AMERICAN BANKRUPTCY INSTITUTE

2020 Virtual Winter Leadership Conference

Anatomy of a Pharmaceutical Bankruptcy Case

Presented by the Commercial and Regulatory Law & Financial Advisors and Investment Bankers Committees

Jeffrey K. Garfinkle, Moderator
Buchalter, PC | Irvine, Calif.

Benjamin R. Carlsen
McKesson Corporation | Atlanta

Ben Pickering
Ernst & Young | New York

Hon. Elizabeth S. Stong
U.S. Bankruptcy Court (E.D.N.Y.) | Brooklyn

Scott A. Zuber
Chiesa Shahinian & Giantomasi PC | West Orange, N.J.

CONCURRENT SESSION

2020

Anatomy of a Pharmaceutical Bankruptcy Case

American Bankruptcy Institute Winter Leadership Conference

December 3, 2020

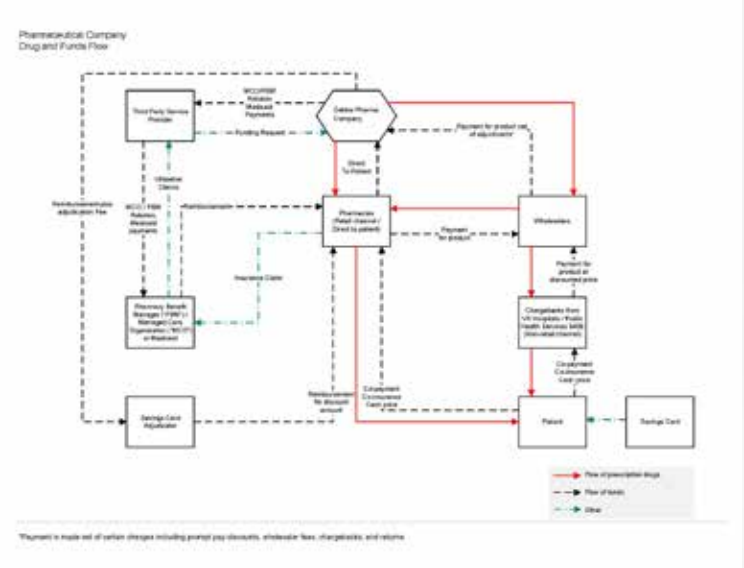
Panelists

- Hon. Elizabeth Stong- U.S. Bankruptcy Court, Eastern District of New York
- Ben Carlsen – McKesson Corporation – Atlanta, GA
- Jeff Garfinkle (Moderator) - Buchalter - Irvine, CA
- Ben Pickering - Ernst & Young - New York, NY
- Scott Zuber - Chiesa Shahinian & Giantomasi - West Orange, NJ

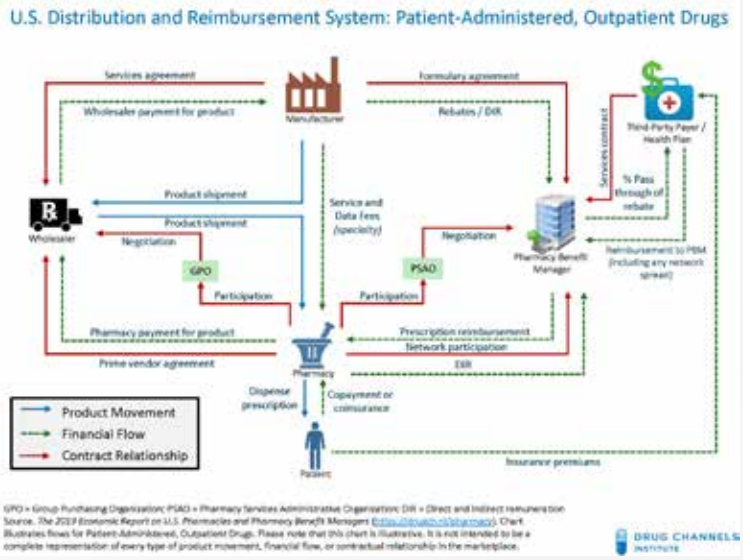
Topics

- Recent surge in pharmaceutical bankruptcy cases, factors leading to bankruptcy, and outcome/resolution of cases.
- Primer on US pharmaceutical industry, including capital structures and development companies versus in-pipeline companies.
- Unique bankruptcy issues for pharmaceutical bankruptcy cases, 363 sales of pharmaceutical companies' assets, and restructuring plans.
- Opiate bankruptcy cases—Purdue, Mallinckrodt, and Insys.
- Ancillary issues that arise in pharmaceutical bankruptcy cases—such, product recalls, regulatory issues (FDA), and IP licensing issues.
- Impact of Covid on Pharmaceutical Industry.

Pharmaceutical Industry Flow



Pharmaceutical Industry Flow



ANATOMY OF A PHARMACEUTICAL BANKRUPTCY CASE

AMERICAN BANKRUPTCY INSTITUTE
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WINTER LEADERSHIP CONFERENCE
—
DECEMBER 3-4, 2020

Panelists

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Hon. Elizabeth Stong- U.S. Bankruptcy Court, Eastern District of New York

TABLE OF CONTENTS

TAB 1

List of Pharmaceutical Bankruptcy Cases—2018 through 2020

LIST OF PHARMACEUTICAL BANKRUPTCY CASES—2018 THROUGH 2020:

Mallinkrodt (Wilmington, DE; October 11, 2020). Chapter 11 case of large multi-faceted specialty and generic pharmaceutical company, with large product portfolio that includes opiate-related pharmaceuticals.

Fortovia Therapeutics, Inc. (Raleigh, NC; August 31, 2020). Chapter 11 case of cancer-related pharmaceuticals company.

Vivus, Inc. (Wilmington, DE; July 7, 2020). Chapter 11 cases of a specialty pharmaceutical company with weight management, pancreatic insufficiency, and erectile dysfunction products.

Akorn, Inc. (Wilmington, DE; May 20, 2020). Chapter 11 cases of generic pharmaceutical company.

Valeritas Holdings (Wilmington, DE; February 9, 2020). Chapter 11 cases of diabetes delivery device company.

Melinta Therapeutics (Wilmington, DE; December 27, 2019). Chapter 11 cases of antibiotic pharmaceutical company.

NeuroproteXeon, Inc. (Wilmington, DE; December 16, 2019). Chapter 11 cases of development-stage pharmaceutical company focused a pharmaceutical-grade xenon gas for inhalation and related delivery system.

Sienna Biopharmaceuticals (Wilmington, DE; September 19, 2019). Chapter 11 case of development-stage company of inflammatory skin disease products.

Purdue Pharma (New York, NY; September 15, 2019). Chapter 11 cases of opiate pharmaceutical company.

Insys Therapeutics (Wilmington, DE; June 10, 2019). Chapter 11 cases of opiate pharmaceutical company.

Achaogen, Inc. (Wilmington, DE; April 15, 2019). Chapter 11 case of developer of antibiotic products.

Mabvax Therapeutics (Wilmington, DE; March 21, 2019). Chapter 11 cases of development-stage pharmaceutical company developing pancreatic cancer drug.

Rising Pharma/Aceto (Newark, NJ; February 19, 2019). Chapter 11 cases of pharmaceutical and chemical company, manufacturing and distributing generic products.

Pernix Therapeutics (Wilmington, DE; February 19, 2019). Chapter 11 case of pharmaceutical company distributing pain products.

Immune Pharmaceuticals, Inc. (Newark, NJ; February 17, 2019). Chapter 11 cases of pharmaceutical company developing and distributing inflammation and leukemia drugs.

Novum Pharma (Wilmington, DE; February 3, 2019). Chapter 11 case of pharmaceutical company distributing dermatological products.
Aegerion Pharmaceuticals (New York City, NY; 2019). Chapter 11 case of pharmaceutical company developing and distributing cholesterol-lowering and lipodystrophy/leptin deficiency products.

Aradigm Corporation (Oakland, CA; February 15, 2019). Chapter 11 case of pharmaceutical company developing an antibiotic drug and related respiratory delivery system for the drug.

Avadel Specialty Pharmaceuticals (Wilmington, DE; February 6, 2019). Chapter 11 case of pharmaceutical company developing and distributing nighttime urinary overproduction drug.

Synergy Pharmaceuticals (New York City, NY; December 12, 2018). Chapter 11 cases of pharmaceutical company developing and distributing GI products.

Egalet Corp. (Wilmington, DE; October 10, 2018): Chapter 11 case of pharmaceutical company developing and distributing pain products.

Product Quest Manufacturing (Winston-Salem, NC; September 7, 2018): Chapter 11 cases of manufacturer of 39 product lines of over-the-counter drugs and other products.

Aralez Pharmaceuticals (New York City, NY; August 18, 2018). Chapter 11 case of pharmaceutical company developing and distributing cardiovascular products.

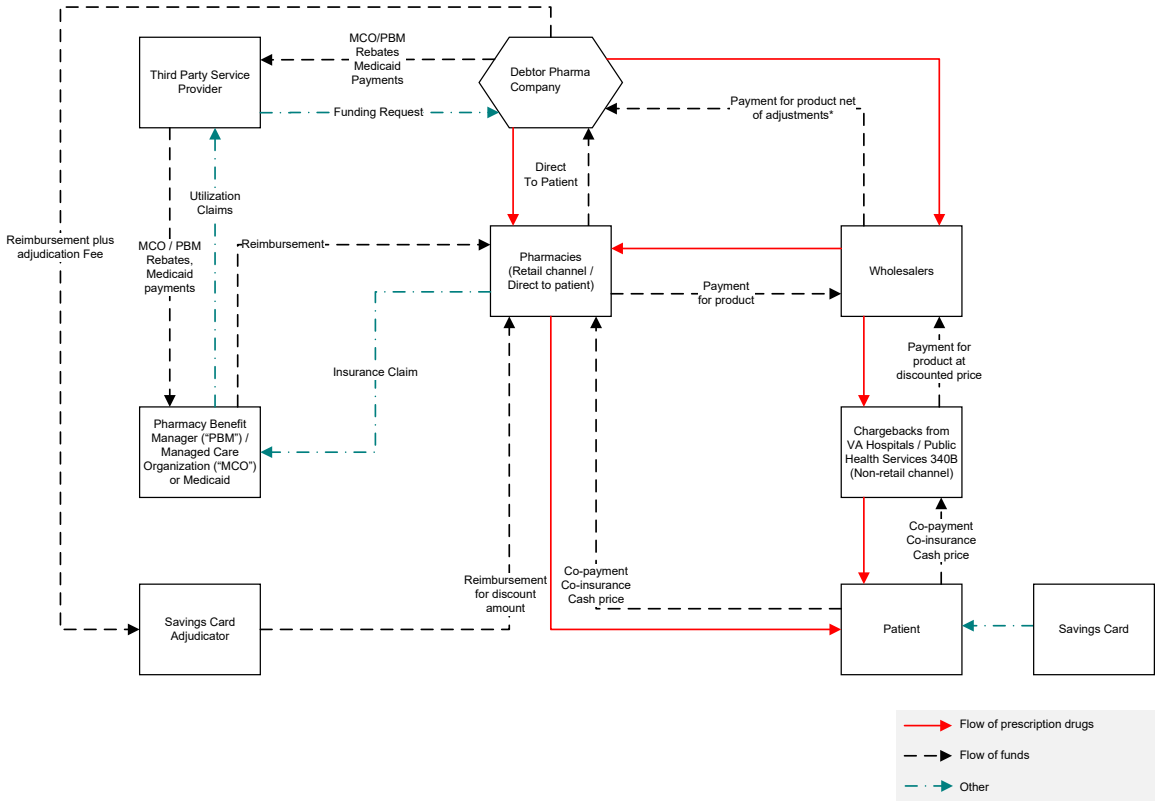
Sancilio Pharmaceuticals (Wilmington, DE; June 5, 2018): Chapter 11 cases of multi-product generic pharmaceuticals company.

Orexigen Therapeutics (Wilmington, DE; March 12, 2018): Chapter 11 of pharmaceutical manufacturer/distributor of weight loss drugs.

TAB 2

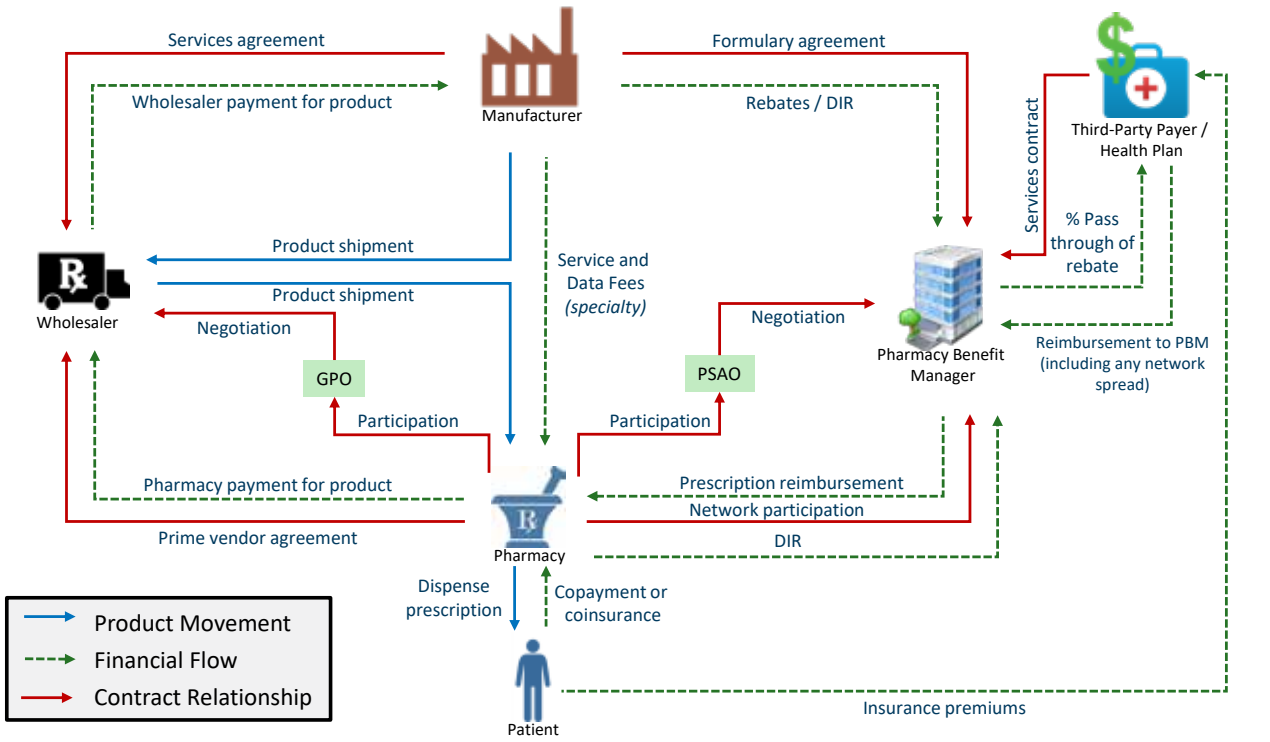
Pharmaceutical Flow Charts

Page 003
Pharmaceutical Company
Drug and Funds Flow



*Payment is made net of certain charges including prompt pay discounts, wholesaler fees, chargebacks, and returns

U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization; DIR = Direct and indirect remuneration
Source. *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (https://drugch.nl/pharmacy). Chart illustrates flows for Patient-Administered, Outpatient Drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of product movement, financial flow, or contractual relationship in the marketplace.

DRUG CHANNELS INSTITUTE

TAB 3

Customer Motion (In re Mallinckrodt)

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
MALLINCKRODT PLC, *et al.*,	)	Case No. 20-_____ (___)
Debtors.[1]	)	(Joint Administration Requested)

MOTION OF DEBTORS FOR INTERIM AND FINAL ORDERS AUTHORIZING THE DEBTORS TO HONOR PREPETITION OBLIGATIONS TO CUSTOMERS AND TO CONTINUE CUSTOMER PROGRAMS

The debtors in possession in the above-captioned cases (collectively, the "***Debtors***") hereby move (this "***Motion***") and respectfully state as follows:

RELIEF REQUESTED

1. By this Motion, the Debtors seek entry of interim and final orders, substantially in the form attached hereto as **Exhibit A** (the "***Proposed Interim Order***") and **Exhibit B** (the "***Proposed Final Order***," and together with the Proposed Interim Order, the "***Proposed Orders***"), respectively, granting them authority, in their discretion, to (a) fulfill and honor (through payment, credit, setoff, or otherwise) their Customer Obligations (as defined below) as they deem appropriate and (b) continue, renew, replace, implement new and/or terminate their Customer Programs (as defined below) and any other customer practices as they deem appropriate, without further application to the Court.

[1] A complete list of the Debtors in these chapter 11 cases may be obtained on the website of the Debtors' claims and noticing agent at http://restructuring.primeclerk.com/Mallinckrodt. The Debtors' mailing address is 675 McDonnell Blvd., Hazelwood, Missouri 63042.

JURISDICTION

2. This Court has jurisdiction to consider this Motion under 28 U.S.C. §§ 157 and 1334 and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware dated as of February 29, 2012. This is a core proceeding pursuant to 28 U.S.C. § 157(b), and, under Rule 7008 of the Federal Rules of Bankruptcy Procedure (the "***Bankruptcy Rules***") and Rule 9013-1(f) of the Local Rules of Bankruptcy Practice and Procedure of the United States Bankruptcy Court for the District of Delaware (the "***Local Rules***"), the Debtors consent to the entry of a final order by the Court in connection with this Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter final orders or judgments in connection herewith consistent with Article III of the United States Constitution. Venue of these cases and this Motion in this district is proper under 28 U.S.C. §§ 1408 and 1409. The statutory and legal predicates for the relief requested herein are sections 105(a), 363(b), 363(c), and 553 of the Bankruptcy Code (as defined below) and Bankruptcy Rules 6003 and 6004.

BACKGROUND

3. On the date hereof (the "***Petition Date***"), the Debtors filed voluntary petitions in this Court commencing cases for relief under chapter 11 of title 11 of the United States Code, 11 U.S.C. §§ 101–1532 (the "***Bankruptcy Code***"). The Debtors continue to manage and operate their businesses as debtors in possession under sections 1107 and 1108 of the Bankruptcy Code. No trustee or examiner has been requested in these cases, and no committees have been appointed.

4. The factual background regarding the Debtors, including their business operations, their capital and debt structures, and the events leading to the filing of these chapter 11 cases, is set forth in detail in the *Declaration of Stephen A. Welch, Chief Transformation Officer, in Support*

of Chapter 11 Petitions and First Day Motions (the "***Welch Declaration***") filed contemporaneously herewith, which is fully incorporated herein by reference.

