have not undergone chemotherapy.

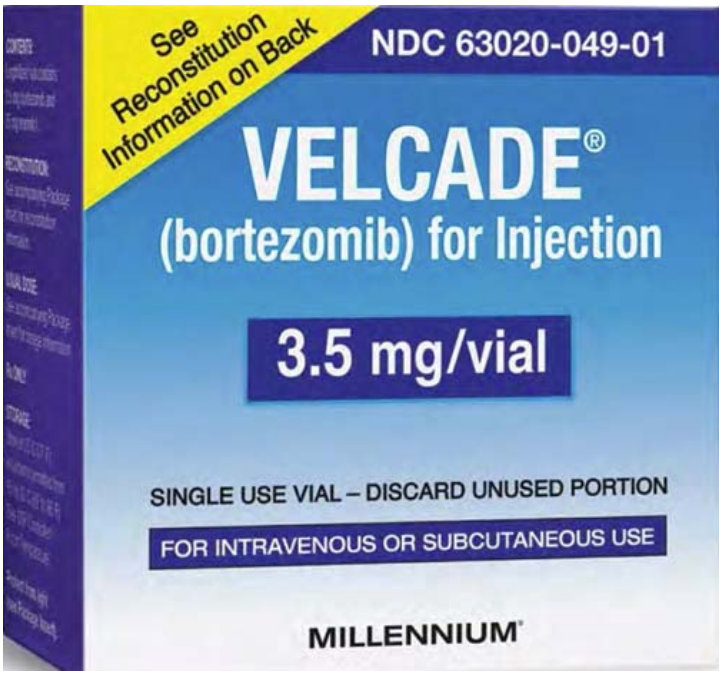
- **In-house sales regions: U.S.**
  Brand Name: VELCADE (U.S.)

17. However, the "Usual Adult Dose" in previously untreated mantle cell lymphoma is 1.3 mg/m2 as a bolus IV injection twice weekly in combination with certain other medications for two weeks.[1] "For use in the treatment of relapsed mantle cell lymphoma," the "usual dose" is 1.3 mg/m2 as a bolus IV injection or subcutaneously twice weekly for two weeks.[2] The "Usual Adult Dose for Multiple Myeloma" is 1.3 mg/m2 administered as a 3 to 5 second bolus IV injection or subcutaneously in combination with certain other medications.[3] "For use in the treatment of relapsed multiple myeloma," the "usual dose" is 1.3 mg/m2 as a bolus intravenous injection or subcutaneously twice weekly for two weeks.[4]

18. The Velcade 3.5-milligram vials "contain enough medicine to treat a person who is six and a half feet tall and weighs 250 pounds. If the patient is smaller—which is usually the

1 http://www.drugs.com/dosage/bortezomib.html (last accessed June 13, 2016).
2 http://www.drugs.com/dosage/bortezomib.html (last accessed June 13, 2016).
3 http://www.drugs.com/dosage/bortezomib.html (last accessed June 13, 2016).
4 http://www.drugs.com/dosage/bortezomib.html (last accessed June 13, 2016).

case—the excess is thrown out."[5] In fact, the Manufacturer Defendants instruct that the Velcade 3.5mg vial is "SINGLE USE" and physicians should "DISCARD UNUSED PORTION" on the vial packaging:



19. Velcade is distributed through ICS under its "Title Model." Under ICS' Title Model, the title ownership of Velcade is transferred to AmerisourceBergen and resold to physicians and hospitals through MillenniumDirect. Under the Title Model, Takeda and Millenium Pharmaceuticals hold the patent and control the sales, while AmerisourceBergen handles all other aspects of distribution, including orchestrating freight and quality control measures, facilitating compliance and licensing requirements, managing cold chain and special product handling needs and owning and supporting the accounts receivable relationships with physicians and customers.[6]

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[5] http://www.thefiscaltimes.com/2016/03/01/Overbuy-and-Bill-Nearly-3-Billion-Pricey-Drugs-Are-Wasted-Each-Year (last accessed June 13, 2016).