THE DEBTORS' PRODUCTS AND CUSTOMER BASE

5. The Debtors comprise two distinct businesses, owned and operated by two different groups of Debtors (as well as certain non-Debtor affiliates).[2] The first business, "***Specialty Brands***," manufactures, markets, and sells brand name biopharmaceutical products (the "***Specialty Brands Products***"), including Acthar® Gel ("***Acthar***"), INOmax®, Ofirmev®, and Therakos®.[3] These products focus on autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology, and ophthalmology, as well as immunotherapy and neonatal respiratory critical care therapies and non-opioid analgesics.

6. The second business, "***Specialty Generics***," manufactures and sells complex generic pharmaceutical products and non-promoted branded products ready for use by the end consumer (the "***Specialty Generics Products***" and, together with the Specialty Brands Products, the "***Products***"). The Specialty Generics Products include more than twenty-five different products, such as acetaminophen and codeine phosphate tablets (including generic forms of Tylenol® with Codeine) and hydrocodone bitartrate and acetaminophen tablets (including generic forms of Norco® and Vicodin®). In addition, the Specialty Generics Debtors manufacture a variety of generic addiction treatment products, which assist recovering addicts' return to functioning in their lives, jobs, and society. Finally, the Specialty Generics Debtors also manufacture and sell over 40 active pharmaceutical ingredients and excipients ("***API(s)***") used in the manufacturing

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[2] As further described in the Welch Declaration, Specialty Brands and Specialty Generics share certain corporate services.

[3] Specialty Brands also sells Amitiza and Rescula to other pharmaceutical manufacturers, but these products do not have any associated Customer Programs or Customer Obligations (each as defined below).

process of other finished products (whether in the Specialty Generics business or by third parties), including acetaminophen, hydrocodone, oxycodone, methylphenidate, naltrexone, and magnesium stearate.

7. Similar to other pharmaceutical manufacturers, the Debtors' direct customers for their Products are primarily wholesale pharmaceutical distributors (the "***Distributors***") that sell the Products directly to pharmacies, hospitals, and other healthcare providers and organizations, some of which are subject to governmental contracts. Certain Specialty Generics Products are also sold to addiction treatment clinics that dispense them to patients (the "***Addiction Treatment Clinics***"). The Debtors also contract directly with payer organizations (the "***Payers***") and pharmacy benefit managers (the "***Pharmacy Benefit Managers***") to ensure coverage and reimbursement for certain Specialty Brands Products to patients that are prescribed these products by their physicians.

8. As for the APIs, in addition to using the APIs themselves, the Debtors also sell APIs to third-party customers, including (a) pharmaceutical manufacturing companies (the "***Pharmaceutical Companies***"), (b) contract manufacturers ("***Contract Manufacturers***"), (c) other associated industrial customers ("***Other Industrial Customers***"), and (d) distributors (the "***API Distributors***" and, together with Pharmaceutical Companies and Contract Manufacturers, the "***API Customers***"; the Distributors, Addiction Treatment Clinics, Payers, Pharmacy Benefit Managers, API Customers, CMS (as defined below) and state Medicaid agencies, and 340B Customers (as defined below) together, the "***Customers***").

9. For the fiscal year ending December 27, 2019, the Debtors generated net sales of approximately (a) $2,423.8 million from the Specialty Brands Products, (b) $364.9 million from

Specialty Generics Products, and (c) $337.1 million from APIs.[4] Sales in Specialty Generics are concentrated among three major distributors, with AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc., individually representing approximately 51%, 33%, and 10%, respectively, of the total gross sales of the Specialty Generics Products during fiscal year 2019. Specialty Brands' sales are less concentrated, with Curascript, Inc. representing approximately 40% of total gross sales of the Specialty Brands Products during fiscal year 2019, but the next largest distributors, AmerisourceBergen Corporation and Cardinal Health, Inc. each representing only approximately 6%.[5]

THE DEBTORS' CUSTOMER PROGRAMS

10. To preserve the Debtors' critical relationships with their Customers and maximize Customer loyalty, in the ordinary course of business, the Debtors provide certain pricing, incentives, discounts, and other accommodations to their Customers (collectively, the "***Customer Programs***" and the obligations incurred thereunder, the "***Customer Obligations***"). The Customer Programs include Chargebacks, Rebates and Fees, Prompt Pay Discounts, Product Returns, Co-Pay Reimbursements, and Other Customer Programs (each as defined below). While the Customer Programs are essential to the success of both Specialty Brands and Specialty Generics, their relevance to the Debtors' bottom line is particularly seen on the Specialty Generics side, where the Debtors are competing more directly on price (along with quality and reliability of supply).

11. The Debtors' goodwill and ongoing business relationships may erode if the Customers perceive that the Debtors are unable or unwilling to fulfill the prepetition commitments

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[4] Net sales include all of the Debtors' Products and APIs, though not all of the Debtors' Products and APIs have associated Customer Programs. The Debtors also generated net sales of approximately $18.2 million from contract manufacturing operations, which does not have any associated Customer Programs.

[5] References to Distributors in this paragraph collectively refer to such Distributor and its affiliates and subsidiaries.

they have made through the Customer Programs. If the Debtors are unable to preserve the loyalty of their Customers, the Debtors' businesses would likely suffer material harm. It is essential, therefore, that the Debtors fulfill their Customer Obligations and continue the Customer Programs to ensure customer satisfaction and maintain the goodwill of their Customers, which is critical to the Debtors' ongoing operations and to preserving and maximizing stakeholder value. Indeed, without the ability to continue the Customer Programs and to satisfy Customer Obligations, the Debtors risk losing market share, harming their future business and revenue growth, and reducing the recoveries of the Debtors' creditors.

12. As further described below, the Debtors estimate that the aggregate value of accrued prepetition Customer Obligations is approximately $357,852,000. This sum is comprised of (a) $132,220,000 in accrued Chargebacks (as defined below), (b) $96,910,000 in accrued Rebates and Fees (as defined below), (c) $9,790,000 in accrued Prompt Pay Discounts (as defined below), (d) $24,860,000 in accrued Product Returns (as defined below), (e), $132,000 in accrued Co-Pay Reimbursements (as defined below), and (f) $93,940,000 in Other Customer Programs (as defined below).

I. CHARGEBACK PROGRAMS

13. The Debtors negotiate certain agreements to establish contract pricing and chargebacks (the "***Chargeback Agreements***") with their Customers. The Chargeback Agreements govern the terms of sale of the Debtors' Products by Distributors to certain eligible retail pharmacies, hospitals, mail-order pharmacies, hospice providers, long-term care providers, and other institutions (the "***Dispensers***"). In addition, certain of the Customers may also negotiate agreements to establish contract pricing and/or distribution arrangements directly with the Debtors (the "***Purchase Agreements***").

14. Based on the existence of certain Chargeback Agreements or statutory rights, Distributors may be entitled to sell the Debtors' Products to certain eligible Dispensers at a special discounted rate or may be entitled to shelf stock adjustments based on price changes for existing stocked Products (the "***Chargeback Program***"). The special discounted rate is less than the wholesale acquisition cost ("***WAC***") that the Distributors pay the Debtors. Thus, when the Distributors sell the Products to eligible Dispensers at a rate lower than WAC, the Debtors are subject to an obligation to compensate the Distributor for the deficiency (a "***Chargeback***"). Similarly, if a Distributor has a Product in stock and the WAC of such Product is adjusted lower, a Chargeback is accrued.[6]

15. When the Distributors ship Products to certain eligible Dispensers, they submit a Chargeback request to the Debtors, which the Debtors promptly review and pay. However, due to standard invoicing terms, the Debtors do not receive payment in the amount of the WAC from the Distributors for approximately thirty (30) to sixty (60) days after the Products are shipped to the Distributors, even though a Chargeback may be generated before such payment. Due to the Debtors' long relationships with most of their Customers, the Customers typically deduct the amount of the Chargeback from payments against outstanding accounts receivable, and the Debtors then review and honor such Chargeback deductions through setoffs within the Debtors' own accounting system. In some limited instances, the Debtors pay the Chargebacks through checks or wire transfers directly to the Distributors.

16. On average, the Debtors accrue approximately $140,000,000 in Chargebacks every month for Specialty Generics Products and approximately $10,000,000 in Chargebacks every

[6] For certain products, a Rebate may be generated instead of a Chargeback. If a Distributor has a Product in stock and the WAC of such Product is adjusted higher, the Distributor is sent an invoice for the difference in WAC or such amount may be offset from such Distributor's accrued Fees.

month for Specialty Brands Products. The Debtors estimate that the aggregate amount of Chargebacks accrued and owing as of the Petition Date under the Chargeback Program is $132,220,000.

17. The Debtors request authority to pay and honor, including through implementing or agreeing to setoffs, prepetition Chargebacks owed to the Customers as they come due in the ordinary course of business and consistent with past practice. The Debtors estimate that the aggregate amount of prepetition Chargebacks so honored during the interim period will be $132,220,000. Failure to pay and honor the prepetition Chargebacks would likely result in serious and irreparable harm to the Debtors, including loss of Customer loyalty, market share, and an erosion of Customer satisfaction and goodwill. In particular, Specialty Generics competes in a price-sensitive market and, therefore, the Chargebacks are particularly important in maintaining competitiveness in the market. If the Debtors are unable to provide the Products on competitive terms, Customers will seek other generic manufacturers or other alternatives to the Debtors' Specialty Brands Products to meet their demand.

18. Additionally, the Debtors request authority to continue to perform, including through implementing or agreeing to setoffs, under the Chargeback Program on a postpetition basis in the ordinary course of business and consistent with past practice.

II. REBATE AND FEE PROGRAM

19. The Debtors also negotiate certain arrangements that contain rebates and fees, including volume price rebates and Medicare Part D rebates (collectively, the "***Rebates and Fees***"), with their Customers (the "***Rebate and Fee Program***"). These Rebates and Fees are mostly part of arrangements that also contain pricing terms and Chargebacks, but are also a part of agreements with Payers or the federal government. For APIs, Rebates and Fees are accrued for

API Distributors in exchange for certain sales data, as well as for baseline raw material price changes which are passed on to the API Customers.

20. Medicare Part D is a voluntary prescription drug program provided to patients through private health insurance plans approved by the federal government. The government partially subsidizes the drugs provided by the private health insurance plans through Medicare Part D, which results in lower health plan cost for patients. Under Medicare Part D, seniors over the age of sixty-five (65) years old may choose from a wide variety of privately administered drug plans that negotiate directly with drug manufacturers. The Debtors have entered into several contracts with private insurers with Medicare Part D business lines and with the Centers for Medicare & Medicaid Services ("***CMS***") to cover certain of their Products, including Acthar and certain of the Specialty Generics Products, pursuant to which the Debtors agreed to pay the private insurers or their representatives which administer the program or CMS certain rebates related to the Medicare Part D program. Rebates under Medicare Part D are generally paid in cash to the private insurers or their representatives or CMS on a monthly or quarterly basis.

21. As with Chargebacks, Rebates and Fees (other than Medicare Part D rebates) may be deducted by the Customers from payments against outstanding accounts receivable, which the Debtors then review and honor such Rebates and Fees deductions through setoffs within the Debtors' accounting system through the issuance of credits against then-outstanding accounts receivable, but the Debtors primarily pay Rebates and Fees, including Medicare Part D rebates and certain other per unit rebates, through checks or wire transfers directly to the Customers or CMS. On average, the Debtors accrue approximately $25,000,000 in Rebates and Fees every month for Specialty Generics Products and approximately $26,600,000 in Rebates and Fees every month for Specialty Brands Products, of which approximately $2,500,000 is on account of Medicare Part D

rebates for all covered Products. The Debtors estimate that the aggregate amount of Rebates and Fees accrued and owing as of the Petition Date (a) for the Specialty Generics Products is $44,770,000 and (b) for the Specialty Brands Products is $52,140,000, of which approximately $3,100,000 is on account of Medicare Part D rebates for all covered Products.

22. The Debtors request authority to pay and honor, including through implementing or agreeing to setoffs, prepetition Rebates and Fees owed to the Customers as they come due in the ordinary course of business and consistent with past practice. The Debtors estimate that the aggregate amount of prepetition Rebates and Fees so honored during the interim period will be $76,400,000. As with Chargebacks, failure to pay and honor the prepetition Rebates and Fees will likely result in serious and irreparable harm to the Debtors, including loss of Customer loyalty, market share, loss of coverage for the Debtors' Products under Medicare Part D, and an erosion of Customer satisfaction and goodwill.

23. Additionally, the Debtors request authority to continue to pay and honor, including through implementing or agreeing to setoffs, the Rebates and Fees on a postpetition basis in the ordinary course of business and consistent with past practice.

III. PROMPT PAY DISCOUNT PROGRAM

24. The Debtors also negotiate payment terms as part of most Purchase Agreements, often including prompt pay discounts ("***Prompt Pay Discounts***") for Product[7] and, in some instances, API purchases by the Customers (the "***Prompt Pay Discount Program***"). Prompt Pay Discounts offer Customers a reduction in the sales price if the Customers pay the amounts owed earlier than their agreed upon payment terms require and within certain early payment windows. The Prompt Pay Discount Program is implemented through a write-off to a specific reserve in the

[7] Prompt Pay Discounts are not offered for Specialty Brands Products Acthar, INOmax, or Therakos.

Debtors' accounting system established when Products are purchased, and does not require a cash outlay from the Debtors.

25. On average, the Debtors accrue approximately $4,700,000 in Prompt Pay Discounts every month for Specialty Generics Products and approximately $1,000,000 in Prompt Pay Discounts every month for Specialty Brands Products, but do not generally accrue any amounts in Prompt Pay Discounts for APIs. The Debtors estimate that the aggregate amount of Prompt Pay Discounts accrued as of the Petition Date is (a) for the Specialty Generics Products is $8,580,000, (b) for the Specialty Brands Products is $1,220,000, and (c) no accrued amounts for the APIs. The Debtors request authority to honor the prepetition Prompt Pay Discounts as they come due in the ordinary course of business and consistent with past practice. The Debtors estimate that the aggregate amount of prepetition Prompt Pay Discounts so honored during the interim period will be $9,800,000. Paying and honoring the Prompt Pay Discounts is vital to preserving Customer loyalty and goodwill, as it demonstrates the Debtors' ability to provide the Products on competitive terms. Failure to pay and honor these obligations will likely cause some of the Customers to seek other generic manufacturers or other alternatives to the Debtors' Specialty Brands Products to meet their demand.

26. Additionally, the Debtors request authority to continue to honor the Prompt Pay Discounts on a postpetition basis in the ordinary course of business and consistent with past practice.

IV. PRODUCT RETURN PROGRAM

27. Similar to other pharmaceutical manufacturers, certain of the Debtors' Specialty Generics Products, APIs, and Specialty Brands Products are eligible for expired product returns and failed or damaged product returns (the "***Product Return Program***" and such returns, "***Product Returns***"). Per company policy for Specialty Generics Products (but not APIs) and certain

Specialty Brands Products, including Ofirmev, short-dated and expired products in original, sealed, unopened packaging may be returned within six (6) months prior to the expiration and up to twelve (12) months after the expiration date. Returns for products purchased at a contract price (as opposed to a list price or WAC) are valued based on the lowest eligible purchase price within the past twenty-four (24) month timeframe. The Debtors also accept returns on certain products they sell without any contract, which returns are valued based on a weighted average selling price for the lot number returned. For API products, the Debtors accept returns for products that are damaged or do not meet product specifications.[8]

28. For the Specialty Brands Product Acthar, the Debtors only accept Product Returns for a refund or credit, or replace damaged, near-expired, or expired Acthar products, in accordance with certain specific distribution agreements providing for such arrangements.

29. For the Specialty Brands Product Therakos, the Debtors only accept Product Returns for product complaints that are primarily for out of box failure of the disposable procedure kits or issues encountered in preparation for patient therapy. Upon return of a Therakos product, the Debtors issue a credit based on the pricing of the Product from the invoice and the quantity of returned Product (or number of hours for the light assembly of the Product system, if applicable).

30. As with Chargebacks and Rebates and Fees, Product Returns may be deducted by Customers from payments against outstanding accounts receivable. The Debtors review and honor such deductions through setoffs through the issuance of credits against then-outstanding accounts receivable. In some instances, however, the Debtors pay the Product Returns through checks or wire transfers directly to the Customers.

[8] Returns are also accepted in the ordinary course of business based on certain agreements with Customers.

31. The Product Return Program is administered by Medturn, Inc., an Inmar company ("***Inmar***"), pursuant to that certain Returns Management Agreement dated as of August 1, 2012 (as amended and supplemented from time to time), by and between Inmar and Debtor Mallinckrodt LLC. The Debtors pay Inmar certain fees for the administration of the Product Return Program, including the processing, sorting, and disposition of the Product Returns. On average, the Debtors accrue approximately $1,200,000 in Product Returns for Specialty Generics Products every month and approximately $800,000 in Product Returns for Specialty Brands Products every month. The Debtors also paid Inmar approximately $300,000 in the fiscal year ending December 27, 2019 on account of its administrative obligations under the Product Return Program.

32. The Debtors estimate that the aggregate amount of the Product Returns accrued and owing as of the Petition Date (a) for the Specialty Generics Products is $19,910,000 and (b) for the Specialty Brands Products is $4,950,000. The Debtors request the authority to pay and honor, including through implementing or agreeing to setoffs, the prepetition Product Returns and to pay all fees owed to Inmar, each as they come due in the ordinary course of business and consistent with past practice. The Debtors estimate that the aggregate amount of prepetition Product Returns so honored during the interim period will be $5,600,000 and the aggregate amount of fees paid to Inmar during the interim period will be $23,000. Paying and honoring Product Returns is vital to maintaining Customer satisfaction and loyalty. Failure to do so would likely cause Customers to purchase from other manufacturers, resulting in decreased market share and revenues which would severely impact the long-term business outlook of the Debtors.

33. Additionally, the Debtors request the authority to continue to pay and honor, including through implementing or agreeing to setoffs, the Product Returns and to pay Inmar on

account of such Product Returns on a postpetition basis in the ordinary course of business and consistent with past practices.

V. SPECIALTY BRANDS CO-PAY REDUCTION PROGRAM

34. The Debtors provide certain patients with co-pay assistance for Acthar to offset their out-of-pocket costs (the "***Co-Pay Reduction Program***"). The Co-Pay Reduction Program is designed to improve access to and the affordability of Acthar by reducing or eliminating out of pocket expenses for eligible patients up to $25,000 per calendar year. These out-of-pocket expenses represent copays through a commercial health insurance plan. To qualify, a patient must be prescribed Acthar for an approved, "on label" indication, be a U.S. permanent resident, be commercially insured, and not be covered through any state or federally funded insurance plan such as Medicare, Medicaid, or Tricare, including secondary or tertiary benefits of such federally funded insurance plans.

35. The Co-Pay Reduction Program is administered by PSKW, LLC d/b/a ConnectiveRX ("***ConnectiveRX***") pursuant to that certain Statement of Work, Program Management Services, dated as of January 1, 2020, by and between ConnectiveRX and Debtor Mallinckrodt ARD LLC. The Debtors prefund the Co-Pay Reduction Program with sufficient funds to cover approximately three weeks of reimbursements (the "***Prefunded Amounts***"). When a patient purchases Acthar at the pharmacy, the pharmacy submits prescription level detail and co-pay values to ConnectiveRX, who then processes and pays the claims from the Prefunded Amounts. Semi-monthly, ConnectiveRX reports claims reimbursed (the "***Co-Pay Reimbursements***") during the previous semi-monthly period and invoices the Debtors to ensure the Prefunded Amount remains at a level sufficient to cover three weeks of Co-Pay Reimbursements. In addition to the Co-Pay Reimbursements, the Debtors pay ConnectiveRX certain fees for the administration of the Co-Pay Reduction Program. For the fiscal year ending

December 27, 2019, the Debtors paid ConnectiveRX approximately $1,030,000 in Co-Pay Reimbursements and approximately $480,000 on account of its administrative obligations under the Co-Pay Reduction Program.

36. The Debtors estimate that as of the Petition Date, approximately $100,000 has accrued but has not been invoiced or paid for Co-Pay Reimbursements and fees. The Debtors request the authority to pay and honor the prepetition Co-Pay Reimbursements and to pay all fees owed to ConnectiveRX, each as they become due in the ordinary course of business and consistent with past practice. The Debtors estimate that the aggregate amount of prepetition Co-Pay Reimbursements so honored during the interim period will be $100,000 and the aggregate amount of fees paid to ConnectiveRX during the interim period will be $40,000. Additionally, the Debtors request the authority to continue to pay and honor the Co-Pay Reimbursements and to pay ConnectiveRX on account of such Co-Pay Reimbursements on a postpetition basis in the ordinary course of business and consistent with past practices.

VI. OTHER CUSTOMER PROGRAMS

37. The Debtors' other customer programs (collectively, the "***Other Customer Programs***") include (a) rebates and refunds in connection with Medicaid and the 340B Program (as defined below), (b) allowances that the Debtors negotiate with their customers along with pricing, Chargebacks, and Rebates and Fees, such as stocking allowances for new products or products added to an existing contract, certain allowances for inventory on hand at the Customer or in-transit to a Distributor in the event of decreases in WAC or contract price, and certain other negotiated price protections related to increases in contract price, and (c) three patient assistance programs (together, the "***Patient Assistance Programs***"). Payments on account of Other Customer Programs for Medicaid, the 340B Program, and Patient Assistance Programs are paid by check or

wire, while allowances to Customers are generally honored by setoffs within the Debtors' accounting system through the issuance of credits against then-outstanding accounts receivable.

38. Medicaid is a government program that assists low income individuals and families in obtaining health care. Medicaid covers a number of the Debtors' Products under a designated rebates program (the "***Medicaid Rebates Program***"). The Medicaid Rebates Program works as a partnership between the CMS, state Medicaid agencies, and participating drug manufacturers, such as the Debtors, to allow drug manufacturers to help offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid programs. Pursuant to the Medicaid Rebates Program, the Debtors entered into a national rebate agreement with the Secretary of Health and Human Services in exchange for Medicaid coverage of the Products. A statutory formula determines the Medicaid rebate due for each unit of medication dispensed to a Medicaid patient. The Debtors subsequently pay the Medicaid rebates to the applicable states on a quarterly basis.

39. Under its agreement with CMS for Medicaid and relevant statutes, the Debtors are required to comply with the United States Department of Health and Human Services' 340B Drug Pricing Program (the "***340B Program***") established under Section 340B of the Public Health Service Act (the "***Act***"). Under this program, the Debtors must sell their Products to certain "covered entities" under the Act such as hospitals, clinics, and other entities that meet the statutory participation requirements (the "***340B Customers***") at specified prices that reflect a substantial discount to WAC. In the ordinary course of business, the 340B Customers purchase the Debtors' Products from the Distributors at the price established under the Act. However, in the event that a 340B Customer purchases the Debtors' Products at a price greater than the prices established under the Act due to a retroactive price restatement, the Debtors are required to issue a refund directly to such 340B Customer (a "***340B Refund***"). As the majority of 340B Customers do not

purchase the Products directly from the Debtors, identifying and processing the 340B Refunds can be a complex and a time consuming task. As such, the Debtors use Apexus, LLC ("***Apexus***") to administer the 340B Refunds under the 340B Program pursuant to that certain Manufacturer Refund Services Agreement dated as of March 10, 2019, between Apexus and Mallinckrodt Enterprises LLC. If a 340B Refund is required, the Debtors transfer the 340B Refund amounts to Apexus, who processes and issues the 340B Refunds to the 340B Customers. Apexus is paid a per transaction fee for these services. Failure to comply with the 340B Program or failing to issue the 340B Refunds may result in fines and penalties, and exclusion from other federal programs.

40. On average, the Debtors currently accrue approximately $26,800,000 in Medicaid Rebates every month, while 340B Refunds are only accrued upon the occurrence of a retroactive price restatement of a Product. As of the Petition Date, the Debtors estimate that approximately $79,310,000 has accrued but has not yet been invoiced or paid on account of the Medicaid Rebates Program and 340B Program, of which $26,800,000 will come due in the interim period.[9]

41. Specialty Brands and Specialty Generics each have their own Patient Assistance Program, with Specialty Brands maintaining two separate Patient Assistance Programs. The first Specialty Brands' Patient Assistance Program is administered by The Assistance Fund, Inc., a 501(c)(3) tax exempt charitable organization (the "***Fund***"). Pursuant to a Donor Agreement, dated as of January 18, 2020 with the Fund, the Debtors donate $10 million per year to the Fund in eleven (11) monthly installments. The Fund provides critically or chronically ill individuals whose household income is below the federal poverty level with access to advanced therapies through a continuum of services and programs, including education and financial aid, based on disease

[9] The amounts in this paragraph are exclusive of any amounts related to the CMS Action, as described in the Welch Declaration.

indication. While the use of the donation is solely at the discretion of the Fund, including which medications patients are able to receive assistance for, the Debtors direct their donations to be used for specific disease indications that their Products are designed to treat.

42. The second Specialty Brands' Patient Assistance Program is the Acthar Patient Assistance Program (the "***Acthar Patient Assistance Program***"), which consists of a free drug program (the "***Free Goods Program***") and a starter program (the "***Starter Program***"). The Free Goods Program provides Acthar free of charge to qualifying patients with limited incomes or insurance coverage that would not otherwise be able to access Acthar needed for their care. The Starter Program is designed to allow eligible patients with a valid on-label prescription for Acthar for certain approved indications quick access to Acthar before commercial or private insurance approves the use of Acthar.

43. McKesson Specialty Pharmacy, LP ("***McKesson***") administers the patient application process for the Acthar Patient Assistance Program and dispenses free product to eligible and enrolled patients pursuant to that certain Statement of Work #1, Statement of Work #2, and Statement of Work #3, each dated as of May 15, 2018 between McKesson and Mallinckrodt ARD LLC. After screening and meeting the eligibility requirements, Acthar is provided to the patient under the Free Product Program for up to one calendar year free of charge, while the Starter Program provides therapy-naive patients with commercial or private insurance a maximum of five vials of Acthar free of charge.[10] Charges for this program are divided into administrative fees for costs related to the administration of the program and pharmacy fees for costs related to the actual dispensing of product. For the fiscal year ending December 27, 2019,

[10] In certain circumstances, an additional three vials of Acthar may be provided free of charge.

the Debtors donated $1,614,000 in Acthar and paid McKesson $2,087,000 on account of its obligations under the Acthar Patient Assistance Program.

44. The Specialty Generics' Patient Assistance Program is administered by Pharmacy Providers of Oklahoma, Inc., d/b/a MaxCare Prescription Benefit Services ("***MaxCare***" and, together with Inmar, ConnectiveRX, Apexus, the Fund, and McKesson, the "***Program Administrators***"). Pursuant to that certain Patient Assistance Program Agreement, dated as of December 1, 2013 between MaxCare and Mallinckrodt LLC, MaxCare provides certain individuals whose household income is at or below 200% of the federal poverty level and who have no insurance coverage with a prescription drug card that allows them to receive certain of the Debtors' Specialty Generics Products with a $20 co-payment by the patient. The dispensing pharmacy charges MaxCare for such products, who in turn are reimbursed by the Debtors. For the fiscal year ending December 27, 2019, the Debtors paid MaxCare approximately $2,700,000 on account of its administrative obligations under the Specialty Generics Patient Assistance Program.

45. The Debtors estimate that the aggregate amount of Other Customer Programs accrued and owing as of the Petition Date is $93,940,000, the majority of which are on account of the Medicaid Rebates Program. The Debtors request authority to pay and honor the prepetition Other Customer Programs obligations owed to the Customers and to pay all fees owed to McKesson and MaxCare, each as they become due in the ordinary course of business and consistent with past practice. The Debtors estimate that the aggregate amount of prepetition Other Customer Programs obligations so honored during the interim period will be $28,100,000, the aggregate amount of fees paid to McKesson during the interim period will be $100,000, and the aggregate amount of fees paid to MaxCare during the interim period will be $200,000. Failure to pay and honor the prepetition Medicaid Rebates Program and 340B Program obligations could

result in termination or exclusion from Medicaid and the loss of coverage of the Debtors' Products, which would cause a significant impact to the Debtors' future revenues and market share. Further, the Patient Assistance Programs are essential to providing patients with access to the Debtors' Products.

46. Additionally, the Debtors request authority to continue to pay and honor the Other Customer Programs obligations on a postpetition basis in the ordinary course of business and consistent with past practice.

BASIS FOR RELIEF

I. PAYING PREPETITION CUSTOMER OBLIGATIONS REFLECTS THE DEBTORS' SOUND BUSINESS JUDGMENT

47. The relief requested is appropriate under section 363(b)(1) of the Bankruptcy Code. Under section 363(b)(1) of the Bankruptcy Code, a debtor may, in the exercise of its sound business judgment and after notice and a hearing, "use, sell or lease, other than in the ordinary course of business, property of the estate." 11 U.S.C. § 363(b)(1). Generally, the debtor is only required to "show that a sound business purpose" justifies the proposed use of property. *In re Montgomery Ward Holding Corp.*, 242 B.R. 147, 153 (D. Del. 1999); *see also In re Phx. Steel Corp.*, 82 B.R. 334, 335–36 (Bankr. D. Del. 1987) (requiring "good business reason" for use under section 363(b) of the Bankruptcy Code). This standard prohibits other parties from second-guessing the debtor's business judgment if the debtor has shown that the proposed use will benefit the debtor's estate. *See In re Johns-Manville Corp.*, 60 B.R. 612, 616 (Bankr. S.D.N.Y. 1986) ("Where the debtor articulates a reasonable basis for its business decisions (as distinct from a decision made arbitrarily or capriciously), courts will generally not entertain objections to the debtor's conduct."); *see also In re Tower Air, Inc.*, 416 F.3d 229, 238 (3d Cir. 2005) ("Overcoming the presumptions of the business judgment rule on the merits is a near-Herculean task.").

48. The Debtors submit that the requested relief represents a sound exercise of the Debtors' business judgment, is necessary to avoid immediate and irreparable harm, and is justified under sections 363(b) of the Bankruptcy Code. If the Debtors are prohibited from honoring the Customer Obligations and maintaining their Customer Programs consistent with their past business practices, their Customers may lose confidence in the Debtors' ability to provide the Products on competitive terms, and will likely cause some of the Customers to seek other generic manufacturers or other alternatives to the Debtors' Specialty Brands Products to meet their demand. In addition, the damage from refusing to honor these obligations far exceeds the cost associated with honoring prepetition obligations and continuing these practices. The relief requested herein will protect the Debtors' goodwill with their Customers during this critical time and enhance the Debtors' ability to generate revenue. Consequently, all of the Debtors' creditors will benefit if the requested relief is granted.

49. Accordingly, the Debtors request that they, in their discretion, be authorized to (a) fulfill and honor (through payment, setoff, credit, or otherwise) such of their Customer Obligations, whether arising prepetition or postpetition, as they deem appropriate, and (b) continue, renew, replace, implement new, and/or terminate the Customer Programs and any other customer practices as they deem appropriate, without further application to the Court.

II. PAYING PREPETITION CUSTOMER OBLIGATIONS IS NECESSARY TO THE DEBTORS' REORGANIZATION

50. In addition, the Debtors submit that the Court may grant the relief requested herein, including payment of prepetition Customer Obligations, under the "doctrine of necessity" and section 105(a) of the Bankruptcy Code. Section 105(a) of the Bankruptcy Code empowers the Court to "issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of [the Bankruptcy Code]." 11 U.S.C. § 105(a). Courts have interpreted this provision

to authorize payments on prepetition claims where the payments are essential to the success of the debtor's reorganization under what is known as the "necessity of payment doctrine." *See In re Lehigh & New Eng. Ry.*, 657 F.2d 570, 581 (3d Cir. 1981) ("Thus, the 'necessity of payment' doctrine…teaches no more than, if a payment of a claim which arose prior to reorganization is essential to the continued operation of the [debtor's business] during reorganization, payment may be authorized…"); *see also In re Just for Feet, Inc.*, 242 B.R. 821, 824–25 (D. Del. 1999) (holding that section 105(a) "provides a statutory basis for payment of pre-petition claims" under necessity of payment doctrine); *In re Columbia Gas Sys., Inc.*, 171 B.R. 189, 191-92 (Bankr. D. Del. 1994) ("The appropriate standard…is commonly referred to as 'the necessity of payment doctrine.'").

51. Failing to obtain the relief sought herein—indeed, even being forced to advise Customers that further judicial relief is necessary—could result in the Debtors losing a portion of their customer base and severe harm to the estates. Such disruption and value degradation could undermine the Debtors' reorganization efforts, and, accordingly, this Motion should be granted under section 105(a) of the Bankruptcy Code.

III. THE COURT SHOULD AUTHORIZE BANKS TO HONOR AND PAY CHECKS ISSUED AND ELECTRONIC FUNDS TRANSFERRED TO PAY THE PREPETITION CUSTOMER OBLIGATIONS

52. The Debtors further request that the Court authorize, but not direct, their banking institutions and all other applicable banks and other financial institutions to receive, process, honor, and pay any and all checks drawn or electronic funds relating to the Prepetition Customer Obligations, whether such checks were presented before or after the Petition Date. The Debtors expect to have sufficient liquidity to pay such amounts as they become due in the ordinary course of business, and under the Debtors' existing cash management system, checks or wire transfer requests can be readily identified as relating to an authorized payment of the Customer Obligations. As such, the Debtors believe that checks or wire transfer requests, other than those relating to

authorized payments, will not be honored inadvertently. The Debtors also seek authority to issue new postpetition checks or effect new electronic fund transfers on account of the Customer Obligations to replace any prepetition checks or electronic fund transfer requests that may be dishonored or rejected as a result of the commencement of the Debtors' chapter 11 cases.

IV. INTERIM RELIEF IS NECESSARY TO AVOID IMMEDIATE AND IRREPARABLE HARM

53. Under Bankruptcy Rule 6003, the Court may grant a motion to "use . . . property of the estate, including a motion to pay all or part of a claim that arose before the filing of the petition" within 21 days after the chapter 11 case's commencement to the extent "relief is necessary to avoid immediate and irreparable harm." Fed. R. Bankr. P. 6003. Here, the relief requested is necessary to avoid immediate and irreparable harm to the Debtors and their estates, as set forth in the Welch Declaration, and relief on an interim basis is therefore appropriate under Bankruptcy Rule 6003, if applicable.[11]

54. Additionally, with respect to any aspect of the relief sought herein that constitutes a use of property under section 363(b) of the Bankruptcy Code, the Debtors seek a waiver of the notice requirements under Bankruptcy Rule 6004(a), to the extent not satisfied, and of the fourteen-day stay under Bankruptcy Rule 6004(h). As described above, the relief that the Debtors seek in this Motion is immediately necessary for the Debtors to be able to continue to operate their businesses and preserve the value of their estates. The Debtors thus submit that the requested waiver of the notice requirements of Bankruptcy Rule 6004(a) and of the fourteen-day stay imposed by Bankruptcy Rule 6004(h) is appropriate.

[11] *See* the Welch Declaration filed concurrently with this motion.

RESERVATION OF RIGHTS

55. Nothing in this Motion shall be deemed: (a) an admission as to the amount of, basis for, or validity of any claim against the Debtors under the Bankruptcy Code or other applicable nonbankruptcy law; (b) a waiver of the Debtors' or any other party in interest's right to dispute any claim; (c) a promise or requirement to pay any particular claim; (d) an implication or admission that any particular claim is of a type specified or defined in this Motion; (e) a request or authorization to assume, adopt, or reject any agreement, contract, or lease pursuant to section 365 of the Bankruptcy Code; (f) an admission as to the validity, priority, enforceability, or perfection of any lien on, security interest in, or other encumbrance on property of the Debtors' estates; or (g) a waiver of any claims or causes of action which may exist against any entity under the Bankruptcy Code or any other applicable law. If the Court enters any order granting the relief sought herein, any payment made pursuant to such order is not intended and should not be construed as an admission as to the validity of any particular claim or a waiver of the Debtors' rights to subsequently dispute such claim.

NOTICE

56. Notice of this Motion will be given to: (a) the Office of the United States Trustee for the District of Delaware; (b) counsel to the ad hoc group of the Debtors' prepetition secured lenders; (c) the agent under the Debtors' secured term and revolving financing facilities; (d) counsel to the ad hoc group of holders of the Debtors' unsecured notes; (e) the indenture trustees for the Debtors' outstanding notes; (f) counsel to the ad hoc committee of governmental entities holding opioid claims; (g) the parties included on the Debtors' consolidated list of fifty (50) largest unsecured creditors; (h) the United States Attorney's Office for the District of Delaware; (i) the attorneys general for all 50 states and the District of Columbia; (j) the United States Department of Justice; (k) the Internal Revenue Service; (l) the Securities and Exchange

Commission; (m) the United States Drug Enforcement Agency; (n) the United States Food and Drug Administration; (o) the Customers; (p) the Program Administrators; (q) CMS; and (r) all parties entitled to notice pursuant to Local Rule 9013-1(m). The Debtors submit that, under the circumstances, no other or further notice is required.