[6] http://www.icsconnect.com/strategic-planning/title-model.

20. The Manufacturer Defendants reported net sales in the United States of Velcade in 2014 at ¥111 billion yen, or $1,045,562,280, with a year over year increase of 16.9%.

B. What is Cancer Drug Waste

21. Waste is when expensive infused drugs are packaged in quantities larger than the amount needed to treat a patient. This is particularly true for drugs for which dosage is based on a patient's weight or body size and that come in single-dose packages. These drugs must be either administered or discarded once open, and because patients' body sizes are unlikely to match the amount of drug included in the vial, there is nearly always some left over. The leftover drug still has to be paid for, even when discarded, making it possible for drug companies to artificially increase the amount of drug they sell per treated patient by increasing the amount in each single-dose vial relative to the typically required dose.

22. Increasing the amount of drug sold per treated patient also increases profits to doctors and hospitals in the United States. Under a system nicknamed "buy and bill," doctors and hospitals buy single-dose vials of drugs and then bill insurers or patients when they are used. The bill includes a percentage based mark-up, which can equate to large amounts of money given that many of the drugs cost thousands of dollars per vial.

23. Although doctors and hospitals sometimes use leftover drug to treat a subsequent patient, thus reducing the amount of leftover drug for which they bill, this practice is very limited. Safety standards from the U.S. Pharmacopeial Convention permit sharing only if leftover drug is used within six hours, and only in specialized pharmacies. Here, however, for Velcade, the sharing of vials among patients is not supposed to occur per the Defendants' instructions.

C. Third Party Payors and Consumers Spend an Estimated $1.8 Billion Annually to Pay for Discarded Drugs

24. Researchers from the Memorial Sloan Kettering Cancer Center, including the Center for Health Policy and Outcomes, Research Pharmacy and Department of Medicine, and the University of Chicago's Departments of Pediatrics Hematology/Oncology and Health Studies, recently published a study, in which they analyzed spending on cancer drugs that are packaged in single-dose vials and dosed based on body size in the United States to estimate the extent of cancer drug waste.

25. The researchers focused on the U.S. because, unlike in most other Western countries, the government plays no role in how drugs are priced and doctors and hospitals can profit from leftover drugs. Moreover, the FDA does not regulate vial size.

26. The researchers examined the top 20 cancer drugs, including Velcade, that are dosed by body size and packaged in single-dose vials (based on 2016 projected sales), which collectively account for 93% of all sales of such drugs. During their examination, the researchers calculated the total amount of unused or wasted drug and the 2016 U.S. revenues associated with the waste for each drug.

27. In sum, they estimated how often vial sharing occurred by examining how often claims filed with the Medicare program included amounts of drug that did not total the full contents of the vial. They then calculated the most efficient way to combine available vial sizes to achieve the lowest FDA-approved dose in a representative sample of the U.S. population derived from the National Health and Nutrition Examination Survey.

28. After correcting the vial sharing percentage where appropriate, and adjusting the population to mirror a cancer patient population, they apportioned projected 2016 U.S. revenues to administered or leftover drug. When calculating the effect of vial sharing, they assumed that

doses that were not multiples of available vial sizes had no leftover drug, an assumption that made their estimates of leftover drug conservative.

29. For the 20 drugs studied, the researchers estimated total U.S. revenue from these drugs to be $18 billion in 2016 alone, ***with 10% or $1.8 billion from discarded drug.***

30. The researchers reported that sensitivity analyses suggested their results were robust. If every person received the highest dose approved by the FDA, revenue from discarded drugs falls to $1.4 billion; if every cancer patients weighed 10% less than the survey participants, the estimate rises to $2 billion.

D. Insurers and Patients Incur Costs of $308 Million Annually to Pay for Velcade Waste

31. Despite the fact that Velcade is available in the U.S. in only a 3.5mg vial, the average required dose is just 2.5mg based on the drug's dose of 1.3 mg/m2 and the average weight of a cancer patient.

32. The researchers estimate that 27% to 30% of Velcade sales in the US are related to leftover drug or Velcade Waste, ***which costs third party payors and patients $308 million annually***:

33. In fact, the large vial size of bortezomib appears to be unique to the U.S. market. The drug is sold in 1mg vials in the United Kingdom.

34. By only selling Velcade in the U.S. in the larger 3.5mg vials rather than the 1mg vials sizes available in Europe, the Manufacturer Participants will increase their 2016 U.S. revenues by hundreds of millions of dollars. The Distributor Participants purchase Velcade from the Manufacturer Participants at wholesale acquisition cost and resell it to the Physician Participants at a mark-up. With additional mark-ups of as much as 142% by physicians and hospitals, the additional costs to patients and their insurers for Velcade Waste exceeds $1 billion over the Relevant Period.

E. The Velcade Distribution Enterprise Restricts Distribution of Velcade to Incentivize Physicians to Prescribe Velcade and Profit on Velcade Waste

1. Traditional Distribution Methods.

35. Traditionally, physicians administering specialty pharmaceuticals, like Velcade, in their offices have purchased medications directly from manufacturers or through wholesale distributors and billed the patient's insurers for the cost of the medications plus a mark-up ("Buy-and-Bill Model").

36. Beginning in the 1960s, reimbursement rates paid to providers for in-office administered pharmaceuticals were based on the drug's Average Wholesale Price ("AWP"), which was a list price set by manufacturers relied upon by governmental payors and private third party payors as the primary benchmark for setting reimbursement rates.

37. Because manufacturers set the AWP for specialty drugs, they could offer providers discounts off the AWP without sacrificing their own profit margins. Discounts of 15% in the 1990s were common. Providers purchasing specialty pharmaceuticals at these discounted rates were then reimbursed by Medicare and other insurers at an undiscounted or minimally discounted AWP rate, resulting in considerable provider profits on drugs for which a manufacturer's AWP represented artificially inflated prices, rather than being truly representative of a drug's average wholesale price.

38. In 2003, however, against a backdrop of increasing Medicare costs and concerns that the profit margins physicians were experiencing on particular drugs could lead providers to prescribe specialty pharmaceuticals for profit rather than medical appropriateness, lawmakers revised Medicare's drug reimbursement benchmark from AWP to Average Sales Price (ASP) as part of the Medicare Modernization Act.

39. Most private payors shifted to ASP-based models following Medicare's implementation of ASP-based reimbursement. By 2013, approximately 80% of individuals covered by private payors had coverage plans that reimbursed providers for in-office administered specialty pharmaceuticals based upon a percentage higher than ASP. In 2013, private payors using ASP-based reimbursement rates paid physicians 8% over ASP on average.

40. Among private payors in 2012, approximately 60% of physician-administered, infused chemotherapy drugs and approximately 36% of physician-administered, infused non-chemotherapy drugs were acquired and reimbursed using a buy-and-bill process. By 2013, among private payors, approximately 75% of physician-administered, infused chemotherapy drugs and approximately 71% of physician-administered, infused non-chemotherapy drugs were acquired and reimbursed through a buy-and-bill process.

41. Payors became concerned that, even with the switch to payments based on ASP, physicians and hospitals were still incentivized to prescribe a medication based on the mark-up or profit they could charge on the cost the of the drug.

42. Accordingly, the "white-bagging model of acquisition" was developed to reduce payor costs associated with specialty drugs by ensuring proper utilization by physicians and improving patient outcomes through monitoring services offered by specialty pharmacies as to patient compliance and adherence.

43. In the white-bagging model, the physician submits a patient-specific prescription to a specialty pharmacy that is contracted with the patient's insurer, rather than purchasing the medication directly or through an authorized distributor and billing the payor for its cost when the medication is administered.