57. A copy of this Motion is available on (a) the Court's website, www.deb.uscourts.gov, and (b) the website maintained by the Debtors' proposed claims and noticing agent, Prime Clerk LLC, at http://restructuring.primeclerk.com/Mallinckrodt.

NO PRIOR MOTION

58. The Debtors have not made any prior motion for the relief sought in this Motion to this Court or any other court.

[*Remainder of page intentionally left blank.*]

WHEREFORE, the Debtors respectfully request that the Court enter the Proposed Orders, granting the relief requested in this Motion and such other and further relief as may be just and proper.

Dated: October 12, 2020
Wilmington, DE

/s/ Brendan J. Schlauch

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Proposed Counsel for Debtors and Debtors in Possession

TAB 4

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

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Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Women First Healthcare (Bankr. D. Delaware 2004) (Case No. 04-11278-MWF) (Docket No. 562)	Section 1.01 Defined Terms. "NDC Number" means the unique, identifying number assigned to a drug product, including the labeler code, product code and package code, in connection with the drug listing requirements of Section 510(j) of the FD&C Act and applicable FDA rules and regulations. "Acquired Assets" set forth in Schedule 1.01(a) includes "Regulatory Documentation" which is defined to include "all records maintained under record keeping or reporting requirements of the FDA or any other Governmental Entity"	Section 8.01(a), "Promptly after the Closing and in any event within thirty (30) days after the Closing, Purchaser shall file with the FDA the information required pursuant to 21 C.F.R. Part 314, or any successor regulation thereto, to transfer the Product Registrations from Seller to Purchaser. The parties also agree to use all reasonable commercial efforts, and in any event within thirty (30) days, to take any and all other actions required by the FDA, or other Governmental Entity, if any, to effect the transfer of the Product Registrations from Seller to Purchaser."	Section 8.04 No Use of Certain Names. (c) Purchaser shall use all reasonable commercial efforts to obtain its own NDC Numbers for the Products as soon as practicable after the Closing and in any event within ninety (90) days thereafter.

Bankruptcy Entity Seller	Relevant Provisions		
aaiPharma (Bankr. D. Delaware 2005) (Case No. 05-11341) (Docket No. 296)	Section 2.1 "Purchased Assets" includes "Product Registration Data" Section 1.1 defines "Product Registration Data" as "(i) all regulatory files relating [to Product] including, but not limited to, any Permits (to the extent transferrable) . . . drug master files, FDA approvals for export, documents relating to Phase IV studies and pediatric studies, and all correspondence with the FDA regarding the marketing status of such applicable Product; and (ii) all records maintained under current good manufacturing practices or other	Section 8.14 Returns, Rebates, and Chargebacks. (a) (i) Sellers shall be financially responsible for returned Marketed Products sold by Sellers prior to the Closing Date and Purchaser shall be financially responsible for returned Marketed Products sold by Purchaser on or after the Closing Date, provided that Sellers and Purchaser shall be financially responsible for their own allocated percentage of Split Lots of returned Marketed Products that will be set forth on a schedule of Split Lots to be provided by Sellers within ten (10) Business Days after the Closing Date; provided, however, that Sellers' financial obligation for such returns shall terminate two hundred seventy (270) days after the Closing Date, Such allocated percentage of a Split Lot that Purchaser shall be responsible for under this Section S.14(aXi) shall be equal to the percentage of such Split Lot located at SPS Cord on the Closing Date and such allocated percentage of a Split Lot that Sellers shall be responsible for under this Section 8.14(a)(1) shall equal the percentage of such Split Lot not located at SPS Cord on the Closing Date. (jj) As of the Closing, Purchaser and Sellers will use commercially reasonable efforts in requesting that customers direct all returned Marketed Products to Purchaser; provided, however, that except as set forth on Schedule S.HfaMH. returned Marketed Products received by Purchaser or Sellers after the Closing Date will be handled by such party at its respective returns handling facility. Neither Purchaser nor Sellers shall issue credits or make any cash payments for returned Marketed Products for which the other party is financially responsible as set forth in Section 8.14(a)(i) above; provided, however, that such party shall destroy such returned Marketed Product and invoice the other party for the reasonable cost of destruction. Each such invoice	Section 8.19 Differentiation of Products. Not later than three (3) months following the Closing, Purchaser shall use commercially reasonable efforts to ensure that Marketed Products manufactured, finished or sold by, or on behalf of, Purchaser bear an NDC code different than that used by the Sellers for the Marketed Products.

Bankruptcy Entity Seller	Relevant Provisions		
	record keeping or reporting requirements of the FDA, the DEA, the Occupational Safety and Health Administration or any other Governmental Body, including, but not limited to, FDA warning letters, FDA Notices of Adverse Finding Letters, FDA audit reports (including any comments on such reports), all other correspondence and communications with regulatory agencies in connection with such Product . . . adverse event files, complaint files and manufacturing records."	shall set forth information as shall be necessary to support the invoice. Sellers and Purchaser shall, within thirty (30) days of such party's receipt of invoice, pay the other party for the full invoiced amount. Notwithstanding anything else contained herein, if either Purchaser or Sellers issue financial credit or other reimbursement for returned Marketed Products and related administrative fees for which the other party was financially responsible as set forth in this Section S.Mfal. such party shall invoice the other party for such amount setting forth information as shall be reasonably necessary to support the invoice. Purchaser and Sellers shall, within thirty (30) days of Purchaser's or Sellers' receipt of invoice, pay the other party for the full invoiced amount. (iii) Neither Purchaser nor Sellers shall encourage Marketed Product returns or accept Marketed Product returns outside of its normal course of business without the prior written approval of the other party. Sellers shall be financially responsible for all rebates pursuant to any rebate programs, including government rebate programs, with respect to claims for the Marketed Products dispensed (the dispense date contained in any report from a rebate program shall be used for purposes of determining the date of such rebate) on or before thirty (30) days after the Closing Date; provided, however, that Sellers' financial obligation for such rebates shall terminate one-hundred eighty (180) days after the Closing Date (the ^Rebates Termination Date"1!. Purchaser shall assume financial responsibility for all rebates pursuant to any such rebate programs with respect to claims for the Marketed Products dispensed after the Rebates Termination Date, Purchaser and Sellers acknowledge that	

Bankruptcy Entity Seller	Relevant Provisions		
	Section 1.1 defines "Permits" as "any approvals, authorizations, consents, licenses, permits or certificates."	government rebates are billed on a calendar quarter basis and to the extent that the periods set forth in this Section 8.14(b) do not end on a calendar quarter, the Purchaser and Seller shall make payments for such fractional periods of any applicable quarter on a pro-rata basis based on the number of days for which such party is responsible for rebates in the applicable quarter. Purchaser acknowledges that Sellers will require certain information from Purchaser in order to calculate the Medicaid rebate for Marketed Products bearing Sellers' NDC number. Accordingly, Purchaser agrees that, from and after the Closing Date until the date which is one (1) calendar year after the expiration date of the last lot of Marketed Products produced with Sellers' NDC number, Purchaser will provide to Sellers, concurrently with its timely delivery of related information to the Centers for Medicare and Medicaid Services (or any successor agency), the following information: (a) the "best price" (as defined under the Social Security Act, 42 U.S.C. Section 1396r8(c)(l)(C)) for each Marketed Product identified by NBC number, (b) on the twentieth (2001) day after the end of each calendar quarter during such one (1) year period, all information reasonably necessary for Sellers to calculate the "average manufacturer price" (as defined under the Social Security Act, 42 U.S.C. Sections 1396r-8(k)(l)) for each Marketed Product identified by NBC number, and (c) any additional data or other information related to such Medicaid issues reasonably requested by Sellers.	

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Oscient Pharmaceuticals (Bankr. D. Mass. 2009) (Case No. 09-16576) (Docket No. 438)	Section 7.8.4. Product Responsibility. Subject to Section 7.11, from and after the Closing, Buyer shall be responsible for conducting, handling, or processing, all voluntary and involuntary recalls of units of Product, including recalls required by any Governmental Body, regardless of whether such Product was sold before or after the Closing.	Section 7.8.5 Product Responsibility. As soon as practicable following the Closing Date, Buyer shall use commercially reasonable efforts to obtain a new National Drug Code Number ("NDC Number") for the Product and thereafter shall cause such NDC Number to be used on the labeling and packaging for Product manufactured or packaged after receipt of the new NDC Number. During the ninety (90) day period following the Closing Date, Buyer shall be permitted to sell Inventory that that are finished goods (i.e., goods that are fully packaged and ready for immediate sale) as of the Closing Date bearing the Number that that is affixed thereon. Following the expiration of such 90 day period. Buyer shall not sell Product bearing Seller's NDC Number that that is not accompanied by an "over-label," "sticker" or packaging insert containing disclosure substantially similar to the: following: "Manufactured by Ethypharm S.A. for Akrimax Pharmaceuticals, LLC. Distributed and marketed by Akrimax Pharmaceuticals, LLC. For product information 1- 999-383-1733." Following the Closing, Buyer shall have no right to manufacture or have manufactured or	Section 7.5 Product Returns, Rebates, Chargebacks, and Vouchers. (a) Government Rebates. (i) The Seller acknowledges that the Purchaser will require certain information and cooperation from the Seller to meet its obligations with regard to pricing and calculating the rebates pursuant to any governmental rebate program ("Government Rebates") for Products bearing NDC numbers of the Seller or any of its Affiliates. Accordingly, from and after the Closing Date until the date that is one calendar year after the expiration date of the last lot of each Product produced with any NDC number of the Seller, the Seller shall provide the Purchaser cooperation and assistance in connection with appropriately submitting to the Centers for Medicare and Medicaid Services, the following information: (A) the Best Price for each Product identified by NDC number; (B) the "average manufacturer price" (as defined under the Social Security Act, 42 U.S.C. § 1396r-8(k)(l)) ("AMP"") for each Product identified by the NDC number, (C) all data used by the Purchaser or the Seller to calculate the AMP and Best Price for

Bankruptcy Entity Seller	Relevant Provisions		
		package or have packaged any Product that that is labeled with a Seller NDC Number.	each Product identified by NDC number; and (D) any additional pricing and/or claims data or other information related to such Medicaid issues reasonably requested by the Purchaser. Without limiting the generality of the foregoing, or being limited thereby, after the Closing, the Purchaser shall make all appropriate filings and submissions with the Centers for Medicare and Medicaid Services in regard to all Government Rebates for Products dispensed prior to the Effective Time for which such filings or submissions have not previously been made by the Seller, including any filings covering Products dispensed in any partial calendar quarter period leading up the Closing Date.

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Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
Middlebrook Pharmaceuticals (Bankr. D. Delaware 2010) (Case No. 10-11485-MFW) (Docket No. 64)	Exhibit A Definitions. "NDC" means the "National Drug Code", which is the eleven digit code registered by a company with the FDA with respect to a pharmaceutical product "Product Records" is defined to include "documentation or records . . . relating to any Product or any Business or any of the foregoing: (i) any and all data and correspondence supporting and/or utilized or made in connection with obtaining and/or maintaining any of the Regulatory Filings and Approvals and/or the drug master file for the Product; . . . (vii) all books and records owned by the Seller relating to either or both of the Products, including copies of all customer and supplier lists, account lists, call data, sales history, call notes, research data, marketing studies, consultant reports, physician databases, and correspondence (including invoices) with respect to either or both of the Products, and all complaint files and adverse event reports and files; . . ." "Purchased Assets" includes "the Product Records (including any intangible rights in and to the Product Records" Section 2.2(a) of the APA provides that "At the Closing, the Seller shall deliver or cause to be delivered to the Purchaser: . . . (x) all tangible Product Records, at the Purchaser's sole cost and expense; . . ."	Section 7.5 Product Returns, Rebates, Chargebacks, and Vouchers. (a) Government Rebates. (i) The Seller acknowledges that the Purchaser will require certain information and cooperation from the Seller to meet its obligations with regard to pricing and calculating the rebates pursuant to any governmental rebate program ("Government Rebates") for Products bearing NDC numbers of the Seller or any of its Affiliates. Accordingly, from and after the Closing Date until the date that is one calendar year after the expiration date of the last lot of each Product produced with any NDC number of the Seller, the Seller shall provide the Purchaser cooperation and assistance in connection with appropriately submitting to the Centers for Medicare and Medicaid Services, the following information: (A) the Best Price for each Product identified by NDC number; (B) the "average manufacturer price" (as defined under the Social Security Act, 42 U.S.C. § 1396r-8(k)(l)) ("AMP"") for each Product identified by the NDC number, (C) all data used by the Purchaser or the Seller to calculate the AMP and Best Price for each Product identified by NDC number; and

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
		(D) any additional pricing and/or claims data or other information related to such Medicaid issues reasonably requested by the Purchaser. Without limiting the generality of the foregoing, or being limited thereby, after the Closing, the Purchaser shall make all appropriate filings and submissions with the Centers for Medicare and Medicaid Services in regard to all Government Rebates for Products dispensed prior to the Effective Time for which such filings or submissions have not previously been made by the Seller, including any filings covering Products dispensed in any partial calendar quarter period leading up the Closing Date.

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
Graceway Pharmaceuticals (Bankr. D. Delaware 2011) (Case No. 11-13036-KJC) (Docket No. 306)	Section 8.4 Rebates, Chargebacks and Returns. (a) On or following the Closing, Buyer shall take all actions necessary to obtain its own NDC Numbers and any other license number, code or other similar reference required for the distribution, marketing, and sale of each Product by Buyer in the United States (collectively, "Buyer Required Code"). Such actions shall include labeling all Product inventory acquired by Buyer in the United States pursuant to this Agreement with Buyer's Buyer Required Code, as applicable, such that all sales of Product by Buyer in the United States are tracked with Buyer Required Code. Buyer will not sell or otherwise transfer any Products in the United States that have a label or packaging that includes any Seller NDC Number. On or following the Closing, Buyer shall take all necessary actions, including, without limitation, completion of the filings and submissions contemplated by Section 8.5. to have the current DIN for each Product in Canada assigned to Buyer and Canadian Seller shall agree to such assignments. Each party hereby agrees and undertakes to provide to the other party copies of all written notices and information filed or delivered by such party to Health Canada in furtherance of the foregoing. For greater certainty, subject to compliance with the filing requirements contemplated by Section 8.5(a) from and after the Closing, Buyer may sell or transfer Products in Canada bearing the current DIN for each Product in Canada, and Buyer shall not be required to obtain a new DIN for each such Product, except for Products that received a DIN prior to September 1994 and have not been notified. (b) As promptly as practicable following the Closing, Sellers and Buyer will issue a joint letter to customers of the Products, advising such customers of Sellers' and Buyer's responsibilities in	Section 8.5 Transfer of Regulatory Matters. Promptly after the Closing and in any event within thirty (30) days after the Closing, Sellers and Buyer shall make all appropriate filings and submissions with Governmental Authorities, including but not limited to, the Centers for Medicare & Medicaid Services, the FDA and Health Canada, to register NDC Numbers and DINs and transfer all regulatory responsibilities, excluding all Excluded Liabilities, attaching thereto of each Product, from Sellers to Buyer.

Bankruptcy Entity Seller	Relevant Provisions	
	connection with returns and credits. Sellers shall be responsible only for returned Product that bears Sellers' NDC Number or as evidenced as being sold by Sellers prior to the Closing by lot number or otherwise, provided that, any processing of returns of Product shall be in compliance with Sellers' return policy. Buyer shall be responsible only for returned Product that bears the Buyer's NDC Number or as evidenced as being sold by Buyer on or after the Closing Date by lot number or otherwise, provided that, any such returns of Product shall be in compliance with Buyer's then current return policy. Notwithstanding the foregoing, if Product returns in Canada involve a split lot of Product, a portion of which was sold by Canadian Seller prior to the Closing and a portion of which was sold by Buyer after the Closing, Buyer shall be responsible for returns of all Product from such split lot. Neither Sellers nor Buyer shall take any action to encourage or delay return of any Product. If Sellers or Buyer receive a Product for which the other was responsible as set forth in Section 8.4(b) that party shall ship the returned Product to the responsible party at the expense of the responsible party, together with such information as is necessary to support the return. All payments due to Sellers from Buyer or due to Buyer from Sellers under this Section 8.4(b), shall be made within 30 days of submission to the responsible party of invoices that describe the requested payment in reasonable detail.	

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Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions
Dendreon (Bankr. D. Delaware 2015) (Case No. 14-12515-LSS) (Docket No. 410)	Section 5.19 NDC Code. To the extent not transferred as part of the Acquired Assets, the Sellers hereby grant, effective as of the Closing Date, to the Purchaser (and the Purchaser's Affiliates) a royalty-free, paid-up license under the Sellers' NDC numbers used in connection with the Business (including the NDC number for the biologic Provenge) to the extent necessary to allow the Purchaser and its Affiliates and their designees to market, distribute and sell the inventory acquired as part of the Acquired Assets and any additional inventory bearing such NDC numbers.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions			
Synergy Pharmaceuticals (Bankr. S.D.N.Y. 2018) (Case No. 18-14010) (Docket No. 484)	Section 1.3. Assumed Liabilities. 1.3(d) (i) all current accounts payable (and excluding any noncurrent accounts payable) as to which any of the Sellers is responsible or liable and which are owed by any of the Sellers as of the Closing, in each case to the extent such amounts are in respect of (1) manufacturing costs related to Inventory, but excluding any payables related to API (including related to any purchases of API pursuant to Section 5.23) which shall be deemed to be a Cure Cost, or (2) accrued liabilities as of the Closing Date for research and development related to the Products up to $312,000 and (ii) all claims related to or	Section 3.18 Healthcare Regulatory Matters (a) Section 3.18(a) of the Seller Disclosure Schedule sets forth a true and complete list, as of the date of this Agreement, and the Sellers have made available to the Purchaser true and complete copies of, all Regulatory Authorizations from the FDA, the EMA and all other applicable Regulatory Authorities held by the Sellers relating to the Products and/or necessary to conduct the Business. All such Regulatory Authorizations are (i) in full force and effect, (ii) validly registered and on file with applicable Regulatory Authorities, (iii) in compliance with all material filing and maintenance requirements, and (iv) in good standing, valid and enforceable. Each Seller has fulfilled and performed all of its material obligations with respect to such Regulatory Authorizations, and no event has	Section 5.17 Use of Names and Marks The Purchaser and its Affiliates acknowledge and agree that, notwithstanding the transfer of Intellectual Property included in the Acquired Assets, (a) the Sellers will continue using their current corporate names during the pendency of the Chapter 11 Case and any additional time during which the Sellers wind down their affairs, and (b) the Sellers shall be entitled to refer to names and marks included in the Acquired Assets in filings with Governmental Entities, for factual or historical reference and for any other purposes that do not constitute trademark infringement and are not	Section 5.19 Transfer of Regulatory Matters As promptly as practicable after the Closing, Sellers and the Purchaser shall file with the FDA and any other applicable Governmental Entity the notices and information required pursuant to any applicable regulation or requirement to transfer the Regulatory Authorizations from the Sellers to the Purchaser. The parties also agree to use all commercially reasonable efforts to take any and all other actions required by the FDA and any other applicable Governmental Entity to effect the transfer of the Regulatory

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions			
	arising from rebates, coupon programs, chargebacks and credits;	occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof. Except as have not had and would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, (x) each Seller has filed, maintained or furnished with the applicable Regulatory Authorities all required filings, declarations, listings, registrations, submissions, amendments, modifications, notices and responses to notices, applications and supplemental applications, reports (including all adverse event/experience reports) and other information (collectively, the "Health Care Submissions") with the FDA, the EMA and all other applicable Regulatory Authorities and (y) all such Health Care Submissions were complete and accurate and in compliance with applicable Health Laws when filed (or were corrected or completed in a	otherwise prohibited by applicable Law. Section 5.18 NDC Code (a) To the extent not transferred as part of the Acquired Assets, the Sellers hereby grant, effective as of the Closing Date, to the Purchaser (and the Purchaser's Affiliates) a royalty-free, paid-up license under the Sellers' NDC numbers used in connection with the Business to the extent necessary to allow the Purchaser and its Affiliates and their designees to market, distribute and sell the inventory acquired as part of the Acquired Assets. (b) To the extent necessary to enable the	Authorizations from the Sellers to the Purchaser.