44. The specialty pharmacy, typically staffed with specialist pharmacists and nurses who purchase, store, and deliver medication, will review and obtain the insurer's approval for the prescription, bills the insurer, and sends the patient's filled prescription—***at the exact prescribed dosage***—to the physician for administration.

45. When a physician acquires specialty drugs through white-bagging, the cost of the drug itself is billed to the patient's payor by the specialty pharmacy, rather than the physician.

46. The physician's claim to the payor is limited to her professional fee for administering the drug. Unlike the ASP-based reimbursement rate available in the buy-and-bill context, the physician adopting the white-bagging method does not receive additional reimbursement added to the cost of the drug.

47. For payors, the white-bagging model can provide a greater degree of control over the types of specialty medications administered to beneficiaries and increase patient adherence. In this instance, white-bagging would also control for excess waste, as the specialty pharmacy only delivers the amount of the drug prescribed to the patient for administration by the physician.

48. However, the increased use of white-bagging, encouraged by payors, threatened the ability of manufacturers and distributors, like the Manufacturer Participants and Distributor Participants, to push their specialty pharmaceuticals over competitors through incentives like the mark-up on drug waste.

2. Implementation of the Dropship Model.

49. Accordingly, with respect to Velcade, the Manufacturer Participants and Distributor Participants implemented a sole source open access drop ship model called MillenniumDirect. As a result of the program, Velcade is not available through the white-bagging model.

50. Drop shipping is a supply chain management technique in which the retailers (here, the physicians or hospitals) do not keep goods (here, Velcade) in stock but instead transfer customer orders (here, patient prescriptions) and shipment details to either the manufacturer, another retailer, or a wholesaler (here, the Distributor Participants), who then arranges for the drug to be shipped directly to the customer (here, to the patients through the physicians).

51. As a result, the Manufacturer Participants and Distributor Participants retain control of the Velcade Distribution Enterprise, because they can continue to incentivize physicians and hospitals to prescribe Velcade knowing that they can bill for wasted Velcade at a mark-up or profit. From its introduction in the U.S. market, Defendants offered Velcade primarily through the dropship method. As a result, they were able to control the size of the vial and offered only 3.5mg vials as opposed to the 1mg vials offered outside the U.S.

F. Plaintiffs and the Class Were Damaged

52. Plaintiffs and the Class have no choice but to pay for Velcade Waste (and at significant mark-ups) given that the Manufacturer Participants and Distributor Participants (i) only sell Velcade in oversized 3.5mg vials; and (ii) do not permit white-bagging, but instead have locked up the distribution of Velcade in the MillenniumDirect system where Velcade is shipped directly from the Manufacturer to the physician even if an order is placed through a wholesaler.

G. Use of Mails and Wires

53. Defendants used thousands of mail and interstate wire communications to create and manage the fraudulent scheme and RICO enterprise. Defendants' scheme involved agreements to manufacture, market, distribute and sell Velcade in 3.5mg vials, knowing that the "usual dose" of Velcade was far less than the amount sold and would result in a significant amount of Velcade Waste.

54. Defendants' use of the mails and wires to perpetrate the fraud involved thousands of communications, including:

a. Contracts and related negotiation communications exchanged via the mail, facsimile, and electronic mail for the sale of Velcade from the Manufacturer Participants to the Distributor Participants and from the Distributor Participants to physicians and hospitals;

b. Marketing materials from the Manufacturing Participants and the Distributor Participants sent to physicians and hospitals, including but not limited to instructions on how to obtain reimbursement from Plaintiffs and the Class, for the marked-up price of Velcade, including Velcade Waste;

c. Invoices and bills for the sale and purchase of Velcade, including significant mark-ups on the cost of the Velcade Waste;

d. Payments for Velcade, including for Velcade Waste, from the Distributor Participants to the Manufacturer Participants, from physicians and hospitals to the Distributor Participants, and from Plaintiffs and the Classes to physicians and hospitals at significant mark-ups; and

e. Receiving the proceeds of the Defendants' improper scheme.