Bankruptcy Entity Seller	Relevant Provisions			
		subsequent filing). (b) (i) Each Seller is in material compliance with all applicable Health Laws that affect the Business, Products, properties, assets and activities of such Seller, (ii) as of the date of this Agreement, no Seller has received any written notice or written communication from any Regulatory Authority (A) withdrawing or placing any of the Products on "clinical hold" or requiring the termination or suspension or investigation of any pre-clinical studies or clinical trials of the Products or (B) alleging any material violation of any Health Law and (iii) there are no investigations (except routine audits), suits, claims, actions or proceedings pending, or to the Knowledge of the Sellers, threatened against any Seller with respect to any of the Products or alleging any violation by a Seller or the Products of any such	Sellers to comply with U.S. Government Pricing and Compliance submission requirements related to the Acquired Assets, the Purchaser shall use its reasonable best efforts to provide to the Sellers the following information: (i) within twenty-five (25) days after the end of each calendar quarter, (A) the Non- Federal Average Manufacturer's Price for each Product identified by NDC, (B) the "average manufacturer price" (as defined under the Social Security Act, 42 U.S.C. Sections 1396r-8(k)(l)) and units for each Product identified by NDC and (C) the "best price" (as defined under the Social Security Act, 42 U.S.C. Sections 1396r-8(c)(1)(C)) for each	

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions			
		Health Law. (c) All pre-clinical studies and clinical trials conducted or being conducted with respect to the Products by or at the direction of any Seller have been and are being conducted in material compliance with the required experimental protocols, procedures and controls, and all applicable Health Laws and Information Privacy and Security Laws. No clinical trial conducted by or, on behalf of, any Seller has been terminated or suspended by any Regulatory Authority and no Seller has received any written notification or other written communication from any institutional review board, ethics committee or safety monitoring committee raising any issues that may result in a clinical hold or otherwise delay or materially restrict any clinical studies proposed or currently conducted by, or on behalf of, a Seller, or in which a Seller has participated	Product identified by NDC, (ii) within twenty-five (25) days after the end of each calendar month, the "average manufacturer price" (as defined under the Social Security Act, 42 U.S.C. Sections 1396r-8(k)(l)) and units for each Product identified by NDC and (iii) any other information reasonably requested by the Sellers to allow the Sellers to comply with such requirements, and, in each case, a certification to the best of the Purchaser's knowledge of the accuracy and completeness thereof (subject to any updates of the information included in such certification) in all material respects, within ten (10) days after BH publicly announces its	

Bankruptcy Entity Seller	Relevant Provisions			
		and, to the Knowledge of the Sellers, no such action has been threatened against any Seller. With respect to each Product, the Sellers have made available to the Purchaser complete and accurate copies of all material clinical and preclinical data in the possession of the Sellers and all material written correspondence that exists as of the date hereof between any of the Sellers and the applicable Regulatory Authorities (including letters, memoranda and emails).	quarterly financial results; provided, that the Purchaser's obligations pursuant to this Section 5.18(b) shall expire thirty (30) days after the end of the calendar quarter in which the Purchaser suspends its usage of the Sellers' NDC numbers in connection with the Business.	

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions				
Aralez Pharmaceuticals (Bankr. S.D.N.Y. 2018) (Case No. 18-12425) (Docket No. 144)	1.1.59 "Excluded Liabilities" means all Liabilities of Seller or any of its Affiliates other than the Assumed Liabilities. For the avoidance of doubt, Excluded Liabilities shall include (a) (i) Liabilities relating to Taxes of Seller or any of its Affiliates for any Tax period, (ii) Taxes relating to the Purchased Assets or the Product Business attributable to periods ending on or prior to the Closing Date, *provided* that Apportioned Obligations shall be allocated between Buyer and Seller as provided in Section 5.10.1 hereof, and (iii) Taxes for which Seller or any of its Affiliates is liable by reason of being or having been	Section 3.1.15 Regulatory Matters (a) Seller, or an Affiliate of Seller, possesses all material licenses, franchises, permits, certificates, approvals or other similar authorizations issued by applicable Governmental Authorities and affecting or relating to the operation of the Product Business, including the Purchased Regulatory Approvals and associated Regulatory Submissions. The Purchased Regulatory Approvals are valid and are in full force and effect, and none of the Purchased Regulatory Approvals will be terminated as a result of the transactions	4.1 Ordinary Course of Business. 4.1.1.(f) other than in the Ordinary Course of Business (A) offer any rebates, discounts, promotions or credits, to customers with respect to the Product (solely in the Territory), or (B) make any change to any promotional programs or in the manner in which Seller generally extends rebates, discounts or credit to, or otherwise similarly deal with, customers with respect to the Product (solely in the Territory);	Section 5.6 Regulatory Transfers Buyer and Seller shall (a) cooperate with one another and use their respective commercially reasonable efforts to complete, execute and file with the applicable Governmental Authorities all documentation required to effect the transfer of the Purchased Regulatory Approvals as soon as reasonably practicable following the Closing; and (b)	Section 5.7 Regulatory Responsibilities 5.7.1 NDC. Promptly following the date hereof, Buyer shall initiate the process to obtain its own NDC for the Product and shall have in place all reasonable resources such that sales of the Product in the Territory can be accomplished under the NDCs of Buyer. Following the Closing Date, Buyer and its Affiliates shall be permitted to distribute or sell any Product in the

Bankruptcy Entity Seller	Relevant Provisions				
	part of a consolidated, combined, unitary or similar Tax group, or as a transferee or successor, or under any Contract or otherwise; (b) all Liabilities arising out of claims, including product liability or similar claims, of Third Parties in respect of the marketing, promotion or sale of the Product (whether or not defective) prior to the Closing, or the use after the Closing of any Product sold prior to the Closing, all Liabilities relating to any returns, rebates or chargebacks of any unit of Product sold prior to Closing, and all Liabilities arising out of claims of Third Parties due to or relating to any recall of any unit of Product sold prior to Closing,	contemplated by this Agreement. As of the Execution Date, no proceeding is pending or, to Seller's Knowledge, threatened regarding the validity, withdrawal, material modification or revocation of any Purchased Regulatory Approval. As of the Execution Date, neither Seller nor its Affiliates has received any written communication from any Governmental Authority threatening to withdraw, materially modify or suspend any Purchased Regulatory Approval. Neither Seller nor any of its Affiliates is in material violation of the terms of any Purchased Regulatory Approval. Seller, or an Affiliate of Seller, has completed		without limiting the foregoing, promptly file the Buyer FDA Transfer Letter and the Seller FDA Transfer Letter, respectively, with FDA. Transfer of title to the Purchased Regulatory Approvals and associated Regulatory Submission shall be effective as of the Closing. For clarity, Buyer shall be responsible for all reasonable out-of-pocket costs incurred in connection with any regulatory transfers contemplated in	Territory labeled with Seller's NDC until such Product has been sold in full. 5.7.2 Other Regulatory Responsibilities. Except as required by a Party to comply with applicable Law or to exercise its rights and obligations hereunder or under any Ancillary Agreement, from and after the Closing, Buyer shall have the sole right and responsibility for (and shall bear the cost of) preparing, obtaining and maintaining all

Bankruptcy Entity Seller	Relevant Provisions				
	including all Liabilities for any credits, rebates, refunds or other amounts payable in respect of any such recalled unit of Product; (c) all Liabilities arising out of, resulting from, or relating to any Excluded Assets; (d) all accrued receipts and Accounts Payable arising out of the operation or conduct of the Product Business prior to the Closing, *provided* that nothing in this clause (d) affects any obligation hereunder to pay any Cure Costs; (e) all indebtedness of Seller and its Affiliates; (f) all Liabilities arising out of, resulting from, or relating 18-12425-mg Doc 674 Filed 05/07/19 Entered 05/07/19 15:25:40 Main	and filed all material reports, documents, claims, Permits, fees and notices required by any Governmental Authority to maintain the Purchased Regulatory Approvals. Neither Seller nor, to Seller's Knowledge, any director, officer, employee, or agent of Seller or an Affiliate of Seller has made an untrue statement of a material fact or fraudulent statement to the FDA, failed to disclose a material fact required to be disclosed to the FDA, or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to		this Section 5.6 and in Section 5.7, including costs arising from procurement of certain ancillary documents, registration file transfer, document transfer, archive copying and document legalization.	Regulatory Approvals, and for conducting communications with Governmental Authorities of competent jurisdiction, for the Subject Products in the Territory.

Bankruptcy Entity Seller	Relevant Provisions				
	Document Pg 33 of 116 7 US_138272717v12 to any unit of Product sold prior to the Closing or the Purchased Assets to the extent arising prior to the Closing; (g) all Liabilities related to any employee or other service provider of Seller and its Affiliates; and (h) any Liabilities in respect of Cure Costs in excess of the Cure Costs Cap.	invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (Sept. 10, 1991). With respect to the Product, Seller is in compliance in all material respects with the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder, and any state Laws in the United States that apply to the manufacture, development, testing, safety, efficacy approval, marketing, sale, promotion, distributions, import or export of pharmaceutical products			

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions				
		("Pharmaceutical Laws"). Neither Seller nor any of its Affiliates has received any written, or, to Seller's Knowledge, other notice from the FDA or any other Governmental Authority alleging noncompliance with any Pharmaceutical Law.			

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Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Sancilio Pharmaceuticals (Bankr. D. Del. 2018) (Case No. 18-11333) (Docket No. 156)	Section 3.6 Compliance with Laws; Permits and Licenses (a) Except as disclosed on Schedule 3.6(a) of the Seller Disclosure Schedule, each Seller is. and since February 1, 2016 has been, and, to the Knowledge of the Sellers, each counterparty to any Contract to which any Seller is a party is and since February I, 2016 has been, in compliance with all Laws, Orders, ordinances, decrees, rules or regulations of any Governmental Authority applicable to such Seller, the Business or the Purchased Assets, except such noncompliance which has not had, and would not reasonably be expected to have, a Material Adverse Effect. There is no Order of any arbitrator or Governmental Authority outstanding relating to any Seller, the Purchased Assets or the conduct of the Business that is material to the Business. Except as set forth on Schedule 3.64) of the Seller Disclosure Schedule, since February I, 2016. no Seller has received any written notice from a Governmental Authority of any Proceeding, inquiry, investigation, violation or alleged violation of any Laws or Orders related to such Seller, the Business or the Purchased Assets. (b) Each Seller has in effect all Governmental Authorizations necessary to conduct the Business in all material respects as it is currently being conducted in accordance with the Laws of any Governmental Authority having jurisdiction over its properties or activities, except for any such failure to obtain a Pennit that has not had, and would not reasonably be expected to have, a Material	Section 3.13 Products Except as would not be material to the Business: (a) each of the products produced, marketed or sold by the Business is, and at all times up to and including the sale thereof has been. (i) in compliance in all respects with all Laws and the specifications and standards contained in the applicable Governmental Authorization under which such products are sold and (ii) fit for the ordinary purposes for which it is intended to be used; and (b) there is no design defect with respect to any of such products and each of such products contains adequate warnings, presented in a reasonably prominent manner, in	Section 3.14 Inventory Except as would not be material to the conduct of the Business: (a) the Purchased Inventory consists of a quality and quantity usable and salable in the ordinary course of business consistent with past practice; (b) the quantities of Purchased Inventory, taken as a whole, arc consistent with past practice of the Sellers; (c) to the Knowledge of the Sellers. no previously sold inventory is subject to returns in excess of those historically experienced by any Seller; and (d) the Purchased Inventory is not damaged (due to failure to store at the requisite temperature or

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
	Adverse Effect. ,Schedule 2.l(fl sets forth all Governmental Authorizations held by each Seller (it being understood that, subject to Section 5.4 and Section. 112 it shall be the sole and exclusive obligation of the Purchaser to obtain any Permits necessary for future operations, provided that the Sellers shall provide commercially reasonable assistance regarding the transfer of such Permits unless otherwise agreed by Purchaser, except that the failure of the Sellers to include a Governmental Authorization on Schedule 2.1(D shall not be a breach of this Section 3.6(b1 to the extent that such failure has not had, and would not reasonably be expected to have, a Material Adverse Effect. All Governmental Authorizations held by each Seller are in full force and effect and are validly held by such Seller, and such Seller has, and, to the Knowledge of the Sellers each counterparty to any distributor Contract to which such Seller is a party has, complied with all terms and conditions thereof in all material respects. All material fees and charges due and payable with respect to the Governmental Authorizations held by the Sellers have been paid in full. Each Seller is the sole and exclusive owner of its Governmental Authorizations related to the manufacture, production, marketing, commercialization, promotion, distribution and/or sale of products of the Business.	accordance with Laws and current industry practice with respect to its contents and use. No Seller has issued or received written notice of any material recalls, field notifications, investigator notices, safety alerts, serious adverse event reports or other notices of action relating to an alleged lack of safety or regulatory compliance with respect to any such products.	otherwise), recalled or incorrectly packaged or labeled.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Orexigen Therapeutics (Bankr. D. Del. 2018) (Case No. 18-10518) (Docket No. 231)	Section 3.6 Compliance with Laws; Permits and Licenses (a) Except as disclosed on Schedule 3.6(a) of the Seller Disclosure Schedule, each Seller Company is, and since January 1, 2015 has been, and, to the Knowledge of the Seller each countelparty to any distributor Contract to which any Seller Company is a party is and since January I, 2015 has been, in compliance with all Laws, Orders, ordinances, decrees, rules or regulations of any Governmental Authority applicable to such Seller Company, the Business or the Purchased Assets, except such noncompliance which has not had, and would not reasonably be expected to have, a Material Adverse Effect. There is no Order of any arbitrator or Governmental Authority outstanding relating to any Seller Company, the Purchased Assets or the conduct of the Business that is material to the Business. Except as set forth on Schedule 3.6(a) of the Seller Disclosure Schedule, since January I, 2015, no Seller Company has received any written notice from a Governmental Authority of any Proceeding, inquiry, investigation, violation or alleged violation of any Laws or Orders related to such Seller Company, the Business or the Purchased	Section 3.13 Products Except as would not be material to the Business: (a) each of the products produced, marketed or sold by the Business is. and at all times up to and including the sale thereof has been, (i) in compliance in all respects with all Laws and the specifications and standards contained in the applicable Governmental Authorization under which such products are sold and (ii) fit for the ordinary purposes for which it is intended to be used; and (b) there is no design defect with respect to any of such products and each of such products contains adequate warnings, presented in a reasonably prominent manner, in accordance with Laws and current industry practice with respect to its contents and use. Since January I, 2015, no Seller Company has issued or received written notice of any	Section 5.17 Transfer of Permits and Governmental Authorizations. From and after the date hereof, the Seller, on the one hand (subject to the availability of funds for such purpose), and the Purchaser, on the other hand, shall, and shall cause their respective Affiliates to, reasonably cooperate to transfer to Purchaser as of the Closing (or as soon as reasonably practicable thereafter) all Governmental Authorizations included in the Purchased Assets necessary for the import, manufacture, distribution, marketing and salt by the Purchaser of the products of the Business under applicable Law, provided that (a) any reasonable, documented out-of-pocket costs associated with such cooperation by the Seller

Bankruptcy Entity Seller	Relevant Provisions		
	Assets. (b) Each Seller Company has in effect all Governmental Authorizations necessary to conduct the Business in all material respects as it is currently being conducted in accordance with the Laws of any Governmental Authority having jurisdiction over its properties or activities, except for any such failure to obtain a Permit that has not had, and would not reasonably be expected to have, a Material Adverse Effect. Schedule 2.1(f) sets forth all Governmental Authorizations held by each Seller Company (it being understood that, subject to Section 5.4 and Section 5.17 it shall be the sole and exclusive obligation of the Purchaser to obtain any Permits necessary for future operations, provided that the Seller shall provide commercially reasonable assistance regarding the transfer of such Permits unless otherwise agreed by Purchaser), except that the failure of the Seller to include a Governmental Authorization on Schedule 2.1(1) shall not be a breach of this Section 3.6(b) to the extent that such failure has not had, and would not reasonably be expected to have, a Material Adverse Effect. All Governmental Authorizations held by each Seller Company are in full force and effect and are validly held by such Seller Company. and such Seller Company has, and, to	material recalls, field notifications. investigator notices, safety alerts, serious adverse event reports or other notices of action relating to an alleged lack of safety or regulatory compliance with respect to any such products. Section 3.14 Inventory Except as would not be material to the conduct of the Business: (a) the Purchased Inventory consists of a quality and quantity usable and salable in the ordinary course of business consistent with past practice; (b) the quantities of Purchased Inventory, taken as a whole, arc consistent with past practice of the Seller, (c) to the Knowledge of the Seller, no previously sold inventory is subject to returns in excess of those historically experienced by any Seller Company; and (d) the Purchased Inventory is not damaged (due to failure to	after the Closing (including the pro rata portion of the costs of any employee directly providing such cooperation after the Closing, as determined by the amount of time dedicated by such employee to such cooperation as a proportion of all time dedicated by such employee to the Seller) shall be borne by the Purchaser and (b) nothing in this Section shall be deemed to require the Seller to remain a debtor in the Chapter I I Case or maintain its corporate existence for any period of time beyond 30 days after the Closing Date• provided that the foregoing shall not be deemed to require the Seller to take any action in violation of the DIP Loan Agreement.

Bankruptcy Entity Seller	Relevant Provisions		
	the Knowledge of the Seller each counterparty to any distributor Contract to which such Seller Company is a party has, complied with all terms and conditions thereof in all material respects. All material fees and charges due and payable with respect to the Governmental Authorizations held by each Seller Company have been paid in full. The Seller is the sole and exclusive owner of any Governmental Authorization solely related to the manufacture, production, marketing, commercialization, promotion, distribution and/or sale of products of the Business.	store at the requisite temperature or otherwise), recalled or incorrectly packaged or labeled.	

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Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
Melinta Therapeutics (Bankr. D. Del. 2019) (Case No. 19-12748) (Docket No. 67)	"NDA" means a new drug application for a drug submitted to the FDA pursuant to 21 C.F.R. Part 314 (as amended from time to time), and all amendments or supplements thereto, including all documents, data and other information concerning the applicable drug which are necessary for FDA approval to market such drug in the United States, and any equivalent application submitted to any other Regulatory Authority outside of the United States, and all supplements, amendments, variations, extensions and renewals thereof that may be submitted with respect to the foregoing. "Regulatory Authority" means any national or supranational Governmental Entity including the FDA or the EMA, with responsibility for granting any license, registrations or approvals with respect to the Products. "Regulatory Authorizations" means any approvals, clearances,	Section 5.19 FDA and Healthcare Regulatory Matters (a) (i) Each of the Company and its Subsidiaries is in material compliance with all applicable Health Laws that affect the Business, Products, properties, assets and activities of the Company or such Subsidiary, as applicable; (ii) as of the date of this Agreement, none of the Company or any of its Subsidiary has received any written notice from any Regulatory Authority (A) withdrawing any Regulatory Authorization for any of the Products or (B) alleging any material violation of any Health Law; (iii) there are no Governmental Entity investigations (except routine audits), suits, claims, actions or proceedings pending, or to the Knowledge of the Debtors, threatened against the Company or any of its Subsidiaries with respect to any of the Products or alleging any violation by the Company or any of its Subsidiaries or the Products of any such Health Law; (iv) there is no act, omission, event, or circumstance of which the Company and its Subsidiaries have knowledge that would reasonably be expected to give rise to or form the basis for any civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, untitled letter, proceeding or request for information or any liability (whether actual or contingent) for failure to comply with Health Laws; and (v) neither the Company nor its Subsidiaries, nor, to the Knowledge of the Debtors, any director, officer, employee or contractor of the Company or its Subsidiaries, has made any voluntary self-disclosure to any Governmental Entity regarding any potential material non-compliance with any applicable Health Law. (b) Each of the Company and its Subsidiaries holds all Regulatory Authorizations required under any applicable Health Law to research, develop, test, manufacture, handle, label, package, store, supply, promote,

Bankruptcy Entity Seller	Relevant Provisions	
	authorizations, registrations, certifications, licenses and permits granted by any Regulatory Authority, including any INDs, NDAs and any equivalent thereof granted by any Regulatory Authority outside of the United States.	distribute, market, commercialize, import, export, and sell the Products and otherwise conduct Business as presently conducted. With respect to such Regulatory Authorizations, (i) all are in full force and effect, (ii) all are in good standing, valid and enforceable, (iii) all applications, modifications, submissions, information, reports, statistics, data, and other conclusions utilized as the basis for the Regulatory Authorizations are true, complete, and correct in all material respects and (iv) any necessary or required updates, changes, corrections or modifications to such Regulatory Authorizations have been submitted to the applicable Regulatory Authorities. The Company has made available to the Supporting Lenders true and complete copies of all active and pending Regulatory Authorizations submitted by the Company and its Subsidiaries to any Regulatory Authority relating to the Products and/or necessary to research, develop, test, manufacture, handle, label, package, store, supply, promote, distribute, market, commercialize, import, export, and sell the Products and otherwise conduct Business as presently conducted. (c) The Products have been researched, developed, tested, manufactured, handled, labeled, packaged, stored, supplied, promoted, distributed, marketed, commercialized, imported, exported, and sold by or on behalf of the Company and its Subsidiaries, as applicable, in material compliance with all applicable Health Laws. (d) All pre-clinical studies and clinical trials conducted or being conducted with respect to the Products by, or on behalf of, the Company or any of its Subsidiaries have been and are being conducted in material compliance with the FDA's Good Clinical Practices and Good Laboratory Practices requirements, including regulations under 21 C.F.R. Parts 50, 54, 56, 58 and 312, and applicable guidance documents, as amended from time to time, the

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
		Animal Welfare Act, all applicable similar Health Laws in other jurisdictions, all Health Laws relating to protection of human subjects, and the required experimental protocols, procedures and controls. No clinical trial conducted by, or on behalf of, the Company or any of its Subsidiaries has been terminated or suspended by any Regulatory Authority and neither the Company nor any of its Subsidiaries has received any notifications or other communications from the FDA, any other Regulatory Authority, any institutional review board, ethics committee or safety monitoring committee raising any issues that would reasonably result in a clinical hold or that would otherwise reasonably be expected to delay or materially restrict any clinical studies proposed or currently conducted by, or on behalf of, the Company or any of its Subsidiaries, or in which the Company or any of its Subsidiaries has participated and, to the Knowledge of the Debtors, no such action has been threatened against the Company or any of its Subsidiaries. With respect to each Product, the Company has made available to the Supporting Lenders complete and accurate copies of all material clinical and preclinical data in the possession of the Company and its Subsidiaries and all material written correspondence that exists as of the date of this Agreement among the Company or any of its Subsidiaries and the applicable Regulatory Authorities (including letters, memoranda and emails). (e) None of the Company, its Subsidiaries or, to the Knowledge of the Debtors, any Person acting on the Company's or ay of its Subsidiaries' behalf (including a contract manufacturer for the Products) has, with respect to any Product, (i) been subject to a Regulatory Authority shutdown, restriction, or import or export prohibition or (ii) since January 5, 2018, received any FDA Form 483, or other written Regulatory Authority notice of inspectional observations, "warning letters," "untitled letters" or requests or requirements to make changes to the Products that if not complied with

Bankruptcy Entity Seller	Relevant Provisions	
		would reasonably be expected to have a material effect on the Company and its Subsidiaries, or similar correspondence or notice from any Regulatory Authority alleging or asserting noncompliance with any applicable Law. (i) The Company and its Subsidiaries have maintained records relating to the research, development, testing, manufacture, handling, labeling, packaging, storage, supply, promotion, distribution, marketing, commercialization, import, export, and sale of the Products in material compliance with applicable Health Laws, and the Company and its Subsidiaries have submitted to the FDA and other Regulatory Authorities in a timely manner all required notices and annual or other reports, including adverse experience reports and annual reports, related to the research, development, testing, manufacture, handling, labeling, packaging, storage, supply, promotion, distribution, marketing, commercialization, import, export, and sale of the Products.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
Sienna Biopharmaceuticals (Bankr. D. Del. 2019) (Case No. 19-12051) (Docket No. 247)	Section 2.1(m) Purchase and Sale of Assets. (m) all Inventory, supplies, materials and spare parts of the Seller as of the Closing (including all rights of the Seller to receive such Inventory, supplies, materials and spare parts that are on order), in each case, relating primarily to the Acquired Program Assets;	Section 7.3 Regulatory Approvals. Subject to the terms and conditions herein provided, each of the parties agrees to use its reasonable best efforts to take, or cause to be taken, all action, and to do, or cause to be done as promptly as practicable, all things necessary, proper and advisable under applicable Laws to consummate and make effective as promptly as practicable the transactions contemplated by this Agreement. Subject to appropriate confidentiality protections, each party hereto shall furnish to the other parties such necessary information and reasonable assistance as such other party may reasonably request in connection with the foregoing. Following the date of this Agreement, at the Buyer's expense, the Seller agrees to cooperate with the Buyer's reasonable requests to facilitate the transfer of any Permits that are, or relate to, the Purchased Assets to the Buyer, and will make any filings with applicable Governmental Bodies in connection therewith as reasonably requested by Buyer, provided that no such transfers shall delay or be a condition to Closing, nor shall such obligations prohibit the Seller from ceasing operations or winding up its affairs following the Closing.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Insys Therapeutics (Bankr. D. Del. 2019) (Case No. 19-11292) (Docket No. 990)	Section 2.2(a) Transferred Assets and Excluded Assets (a) The term "Transferred Assets" means all the following assets of Seller and its Affiliates, as the same exist as of the Closing: (i) the Equipment; and (ii) the Transferred Records, and copies of all data or information in Seller's possession that is reasonably necessary for Buyer's use of the Equipment to manufacture pharmaceutical products (including for regulatory purposes); provided that Seller shall have continued access to such Transferred Records as are necessary to	Section 5.6 Absence of Debarment Except as has been disclosed in writing to Buyer on or prior to the date hereof, none of Seller, its officers, employees, agents, consultants or any other Person employed or retained by Seller has been or is: (a) debarred, convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Federal Food, Drug, and Cosmetic Act ("FFDCA"), 44 U.S.C. § 335a; (b) listed by any government or regulatory agency as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such	Section 8.1 Filings; Other Actions; Notification and Cooperation (a) Seller and Buyer shall cooperate with each other and use, and shall cause their respective Affiliates to use, their respective reasonable best efforts to take (or cause to be taken) all actions, and do (or cause to be done) all things necessary, proper or advisable under this Agreement and applicable Law to consummate and make effective the Transactions as expeditiously as possible, and in no event later than the Outside Date, including: (i) preparing and filing all documentation to effect all necessary notices, reports and other filings and obtaining as expeditiously as possible all consents, registrations, approvals, permits, expirations of waiting periods and authorizations necessary or advisable to be obtained from any Third Party or any Governmental Entity in order to consummate the Transactions; (ii) satisfying the conditions to consummating the Transactions; (iii) obtaining (and cooperating with each other in obtaining) any consent, approval of, waiver or any exemption by, any non-governmental Third Party, in each case, to the extent necessary, proper or advisable in connection with the Transactions; and (iv) executing and delivering any reasonable additional instruments necessary to consummate the Transactions and to fully carry out the purposes of

Bankruptcy Entity Seller	Relevant Provisions		
	administer the Chapter 11 Cases and Seller may retain copies of any Transferred Records.	pending action. Section 6.7 Absence of Debarment Except as has been disclosed in writing to Seller on or prior to the date hereof, none of Buyer, its officers, employees, agents, consultants or any other Person employed or retained by Buyer has been or is: (a) debarred, convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the FFDCA, 44 U.S.C. § 335a; (b) listed by any government or regulatory agency as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such	this Agreement. (b) Buyer and Seller shall cooperate and shall have joint decision making authority with respect to the appropriate course of action with respect to obtaining the consents, approvals, permits, waiting period expirations or authorizations of any Governmental Entity required to consummate the Transactions prior to the Outside Date. No Party hereto or its counsel shall independently participate in any substantive call or meeting with any Governmental Entity in respect of any such filing, investigation, or other inquiry relating to the matters that are the subject of this Section 8.1 without first giving the other Party or its counsel prior notice of such call or meeting and, to the extent permitted by such Governmental Entity, the opportunity to attend and participate. In furtherance of the foregoing and to the extent permitted by applicable Law: (i) each Party shall notify the other, as far in advance as practicable, of any filing or material or substantive communication or inquiry it or any of its Affiliates intends to make with any Governmental Entity relating to the matters that are the subject of this Section 8.1; (ii) prior to submitting any such filing or making any such communication or inquiry, such Party shall provide the other Party and its counsel a reasonable opportunity to review, and

Bankruptcy Entity Seller	Relevant Provisions		
		pending action.	shall consider in good faith the comments of the other Party in connection with, any such filing, communication or inquiry; (iii) promptly following the submission of such filing or making such communication or inquiry, such Party shall provide the other Party with a copy of any such filing or, if in written form, communication or inquiry; and (iv) such Party shall consult with the other Party in connection with any inquiry, hearing, investigation or litigation by, or negotiations with, any Governmental Entity relating to the Transactions, including the scheduling of, and strategic planning for, any meetings with any Governmental Entity relating thereto. In exercising the foregoing cooperation rights, Seller and Buyer each shall act reasonably and as promptly as reasonably practicable. Notwithstanding the foregoing, materials provided pursuant to this Section 8.1 may be reasonably redacted as necessary to address reasonable privilege concerns. (c) In furtherance and not in limitation of the covenants of the Parties contained in this Section 8.1, Buyer, including its Affiliates, shall use its best efforts (as defined below) to resolve such objections, if any, as may be asserted by any Governmental Entity that would otherwise have the effect of preventing the consummation of the

Bankruptcy Entity Seller	Relevant Provisions		
			Transactions. For the purposes of this Section 8.1, "best efforts" shall include taking any and all actions reasonably necessary to obtain the consents, approvals, permits, waiting period expirations or authorizations of any Governmental Entity required to consummate the Transactions as expeditiously as possible and in no event later than the Outside Date. (d) In furtherance and not in limitation of the covenants of the Parties contained in this Section 8.1, Seller and Buyer each shall, upon request by the other, promptly furnish the other with all information concerning itself, its Affiliates, directors, officers and stockholders and such other matters as may be reasonably necessary or advisable in connection with any statement, filing, notice or application made by or on behalf of Buyer, Seller or any of their respective Affiliates to any Third Party or any Governmental Entity in connection with the Transactions, all of which information shall be true and correct when provided; provided that each Party shall be entitled to redact discussions of the transaction value and competitively sensitive information, and may reasonably designate applicable materials to be reviewed solely by the other Party's outside counsel.

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
			(e) Seller and Buyer each shall keep the other reasonably apprised of the status of matters relating to completion of the Transactions, including promptly furnishing the other with copies of notices or other communications received by Seller or Buyer, as the case may be, or any of their respective Affiliates from any Third Party or any Governmental Entity with respect to the Transactions, other than immaterial communications. (f) Buyer shall bear the cost of any filing fee payable to a Governmental Entity in connection with any filings made under this Section 8.1.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions				
Achaogen (Bankr. D. Del. 2019) (Case No. 19-10844) (Docket No. 371)	Section 2.1 (a) Inventory. All right, title and interests in and to (i) any raw materials (including work in process, buffer stock held by vendors, dies and active pharmaceutical ingredients inventory), finished goods and other inventory of the Product in the possession or control of, or otherwise held by or on behalf of, or owned by the Seller, with a remaining shelf life of at least six (6) months, and (ii) all good and	Section 2.4 (k) Chargebacks. Liabilities arising from chargebacks or related charges by Seller or its Affiliates prior to Closing, and all Liabilities arising out of or relating to the return of any Product, or for any credits, rebates, refunds or other amounts payable in respect of any Product, sold by or on behalf of any of the Seller or its Affiliates or prior to the Closing.	Section 3.6 Compliance With Laws; Governmental Authorizations Each of the Seller and its Subsidiaries are in compliance with all Laws, Orders, ordinances, decrees, rules or regulations of any Governmental Authority applicable to the Plazomicin Business or the Purchased Assets, except such noncompliance which has not had, and would not reasonably be expected to have, a Material Adverse Effect. Schedule 3.6 of the Seller Disclosure Schedule sets forth all material Governmental Authorizations held by the Seller. The Seller has in effect the	Section 5.2 Operation of the Plazomicin Business (a) Until the Closing, except: (i) as required by Law, including in connection with the Chapter 11 Case (it being understood that no provision of this Section 5.2 will require the Seller to make any payment to any of its creditors with respect to any amount owed to such creditors on the Petition Date or which would otherwise violate the Bankruptcy Code); (ii) as expressly set forth in this Agreement or Section 5.2 of the Seller Disclosure Schedule; or (iii) as otherwise consented to by the Purchaser (which consent will not be unreasonably withheld, conditioned or delayed), the Seller will operate, and will conduct the Plazomicin Business in the ordinary course of business in all material respects and use	Section 5.16 Transfer of Governmental Authorizations and IP Registrations From and after the date hereof, the Seller, on the one hand (subject to the availability of funds for such purpose), and the Purchaser, on the other hand, shall, and shall cause their respective Affiliates to, reasonably cooperate to transfer to the Purchaser as of the Closing (or as soon as reasonably practicable thereafter) all Company IP Registrations and

Bankruptcy Entity Seller	Relevant Provisions				
	marketable unbroken lots of packaged finished goods inventory of any Product in the possession or control of, or otherwise held by or on behalf of, the Seller as of Closing which (1) with respect to any commercial lots of any Product, has a remaining shelf life of at least six (6) months, and (2) with respect to samples of any Product, has a remaining shelf life of at least six (6) months, that has already been paid for by the Seller regardless of where located, and all rights to		Governmental Authorizations necessary to conduct the Plazomicin Business in all material respects as it is currently being conducted in accordance with the Laws of any Governmental Authority having jurisdiction over its properties or activities, except for any such failure to obtain a Governmental Authorization that has not had, and would not reasonably be expected to have, a Material Adverse Effect (it being understood that it shall be the sole and exclusive obligation of the Purchaser to obtain any Governmental Authorizations necessary for future	its commercially reasonable efforts to (1) preserve intact the Plazomicin Business's relationships with its suppliers, customers and others doing business with it, subject to the limitation that any payments necessary for the forgoing shall be provided for and within the amounts in the Budget approved from time to time; (2) shall continue to maintain all advertising material, all documentation that would constitute acquired Regulatory Documentation and all books and records on a basis consistent with past practice; and shall (3) continue to make all necessary or appropriate filings and payments with and to Governmental Authorities in connection with the Plazomicin Business in a timely manner, and maintain in effect all existing Regulatory Approvals and	Governmental Authorizations included in the Purchased Assets, including any that is necessary for the import, manufacture, distribution, marketing and sale by the Purchaser of the products of the Plazomicin Business under applicable Law (including the related MAAs made by the Seller or the Subsidiaries), in each case, to the extent such Company IP Registrations and Governmental Authorizations are transferable, and to enable the continued