55. In addition, Defendants' corporate headquarters have communicated by United States mail, telephone and facsimile with various local and regional district managers and employees in furtherance of Defendants' scheme.

V. RELEVANT MARKET

56. The product market is the market for the sale of Velcade to physicians for administration. The geographic market is the United States.

VI. CLASS ACTION ALLEGATIONS

57. Plaintiffs bring this action pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and a Nationwide Class defined as follows:

> All persons or third party payors which paid, in whole or in part, for Velcade not for resale during the period January 1, 2012, to the present in the United States.

Excluded from the Class are governmental entities, persons who paid a fixed-dollar co-pay, Defendants, any entity in which Defendants have a controlling interest, and Defendants' legal representatives, predecessors, successors, assigns, and employees.

58. The definition of the Class is unambiguous. Plaintiffs are members of the Class that they seek to represent. Members of the Class can be identified using records maintained by the Distributor Participants as well as pharmacies nationwide. Class members can be notified of the class action through publication and direct mailings to address lists maintained in the usual course of business.

59. Class members are so numerous that their individual joinder is impracticable. The precise number of Class members is unknown to Plaintiffs, but it is clear that the number greatly exceeds the number to make joinder impossible.

60. Common questions of law and fact predominate over the questions affecting only individual Class members. Some of the common legal and factual questions include:

a. Whether Defendants conspired to restrict distribution of Velcade to physicians through the Buy and Bill Model and eliminate white-bagging;

b. Whether Merck eliminated the 50mg vial size in the United States;

c. The nature of the agreements between the Manufacturers and Distributors;

d. Whether Defendants violated RICO, 18 U.S.C. § 1962;

e. Whether Defendants used the mails and wires to create and manage their unlawful scheme to defraud;

f. Whether the Manufacturers and Distributors engaged in a contract, combination, agreement, arrangement, and or conspiracy to fix, maintain, control, or stabilize the prices or output of Velcade through the agreement to restrict distribution of Velcade to physicians in oversized vials;

g. The operative time period of the alleged conspiracy;

h. Whether Defendants' conduct caused an increase in the effective price of Velcade sold in oversized vials;

i. Whether Defendants' conduct caused injury to the business or property of Plaintiffs and Class members;

j. Whether Defendants' conduct violated federal antitrust law;

k. Whether Defendants violated the common law of unjust enrichment; and

l. The nature and extent of damages and other remedies to which the conduct of Defendants entitles the Class members.

61. Defendants engaged in a common course of conduct giving rise to the legal rights sought to be enforced by the Class members. Similar or identical statutory and common law violations and deceptive business practices are involved. Individual questions, if any, pale by comparison to the numerous common questions that predominate.

62. The injuries sustained by the Class members flow, in each instance, from a common nucleus of operative facts—Defendants' misconduct. In each case Defendants engaged in a scheme to ensure that Velcade is only available in the oversized 3.5mg vials in the United States, ensuring that the individual Plaintiffs or their Third Party Payors would pay for far more drug than they actually needed to treat their cancers.

63. The Class members have been damaged by Defendants' misconduct.

64. Plaintiffs' claims are typical of the claims of the other Class members.

65. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs are familiar with the basic facts that form the bases of the Class members' claims. Plaintiffs' interests do not conflict with the interests of the other Class members that it seeks to represent. Plaintiffs have retained counsel competent and experienced in Class action litigation and intend to prosecute this action vigorously. Plaintiffs' counsel has successfully prosecuted complex Class actions, including RICO class actions. Plaintiffs and Plaintiffs' counsel will fairly and adequately protect the interests of the Class members.

66. The class action device is superior to other available means for the fair and efficient adjudication of the claims of Plaintiffs and the Class members. The relief sought per individual member of the Class is small given the burden and expense of individual prosecution of the potentially extensive litigation necessitated by the conduct of Defendants. Furthermore, it would be virtually impossible for the Class members to seek redress on an individual basis. Even if the Class members themselves could afford such individual litigation, the court system could not.

67. Individual litigation of the legal and factual issues raised by the conduct of Defendants would increase delay and expense to all parties and to the court system. The Class action device presents far fewer management difficulties and provides the benefits of a single, uniform adjudication, economies of scale and comprehensive supervision by a single court. Given the similar nature of the Class members' claims and the absence of material differences in the state statutes and common laws upon which the Class members' claims are based, a nationwide Class will be easily managed by the Court and the parties.

VII. CAUSES OF ACTION

COUNT I

Violation of 18 U.S.C. § 1962(c)

68. On behalf of the Nationwide Class, Plaintiffs incorporate by reference all preceding paragraphs, as if fully set forth herein.

69. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

70. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of the Manufacturer Participants and the Distributor Participants as set forth *supra*

("Velcade Distribution Enterprise"). The Velcade Distribution Enterprise is an ongoing organization that functions as a continuing unit. The Velcade Distribution Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Velcade Distribution Enterprise.

71. The Velcade Distribution Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of manufacturing, marketing, distributing, and selling Velcade in oversized vials to incentivize physician and hospital administration of Velcade through mark-ups on Velcade Waste, overcharging Plaintiffs and the Class and earning profits therefrom.

72. Defendants have conducted and participated in the affairs of the Velcade Distribution Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

73. The Velcade Distribution Enterprise engaged in and affected interstate commerce, because, *inter alia*, the Manufacturer Participants shipped Velcade throughout the United States and the Distributor Participants distributed and sold Velcade to thousands of physicians and hospitals nationwide.

74. Defendants exerted control over the Velcade Distribution Enterprise, and Defendants participated in the operation or management of the affairs of the Velcade Distribution Enterprise, through a variety of actions but not limited to by only selling Velcade in the oversized 3.5mg vial size in the United States (rather than the 1mg vial size available in Europe), and implementing the MillenniumDirect distribution model, ensuring that the individual

Plaintiffs or their Third Party Payors would pay for far more drug than they actually needed to treat their cancers. Defendants placed their own employees and agents in positions of authority and control in the Velcade Distribution Enterprise.

75. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*, the manufacturing, marketing and selling of oversized vials of Velcade, knowing that a significant portion of the Velcade in the 3.5mg vials would go to waste. The Manufacturer and Distributor Participants worked together to restrict distribution of Velcade through the MilleniumDirect portal in order to incentivize physicians to prescribe Velcade through the extra profit to be made on mark-ups on the discarded portion of the drug. The scheme to defraud implemented by the Velcade Distribution Enterprise caused Plaintiffs and the Class to suffer significant out-of-pocket losses as they bore the cost of the discarded portion of Velcade or "Wasted Velcade."

76. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and the Classes to unnecessarily pay for Velcade Waste. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiffs' property.

77. The pattern of racketeering activity alleged herein and the Velcade Distribution Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Velcade Distribution Enterprise.

78. The causal chain in this case is anything but attenuated. Defendants have always known that, because of the structure of the American specialty drug distribution system, neither

the Manufacturer Participants, Distributor Participants, physicians or hospitals would suffer losses from Velcade Waste. Rather, Defendants' fraudulent scheme, which was meant to increase their revenues and profits, only became successful once Defendants received payments for the Velcade Waste. Those payments came from Plaintiffs and the Class.

79. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made thousands of dollars in payments for Velcade Waste that they would not have made had Defendants not engaged in their pattern of racketeering activity.

80. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity, as described above.

81. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiff for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT II

Violation of 18 U.S.C. § 1962(d) by Conspiring to Violate 18 U.S.C. § 1962(c)

82. On behalf of the Nationwide Class, Plaintiffs incorporate by reference all preceding paragraphs, as if fully set forth herein.

83. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

84. Defendants have violated section 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the section 1962(c) Enterprise described previously through a pattern of racketeering activity.