Bankruptcy Entity Seller	Relevant Provisions				
	receive refunds, rebates or credits in connection therewith (for the avoidance of doubt, the Purchased Assets also include all manufactured product, packaging material, compounds and any other similar assets relating to the Product which have already been paid for by the Seller, and any assets that are under manufacture)		operations, provided that the Seller shall provide reasonable assistance regarding the transfer of any Governmental Authorizations held by the Seller in accordance with Section 5.16). The Seller has not received any written notice from a Governmental Authority of any proceeding, inquiry, investigation, violation or alleged violation of any Laws or Orders related to the Plazomicin Business or the Purchased Assets or of any pending or threatened withdrawal, suspension or termination of a Governmental Authorization. All material fees and charges due and payable with respect to	Authorizations required for the ongoing operation of the Plazomicin Business as presently conducted. (b) Until the Closing, except: (i) as required by Law, including in connection with the Chapter 11 Case (it being understood that no provision of this Section 5.2 will require the Seller to make any payment to any of its creditors with respect to any amount owed to such creditors on the Petition Date or which would otherwise violate the Bankruptcy Code); (ii) as expressly set forth in this Agreement or Schedule 5.2 of the Seller Disclosure Schedule; (iii) as otherwise consented to by the Purchaser (which consent will not be unreasonably withheld, conditioned or delayed); or (iv) pursuant to any orders approving debtor in possession financing	maintenance of any Company IP Registrations; provided that: (a) any reasonable, documented out-of-pocket costs associated with such cooperation by the Seller after the Closing (including the pro rata portion of the costs of any Service Provider directly providing such cooperation after the Closing, as determined by the amount of time dedicated by such Service Provider to such cooperation as a proportion of all time dedicated by such Service Provider to the Seller) shall be

Bankruptcy Entity Seller	Relevant Provisions				
			the Governmental Authorizations held by the Seller have been made in full.	and/or use of cash collateral, or any KEIP/KERP orders or other orders affecting employees, entered by the Bankruptcy Court in the Chapter 11 Case, the Seller will not: (i) amend or terminate any Assumed Contract or any other material Contract; (viii) transfer or dispose of, abandon, lapse, allow to lapse, sell, assign, subject to any Lien, grant any right or license to, any Acquired Intellectual Property, or disclose (except as necessary in the conduct of the Plazomicin Business consistent with past practice) to any Person, other than Purchaser or its representatives, any trade secret, formula, process or know-how that is not a matter of public knowledge prior to	borne by the Purchaser; and (b) nothing in this Section 5.16 shall be deemed to require the Seller to remain a debtor in the Chapter 11 Case or maintain its corporate existence for any period of time beyond forty-five (45) days after the Closing Date; provided that the foregoing shall not be deemed to require the Seller to take any action in violation of the DIP Loan Agreement.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions				
				such disclosure; (ix) grant any refunds, credits, rebates or other allowances to any supplier, vendor, customer or distributor related to the Plazomicin Business except in the ordinary course of business;	

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Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions
Mabvax Therapeutics (Bankr. D. Del. 2019) (Case No. 19-10603) (Docket No. 141)	Section 4.11 Compliance with Laws; Permits; Insurance (a) Sellers have complied, and are now complying, with all Laws applicable to the conduct of the Business as currently conducted or the ownership and use of the Purchased Assets. (b) All Permits required for Sellers to conduct the Business as currently conducted or for the ownership and use of the Purchased Assets have either been obtained by Sellers and are valid and in full force and effect or have been applied for by Sellers. All of the Sellers' applications for Permits related to the Business as currently conducted or to the ownership and use of the Purchased Assets (including, without limitation, any Investigational New Drug applications) have not lapsed or been rejected or suspended. All fees and charges with respect to such Permits and applications for Permits as of the date hereof have been paid in full. Section 4.11(b) of the Disclosure Schedules lists all current Permits issued to any Seller and all of Sellers' applications for Permits (including, without limitation, any Investigational New Drug applications) which are related to (i) the conduct of the Business as currently conducted or (ii) the ownership and use of the Purchased Assets. No event has occurred that, with or without notice or lapse of time or both, would reasonably be expected to result in the revocation, suspension, lapse, rejection or limitation of any Permit or application for a Permit set forth in Section 4.11(b) of the Disclosure Schedules. (c) All clinical studies conducted by or on behalf of Sellers have been and are being conducted in accordance with the requirements of 21 CFR §Part 312. No investigator in the clinical studies conducted by or on behalf of Sellers has been debarred under Section 306 of the Food Drug and Cosmetic Act.

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Rising Pharma/Aceto (Bankr. D. N.J. 2019) (Case No. 19-13448) (Docket No. 438)	Section 2.8(j) Deliveries of Sellers (j) one or more powers of attorney or other authorization letters, notices or filings as required by applicable Law in form and substance reasonably satisfactory to Sellers and Buyer (the "Powers of Attorney") reasonably necessary to permit Buyer and/or its Subsidiaries to utilize Sellers' DEA, FDA, EPA, FIFRA and state controlled substance registrations, licenses and/or permits and any other registrations, licenses and/or permits issued by a Governmental Entity that the Sellers and Buyer reasonably agree require Powers of Attorney (collectively,	Section 5.4 Regulatory Approvals; Efforts (a) Prior to the Closing, Buyer and Sellers shall, and shall cause their respective Affiliates to, use their respective reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, all things necessary, proper or advisable under any applicable Laws to consummate the Asset Purchase as promptly as practicable, including (i) preparing and filing all forms, registrations and notifications with any Governmental Entities or third parties required to be filed to consummate the Asset Purchase, (ii) using reasonable best efforts to satisfy the conditions to consummating the Asset Purchase, (iii) using reasonable best efforts to obtain (and to cooperate with each other in obtaining) any consent, authorization, expiration or termination of a waiting period, permit, Order or approval of, waiver or any exemption by, any Governmental Entity required to be obtained or made by Buyer, Sellers or any of their respective Affiliates in connection with the Asset Purchase or the taking of any action contemplated hereby, (iv) defending any lawsuits or other legal Proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the Asset Purchase, and (v) using reasonable best efforts with respect to the execution and delivery of all such instruments, deeds, assignments or assurances and do all other things reasonably necessary or desirable to consummate the	Section 5.14 Controlled Substances. All controlled substances and DEA listed chemicals will be inventoried by Buyer as of the Closing Date and will be maintained by Buyer or one of its Subsidiaries at Buyer's or such Subsidiary's expense as inventory of the applicable Seller under the authority and control of the Sellers' Registrations in accordance with existing Seller-established security systems and procedures. Such controlled substances and DEA listed chemicals will be used, added to and distributed from the registered address, specified by Buyer with Sellers' consent (not to be unreasonably withheld), in accordance with the Sellers' Registrations until the earlier of (x) such date as the requisite Buyer Registrations

Bankruptcy Entity Seller	Relevant Provisions		
	the "Registrations") after the Closing until the Buyer or one of its Subsidiaries, as applicable, has obtained its own Registrations. The Powers of Attorney shall authorize the appropriate personnel of Buyer or its Subsidiaries to take reasonable actions under the Sellers' Registrations including, but not limited to, as applicable, (a) placing and filling orders for controlled substances as well as importing and exporting controlled substances and DEA listed chemicals in accordance with applicable regulations and recordkeeping and reporting requirements, (b) producing and distributing pesticide products (including all	Asset Purchase and to fully carry out the purposes or intent of this Agreement. (b) Buyer, on the one hand, and Sellers, on the other hand, shall each keep the other apprised of the status of matters relating to the consummation of the Closing and work cooperatively in connection with obtaining all required consents, authorizations, Orders or approvals of, or any exemptions by, any Governmental Entity undertaken pursuant to the provisions of this Section 5.4. In that regard, prior to the Closing, each party shall promptly consult with the other parties to this Agreement with respect to and provide any necessary information and assistance as the other parties may reasonably request with respect to (and, in the case of correspondence, provide the other parties (or their counsel and, if reasonably determined necessary, advisable or convenient to protect attorney-client privilege or competitively sensitive information, outside counsel only basis) with copies of) all notices, submissions or filings made by or on behalf of such party or any of its Affiliates with any Governmental Entity or any other information supplied by or on behalf of such party or any of its Affiliates to, or correspondence with, a Governmental Entity in connection with this Agreement and the Asset Purchase. Each party to this Agreement shall promptly inform the other parties to this Agreement, and if in writing, furnish the other parties with copies of (or, in	are issued to Buyer or one of its Subsidiaries or (y) the date on which Sellers are permitted to dissolve their legal existence pursuant to the terms herein. The controlled substances and DEA listed chemicals will be inventoried and transferred to Buyer or its applicable Subsidiary under the Buyer Registrations. With respect to transactions entered into with suppliers and customers, and internal use and transfer of controlled substances, the internal and external documentation of such transactions and activities, including recordkeeping, reporting and invoicing, shall be kept in accordance with the Sellers' Registrations; provided, however, to the extent permitted under applicable regulations or guidance, documentation may be issued and maintained in the name of

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
	products licensed by Sellers for sale as supplemental distributor products) under the existing state and federal pesticide registrations at the contract production facilities used by Sellers, using existing commercial labels, until the EPA or other applicable Governmental Entity approves the transfers of the Registrations to Buyer or Buyer's applicable Subsidiary and (c) maintaining and renewing the existing Registrations. The Powers of Attorney shall not be revocable until Buyer or an applicable Subsidiary of Buyer has obtained its own Registrations ("Buyer Registrations") provided that Buyer is	the case of oral communications, advise the other parties orally of) any communication from or to any Governmental Entity regarding the Asset Purchase, and permit the other parties to review and discuss in advance, and consider in good faith the views of the other parties in connection with, any proposed communication or submission with any such Governmental Entity. No party or any of its Affiliates shall participate in any meeting or teleconference with any Governmental Entity in connection with this Agreement and the Asset Purchase unless it consults with the other parties in advance and, to the extent not prohibited by such Governmental Entity, gives the other parties the opportunity to attend and participate thereat. Notwithstanding the foregoing, Buyer and Sellers may, as each deems advisable and necessary, reasonably designate any competitively sensitive material provided to the other under this Section 5.4(b) as "Antitrust Counsel Only Material." Such materials and the information contained therein shall be given only to the outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers or directors of the recipient unless express permission is obtained in advance from the source of the materials (Buyer or Sellers, as the case may be) or its legal counsel. Notwithstanding anything to the contrary contained in this Section 5.4, materials provided pursuant to this Section 5.4 may be redacted (i) to remove references concerning the valuation of the	Buyer or its Subsidiaries. Buyer agrees that, during the period it or its Subsidiaries are operating using the Powers of Attorney, all ownership of title, service and invoicing is Buyer's (or such Subsidiary's) sole responsibility and all documents using Sellers' license or registration numbers, if required, will disclose that the shipper is "NMC Atlas, L.P. or one of its subsidiaries under Power of Attorney from [the appropriate Sellers' organization that holds the license or Registration]" or such other disclosure as deemed necessary and appropriate by Buyer, provided such disclosure is approved by the DEA or other applicable Governmental Entity.

Bankruptcy Entity Seller	Relevant Provisions		
	in compliance with the terms and conditions of the Powers of Attorney during the term of the Powers of Attorney and has used its commercially reasonable efforts to obtain such Buyer Registrations as promptly as possible at Buyer's expense.	Acquired Business and the purchase of the Purchased Assets, (ii) as necessary to comply with contractual arrangements and (iii) as necessary to address reasonable privilege concerns. (c) Sellers and Buyer acknowledge that they have filed prior to the date hereof with the appropriate Governmental Entity all filings, forms, registrations and notifications required to be filed to consummate the purchase of the Purchased Assets under the HSR Act and any other applicable Antitrust Law, and that early termination of the applicable waiting period under the HSR Act was granted effective March 18, 2019. Sellers and Buyer shall cause their respective Affiliates to, as promptly as practicable, respond to inquiries from Governmental Entities, or provide any supplemental information that may be requested by Governmental Entities, in connection with filings made with such Governmental Entities.	

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Pernix Therapeutics (Bankr. D. Del. 2019) (Case No. 19-10323) (Docket No. 321)	Section 3.7 Compliance with Law; Permits (a) Since January I, 2017, the Business has been conducted in compliance with, and the Sellers have complied with, in all material respects, all applicable Laws relating to the operation of the Business and the Transferred Assets. Since January I, 2017, no Seller (i) has received any written communication (or, to the Knowledge of Sellers, any other communication) from any Governmental Authority or private party alleging noncompliance in any material respect with any applicable Law or (ii) has incurred any material Liability for failure to comply with any applicable Law. To the Knowledge of Sellers, there is no investigation, proceeding or disciplinary action currently pending or threatened against any Seller by a Governmental Authority, except, in each case,	Section 3.14 Regulatory Matters (a) Since January 1, 2017, the Products have been and are being researched, developed, tested, investigated, produced, manufactured, labeled, distributed, stored, sold, imported and exported, and all business operations of the Sellers relating to pre-clinical and clinical investigations sponsored by the Sellers or involving Products, or to the marketing, advertising, medical information and medical affairs activities and communications, sale and pricing of the Products (including by means of the outsourcing by Sellers of any of the foregoing activities) have been and are being conducted in all material respects in compliance with Health Care Laws. (b) Except as set forth on Section 3.14(b) of the Disclosure Letter and as would not, individually or in the aggregate, reasonably be expected to be material to the Business (taken as a whole), the Sellers have all Regulatory Approvals and have all the applicable documentation related to such Regulatory Approvals as provided for in the definition of Product Approvals. Each Product Approval is valid and in full force and effect except as	Section 5.18 Product Approvals With respect to each Product in each jurisdiction, from and after the Closing Date, until the date on which the Buyer receives an assignment or transfer of the Product Approval for such Product in such jurisdiction, or a replacement thereof naming the Buyer as the Product Approval holder for such Product in such jurisdiction, the Sellers shall, with respect to each such Product in each such jurisdiction, maintain in continuous effect all applicable Regulatory Approvals. Buyer shall promptly reimburse all of Sellers' reasonable and documented costs and expenses including upon the presentation of a reasonably detailed invoice, all of Sellers' reasonable legal fees incurred as a result of it complying

Bankruptcy Entity Seller	Relevant Provisions		
	for any such investigation, proceeding or disciplinary action that, if adversely determined, would not reasonably be expected to be material to the Business (taken as a whole). Since January 1, 2017, each Seller has filed all material reports, notifications and other filings required to be filed with any Governmental Authority pursuant to applicable Law, and has paid all material fees and assessments due and payable in connection therewith. (b) The Sellers arc in possession of all permits, licenses, franchises, approvals, certificates, consents, waivers, concessions, exemptions, orders, registrations, notices or other authorizations of any Governmental Authority (the "Permits") necessary for them to own, lease and operate the Transferred Assets and to carry on the Business as currently conducted, except for Permits	would not, individually or in the aggregate, reasonably be expected to be material to the Business (taken as a whole). The Sellers are in compliance in all material respects with, and since January 1, 2017, have fulfilled and performed in all material respects their respective obligations under, each such Regulatory Approval. There is no action or proceeding by any Governmental Authority pending or, to the Knowledge of the Sellers, threatened seeking the revocation or suspension of any of the Product Approvals, and since January 1, 2017, no event has occurred or condition or state of facts exists that would constitute a breach or default, or would reasonably be expected to cause revocation, termination, or modification of any of the Product Approvals, in each case except as would not, individually or in the aggregate, reasonably be expected to be material to the Business (taken as a whole). Since January I, 2017, Sellers have filed with the FDA and any other applicable Governmental Authority all material filings, notices, registrations, reports or submissions which are required under any Product Approval or by any Health Care Law to have been filed or obtained as of the date of the Original Agreement. All such documents	with its obligations pursuant to this Section 5.18 Buyer shall indemnify, defend and hold the Sellers harmless from and against any and all Liabilities arising out of or in connection with any Product Approval from and after the Closing through the date on which the Buyer receives an assignment or transfer of such Product Approval (or the related Regulatory Approval) for such Product, or a replacement thereof naming the Buyer as the Product Approval (or the related Regulatory Approval) holder for such Product.

Bankruptcy Entity Seller	Relevant Provisions		
	that the failure to be in possession of would not reasonably be expected to be material to the Business (taken as a whole). All material Permits held by the Sellers are valid and in full force and effect and no Seller is in default under, or in violation of, any such Permit, except for such defaults or violations which would not reasonably be expected, individually or in the aggregate, to materially restrict or interfere with Buyer' ability to operate the Business as currently operated and, to the Knowledge of Sellers, no suspension or cancellation of any such Permit is pending (other than pursuant to its terms or threatened).	were when filed or submitted, and continue to be, in material compliance with applicable Health Care Laws and to the Knowledge of the Sellers, no material deficiencies have been asserted by any applicable Governmental Authority with respect to any such filings or Product Approvals since January 1, 2017. (c) All Product Regulatory Materials disclosed to Buyer are true, correct and complete in all material respects.	

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions
Immune Pharmaceuticals (Bankr. D. N.J. 2019) (Case No. 19-13273) (Docket No. 343)	Section 7.2 Commercially Reasonable Efforts; Further Assurances Each Seller shall execute such documents and take or cause to be taken all action and do or cause to be done all things necessary, proper or advisable to consummate the transactions contemplated by this Agreement (including, without limitation, to put Buyer in actual possession and operating control of the Acquired Assets, including to record or perfect the transfer of the Acquired Assets to Buyer, to confirm the title of the Acquired Assets in Buyer and to assist Buyer in exercising rights relating thereto), and to make all filings with, give all notices to, and obtain all consents from, all Third Parties which may be necessary or required in order to effectuate the transactions contemplated hereby. Each Seller shall use commercially reasonable efforts to fulfill or obtain the fulfillment of the conditions set forth in ARTICLE 10 of this Agreement.

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Avadel Specialty Pharmaceuticals (Bankr. D. Del. 2019) (Case No. 19-10248)	Section 4.5 Compliance with Laws; Product Recalls; Regulatory Matters (a) Seller is, and for the three (3) year period ending on the date hereof has been, in compliance in all material respects with all Laws relating to the Purchased Assets and the Product. During the three (3) year period ending on the date hereof, neither Seller nor any of its Affiliates has received any written notice from any Governmental Entity to the effect that it is not in compliance with any Law related to the Purchased Assets and the Product. (b) The Product NDA is valid, effective and in full force and effect in all material respects, and all applicable fees and costs that are due and payable with respect to such Product NDA have been paid in full. There is no claim by any Governmental Entity pending or, to the knowledge of Seller, threatened seeking the revocation or suspension of any of the Product NDA.	Section 4.7 Inventory The inventory included within the Purchased Assets are, and will have been at all times prior to the Closing, stored and handled in accordance with the product label and all regulatory requirements and are not, and will not have become prior to the Closing, adulterated or misbranded within the meaning of the FDCA, or applicable foreign equivalents. All such inventory shall have been	Section 7.9 Regulatory Buyer and Seller shall, with respect to the Product NDA, file each Buyer Change in Ownership Letter and each Seller Change in Ownership Letter, respectively, with the FDA as soon as possible and in any event within ten (10) days after the date on which Seller provides to Buyer a copy of the Product NDA underlying each such letter. The letters filed by Seller and Buyer pursuant to this Section 7.9 shall comply with all aspects of 21 C.F.R. 314.72 (Change in Ownership of any Application), and such letters shall provide for transfer of title to the Product NDA to be effective as of the Closing. Each party shall bear its own costs related thereto.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
		manufactured in compliance with (a) all applicable standards that are detailed in the FDA's current Good Manufacturing Practice regulations, and (b) all equivalent Laws promulgated by any Governmental Entity having jurisdiction over the Business.	Seller shall use its reasonable best efforts and take all necessary actions to seek to cause the transfer of electronic copies of the Product NDA to Buyer within five (5) Business Days after the Closing Date. Section 8.4 Product NDA and Related Documents On the Closing Date, Seller shall have delivered to Buyer copies of the Product NDA and each of the documents set forth in Section 4.5(e) and Section 4.5(f) hereof.