85. As demonstrated in detail above, Defendants' co-conspirators, including but not limited to the Manufacturer Participants and Distributor Participants have engaged in numerous

overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs of money.

86. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

87. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs have been and are continuing to be injured in its business or property, as set forth more fully above.

88. Defendants have sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346; and

c. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346.

89. Defendants have sought to and have engaged in the violations of the above federal laws and the effects thereof detailed above are continuing and will continue unless injunctive relief prohibiting Defendants' illegal acts constituting a pattern of racketeering activity is fashioned and imposed by the Court.

COUNT III

CLAIM FOR INJUNCTIVE RELIEF FOR VIOLATIONS OF 15 U.S.C. § 1

90. On behalf of the Nationwide Class, Plaintiffs incorporate by reference all the above allegations as if fully set forth herein.

91. Since at least January 1, 2012 and continuing through the filing of this Complaint, the Manufacturers and Distributors entered into a continuing agreement, understanding, and conspiracy in restraint of trade to artificially fix, raise, maintain, and stabilize prices for Velcade in the United States, in violation of Section 1 of the Sherman Act (15 U.S.C. § 1).

92. In formulating and carrying out the alleged agreement, understanding, or conspiracy to prevent distribution of the 1mg vial size, restrict distribution of Velcade to the 3.5mg vial size in the United States, and implement a distribution model that did not include white-bagging, Defendants effectively fixed, raised, maintained, and stabilized the price of Velcade.

93. The combination and conspiracy alleged herein have had the following effects, among others:

a. Price competition in the sale of Velcade and/or the ability to eliminate overcharges related to Velcade Waste has been restrained or suppressed in the United States;

b. Prices for Velcade sold by the Defendants in oversized vials have been secured, and thereby fixed, raised, maintained, and stabilized at artificially high, non-competitive levels throughout the United States;

c. Those who paid for Velcade, directly or indirectly, have been deprived of the benefits of free and open competition; and

d. Plaintiffs and Class members paid for Velcade Waste.

94. Plaintiffs and members of the Class have been injured and will continue to be injured in their business or property by Defendants' antitrust violations. Their injury consists of

being required to pay for Velcade Waste and thus effectively paying higher prices for Velcade than they would have paid in the absence of those violations.

95. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

96. Plaintiffs and the Class are entitled to an injunction against Defendants, preventing and restraining the violations alleged herein.

COUNT IV

UNJUST ENRICHMENT

97. On behalf of the Nationwide Class, Plaintiffs reallege and incorporate by reference the preceding allegations as if fully set forth above.

98. Defendants have unjustly retained a benefit to the detriment of Plaintiffs and members of the Class. Defendants sold Velcade to Plaintiffs and the Class in oversized vials, knowing that Plaintiffs and the Class would have to pay for Velcade Waste. Defendants did so for the purpose of enriching themselves. Thus, Defendants continue to possess money paid by Plaintiffs and the Class to which it is not entitled.

99. Defendants' retention of the benefit violates the fundamental principles of justice, equity and good conscience. Defendants foreclosed or have attempted to foreclose all options for physicians to eliminate Velcade Waste before administration.

100. As a direct and proximate result of the Defendants' actions, Plaintiffs and the Class have suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class members request that the Court enter an order or judgment against Defendants including the following:

A. Certification of the action as a Class Action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Damages in the amount of out-of-pocket losses for payments for Velcade Waste;

C. Actual damages, statutory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein;

D. Pre-judgment and post-judgment interest on such monetary relief;

E. Equitable relief in the form of restitution, including restitutionary disgorgement into a fluid recovery fund, to restore monies received by Defendants as a result of the unfair, unlawful and/or deceptive conduct alleged in herein;

F. Other appropriate injunctive or declaratory relief;

G. The costs of bringing this suit, including reasonable attorneys' fees; and

H. All other relief to which Plaintiffs and members of the Class may be entitled at law or in equity.

DATED: March 30, 2017

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