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
Akorn (Bankr. D. Del. 2020) (Case No. 20-11177 (KBO) (Docket No. 656)	Section 1.1(o) includes "all Product Registrations, Registration Information, and all other data and information regarding the development and commercialization of the Products, including all safety and efficacy databases, clinical data, non-clinical date and related books and records" as part of the Acquired Assets. Section 11.1 Certain Definitions. (nnn) "Product" means each product manufactured, commercialized, developed, packaged, labeled, stored, used, marketed, imported, exported, distributed or sold by or on behalf of the business of the	3.23. Health Care Regulatory Matters. Except as set forth in Schedule 3.23 or as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and since January 1, 2017: (a) The Company and its Subsidiaries, and to the Knowledge of Sellers, each of their directors, officers, management employees, agents (while acting in such capacity), contract manufacturers, suppliers, and distributors are, and at all times after January 1, 2017 were, in compliance with all Health Care Laws to the extent applicable to the Company or any of its products or activities, except, with respect to such agents, contractors, manufacturers, suppliers and distributors, as would not reasonably be expected to prevent the Company and its Subsidiaries from being in such compliance themselves. To the Knowledge of Sellers, there are no facts or circumstances that reasonably would be expected to give rise to any failure by the Company and its Subsidiaries to be	Section 6.4 Regulatory Matters. (a) Subject to Section 6.5, the Company will (1) make or cause to be made all filings and submissions required to be made by the Company or its Subsidiaries under any applicable Laws for the consummation of the transactions contemplated by this Agreement set forth on Schedule 6.4, including filings or submissions related to Product Registrations and a General Information Notice for each Acquired Leased Real Property in New Jersey subject to ISRA, (2) reasonably cooperate with Purchaser in exchanging such information and providing reasonable assistance as Purchaser may reasonably request in connection with any filings made by the Purchaser Group pursuant to Section 6.4(b), and (3) (A) supply promptly any additional information and documentary material that may be requested in connection with the filings made pursuant to this Section 6.4(a) or Section 6.4(b), and (B) use reasonable best efforts to take all actions necessary to obtain all required clearances in connection with such filings. Prior to Closing, the Company shall engage a Licensed Site Remediation Professional ("LSRP") that is reasonably acceptable to

Bankruptcy Entity Seller	Relevant Provisions		
	Company, or which the process has taken substantial steps towards manufacturing, commercializing, developing, packaging, labeling, storing, using, marketing, importing, exporting, distributing or selling, including all products that are regulated as human or animal drugs, medical devices, or other health care products under Health Care Laws, including drug and biological candidates, compounds or products being researched, tested, stored, developed, labeled, manufactured, packed, marketed, sold and/or distributed by the Company or any of its Subsidiaries. (ooo) "Product Registrations" means (i)	in such compliance under any Health Care Laws that would reasonably be expected to give rise to a Material Adverse Effect. (b) All material Governmental Authorizations required by the Health Care Laws are in full force and effect. Neither the Company nor any of its Subsidiaries have knowledge of any facts or circumstances that would be reasonably likely to lead the revocation, suspension, limitation, or cancellation of a Governmental Authorization required under Health Care Laws or of any application for a Governmental Authorization required under Health Care Laws currently pending before the FDA, DEA, or such other Governmental Body. (c) All reports, documents, claims, notices, or Governmental Authorizations required under Health Care Laws to be filed, maintained or furnished to the FDA, DEA, or any Governmental Body by the Company and its Subsidiaries have been so filed, maintained or furnished, except where	Purchaser to commence performance of a Preliminary Assessment (as defined in ISRA) for each Acquired Leased Real Property in New Jersey for which a General Information Notice was submitted. The Company and Purchaser shall cooperate in good faith regarding the performance of the Preliminary Assessments, including the Company responding as promptly as reasonably practicable to any inquiries from Purchaser about the status of the Preliminary Assessments. Purchaser shall have the reasonable right to review and comment on the Preliminary Assessments, and the Company shall request that the LSRP consider in good faith any reasonable comments on the Preliminary Assessments received from Purchaser. At Closing, the Company shall end its engagement of the LSRP, at which time Purchaser shall directly engage the LSRP in connection with its assumption of responsibility for ISRA under Section 6.4(b)(ii). In the event the Preliminary Assessments have not been finalized at Closing, Purchaser shall be responsible, at its sole cost and expense, to complete the Preliminary Assessments. (b) Subject to Section 6.5, Purchaser will, and will cause its Affiliates

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
	any investigational new drug application, new drug application, abbreviated new drug application, premarket approval, 510(k) clearance, or similar regulatory application of Sellers for any Product that has been submitted to or approved by the FDA in the United States (other than withdrawn submissions or approvals) and (ii) all marketing approvals, clearances, registrations, certifications, markings, consents or other authorizations used to market the Products and granted or pending with any Governmental Body, including establishment registrations and Product listings (qqq) "Registration Information" means any	failure to file, maintain or furnish such reports, documents, claims, notices, or Governmental Authorizations have not had and would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. To the Knowledge of Sellers all such reports, documents, claims, notices, and other Governmental Authorizations were true and complete in all material respects on the date filed (or were corrected in or supplemented by a subsequent filing). (d) All preclinical and clinical trials conducted by or, to the Knowledge of Sellers, on behalf of the Company or any of its Subsidiaries, have been, and if still pending are being, conducted in compliance with research protocols and all applicable Health Care Laws, including the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, 312, 314, 320, 511, and 814. No clinical trial conducted by or on behalf of the Company or its Subsidiaries has been terminated or suspended prior to completion, and no clinical investigator	and Advisors to, (i) make or cause to be made all filings and submissions required to be made by any member of the Purchaser Group under any applicable Laws and necessary to permit the consummation of the transactions contemplated by this Agreement, including any such filings or submissions related to Product Registrations, (ii) two (2) calendar days prior to Closing, submit a Remediation Certification, as defined under ISRA, to the New Jersey Department of Environmental Protection for each Acquired Leased Real Property in New Jersey subject to ISRA identifying Purchaser as the person responsible for ISRA compliance after Closing along with a Remediation Cost Review and RFS/FA Form, a Remediation Funding Source instrument and 1% annual surcharge check, as required, (iii) reasonably cooperate with the Company in exchanging such information and providing reasonable assistance as the Company may reasonably request in connection with any filings made by the Company pursuant to Section 6.4(a), and (iv) (A) supply promptly any additional information and documentary material that may be requested in connection with the filings made pursuant to

Bankruptcy Entity Seller	Relevant Provisions		
	and all original Product Registrations, together with all Regulatory Documentation. (rrr) "Regulatory Documentation" means (i) all regulatory filings, underlying material data, datasets and supporting documents (including copies of all material correspondence between any of Sellers or their Affiliates and the applicable Governmental Body), material CMC data and documentation, preclinical and clinical studies and tests, (ii) any premarket approval or 510(k) clearance application or foreign equivalent, and all regulatory files related thereto, current approved packaging and any other existing files	that has participated or is participating in, or institutional review board that has or has had jurisdiction over, a clinical trial conducted by or on behalf of the Company or its Subsidiaries has placed a clinical hold order on, or otherwise terminated, delayed or suspended, such a clinical trial at a clinical research site based on an actual or alleged lack of safety or efficacy of any Product or a failure to conduct such clinical trial in compliance with applicable Health Care Laws. (e) All manufacturing operations conducted by or, to the Knowledge of Sellers, for the benefit of the Company or its Subsidiaries have been and are being conducted in material compliance with all Governmental Authorizations issued by a Governmental Body under Health Care Laws and in material compliance with all applicable Health Care Laws, including the FDA's current Good Manufacturing Practice (cGMP) regulations at 21 C.F.R. Parts 210-211, Quality System (QS) regulations at 21 C.F.R. Part 820, animal drug cGMP regulations at 21 C.F.R. Part 507, and	this Section 6.4(b) or Section 6.4(a) and (B) use reasonable best efforts to take all actions necessary to obtain all required clearances. (c) From and after the date hereof, the Parties will cooperate in connection with the transfer of the transferable Product Registrations to Purchaser as of the Closing Date and the obtaining by Purchaser of new Product Registrations to the extent a Product Registration is not transferable. Promptly following the date hereof, the Parties will agree upon procedures to ensure a transition from the Sellers to Purchaser of all of the activities required to be undertaken by the holder of the Product Registrations, including adverse experience reporting, quarterly and annual reports to the FDA, handling and tracking of complaints, sample tracking, and communication with health care professionals and customers. Subject to Section 6.4(d), after the Closing, Purchaser shall assume all responsibility for the Product Registrations, including all responsibility for communications with the FDA and any other Governmental Body concerning the Products. The Parties shall cooperate in making and maintaining all required regulatory filings, and reporting all

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
	and dossiers, including the underlying data, datasets or information used to support, maintain or obtain marketing authorization, (iii) all records maintained under record keeping or reporting Laws of the FDA or any other Governmental Body, including all marketing applications, annual and safety reports, master files, FDA warning letters, FDA notices of adverse finding letters, FDA audit reports (including any responses to such reports), periodic safety update reports, complaint files, and annual product quality reviews, and (iv) the complete complaint, adverse event and medical inquiry filings	all comparable foreign regulatory requirements of any Governmental Body. (f) Neither the Company nor any of its Subsidiaries have received any written communication or, to the Knowledge of Sellers, any oral communication from an applicable Governmental Body that relates to an alleged violation or non-compliance with any Health Care Laws, including any notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration, import detention or refusal, subpoena, civil investigative demand, FDA Warning Letter or Untitled Letter, or any action by a Governmental Body relating to any Health Care Laws, in each case, that has not been resolved to the satisfaction of the applicable Governmental Body. (k) Neither the Company nor its Subsidiaries, nor, to the Knowledge of Sellers, any officer, employee, agent, or distributor of the Company or its Subsidiaries has been convicted of any crime or engaged in any conduct that	material communications (whether written or oral) from a Governmental Body in relation to a transfer and, to the extent one Party (Seller or Purchaser, as the case may be) requires the other Party's (Purchaser or Seller, as the case may be) participation to effectuate the transfer of the Product Registrations, it shall give the other Party reasonable notice of all meetings and telephone calls with any Governmental Body expected to have a material impact upon a transfer and give the other Party a reasonable opportunity to participate at each such meeting or telephone call. (d) On the Closing Date (or within such time after the Closing Date as permitted under applicable Law) or as soon as practicable after the Closing Date, Sellers shall submit to the FDA the executed Seller FDA Transfer Letters. To the extent required, Sellers shall submit or deliver to the FDA and other appropriate Governmental Bodies within timelines as prescribed under applicable Law such documents and instruments of conveyance as necessary and sufficient to effectuate the transfer of each Permit and Governmental Authorization to Purchaser under applicable Law on the Closing Date or as soon as

Bankruptcy Entity Seller	Relevant Provisions		
	with respect to any	has resulted, or would reasonably be expected to result, in debarment under 21 U.S.C. § 335a, exclusion under 42 U.S.C. § 1320a-7, or any other Health Care Law applicable in other jurisdictions in which the Products are sold or intended to be sold. (l) The Company and each of its Subsidiaries (i) are and have been in compliance with all applicable statutes, regulations, rules, and regulatory guidance relating to Product pricing, price reporting, discounts, and rebates, including those relating to the Medicaid Drug Rebate Program, the 340B Drug Pricing Program, the Medicare Part B Program, the Veterans Health Care Act Drug Pricing Program, and applicable state price reporting laws, and (ii) have calculated and reported the applicable pricing metrics under the foregoing programs (including Average Manufacturer Price, Best Price, 340B Ceiling Price, Average Sales Price, and Non- Federal Average Manufacturer Price) consistent with the applicable Health Care Laws associated with the foregoing programs.	practicable after the Closing Date. Unless otherwise required by applicable Law, from the Closing Date until the relevant date of transfer for each Product Registration, Sellers shall use commercially reasonable efforts to maintain or cause to be maintained in force each such Product Registration and Purchaser shall promptly reimburse Sellers for the reasonable documented and out-of-pocket costs and expenses incurred by Sellers in connection with maintaining or causing to be maintained such Product Registrations. Unless otherwise required by applicable Law and as may be agreed between the Parties, Sellers shall use commercially reasonable efforts to progress or cause to be progressed any pending application filed prior to the Closing Date for a Product Registration. Notwithstanding anything contained in this Agreement to the contrary (including Section 6.1), Sellers shall not, from the Closing Date until the relevant date of transfer for such Product Registration, absent the prior written consent from Purchaser, or as is required by a Governmental Body, withdraw or suspend a Product Registration that is pending as of the Closing Date. The Sellers shall ensure that an employee or other authorized person

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions		
			is reasonably available to Purchaser to effectuate any transfers contemplated by this Section 6.4 and occurring after the Closing. (e) Prior to the Closing, the actions taken by Sellers pursuant to Section 6.4(c) shall be at the sole cost and expense of the Sellers. All documented and out-of-pocket costs and expenses incurred by Sellers after the Closing at the request of Purchaser in connection with this Section 6.4 shall be reimbursed by Purchaser.

Buchalter

Language in Bankrupt Pharmaceutical Companies' Asset Purchase Agreements Addressing Products, Distribution and Regulatory Issues

Bankruptcy Entity Seller	Relevant Provisions	
Valeritas Holdings (Bankr. D. Del. 2020) (Case No. 20-10290) (Docket No. 232)	Section 1.4 Excluded Liabilities. 1.4(s) all Liabilities of any Seller relating to the sale of any product included in the Purchased Assets prior to Closing (including claims related to or arising from returns, rebates, coupon programs, chargebacks, credits, warranties or expirations);	Section 4.20 Healthcare Regulatory Matters. Each Seller is, and at all times has been, in material compliance with all applicable Healthcare Laws. Each Seller possesses all Permits required to conduct its operations, which are set forth on Schedule 4.20, is in material compliance with all such Permits, and has not received any notice of any revocation of, or modification to, any such Permit. Except as set forth on Schedule 4.20, Seller represents that each Permit is transferrable to Purchaser subject to making all appropriate filings with the applicable Governmental Bodies. In addition, each Seller maintains compliance plans that were created to reasonably assure that (1) any Person providing healthcare services to or on behalf of a Seller or (2) any employee or individual contractor of a Seller, in either case (1) or (2), is in compliance in all material respects with all applicable Healthcare Laws and are structured to account for the guidance issued by the U.S. Department of Health and Human Services regarding characteristics of effective corporate compliance programs. No Seller is a "covered entity" or "business associate" as such terms are defined under HIPAA and has not entered into a business associate agreement as described under HIPAA. No Seller has received any notice of any Action or third party notice alleging that any Seller product, operation or activity is in violation of any Healthcare Laws nor, to any Seller's Knowledge, is any such Action been threatened. Each Seller has filed, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any healthcare Permit or

Buchalter

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		Healthcare Laws in all material respects, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission).

TAB 5

Governmental Letters Opposing Public Benefit Corporation Status
of Reorganized Purdue

October 14, 2020

The Honorable William P. Barr
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530

Dear Attorney General Barr:

We write to ask you to revise a proposed DOJ settlement agreement that reportedly would wrongly mandate that Purdue Pharma's infamous OxyContin business be preserved as a public trust. A business that killed thousands of Americans should not be associated with government. Instead, the business should be sold to private owners, so the government can enforce the law against it with the same impartiality as for any other company.

States sued Purdue Pharma and its billionaire owners, the Sacklers, because their illegal conduct caused much of the national opioid crisis. Their misconduct also forced the company into bankruptcy, and the States and DOJ are participating in the bankruptcy case with the shared goals of distributing Purdue's assets to compensate people who were injured and to abate the opioid epidemic.

A key issue in the bankruptcy is the future of Purdue's OxyContin business. Purdue and the Sacklers proposed that the government should step into their shoes and take over their business of selling OxyContin. They want their OxyContin company preserved as a family legacy and a "public trust." Purdue explained: "We're turning [the company] into a public trust organization … It sells a very valuable product called OxyContin."[1]

We rejected Purdue's proposal. We believe that Purdue's assets should be sold to new owners in the private sector. The role of government in any OxyContin business should be to enforce the law, just as against any other company. The public deserves assurance that no opioid business is given the special protection of being placed under a public umbrella. Although it may take time to find a private sector buyer, the public should be confident that public officials are seeking to avoid having special ties to an opioid company, conflicts of interest, or mixed motives in an industry that caused a national crisis.

In the recent bankruptcy of another notorious opioid company, the assets of Insys Therapeutics Inc. were sold to a private buyer, pursuant to court approval, and our governments were not forced to enter the opioid business.[2] That is a normal, lawful result in a bankruptcy, and the DOJ should encourage Purdue to follow that same path. Compared to Purdue's proposal, selling the

[1] Berkeley Lovelace Jr., *Purdue Pharma chair: Best Way To Fight Opioid Crisis Is For OxyContin Maker To Stay In Business*, CNBC, Sept. 16, 2019, at https://www.cnbc.com/2019/09/16/purdue-pharma-chairman-steve-miller-on-bankruptcy-of-oxycontin-maker.html.

[2] *See* Nate Raymond, *Drugmaker Insys Wins Bankruptcy Court Approval To Sell Off Opioid*, Reuters, Sept. 19, 2019, at https://www.reuters.com/article/us-insys-opioids-bankruptcy/drugmaker-insys-wins-bankruptcy-court-approval-to-sell-off-opioid-idUSKBN1W42KY.

business to a private owner may also deliver more upfront money that cities and States can use to abate the opioid epidemic. At least one potential buyer has already come forward to make a bid to buy Purdue's drug businesses, which would keep the businesses in private ownership. Qualified buyers should be permitted to bid for Purdue's assets.

Instead, the press has reported that DOJ intends to sign agreements that would purport to prohibit the sale of Purdue's businesses to private owners, and would require that Purdue be preserved as a "public benefit company" that will sell OxyContin on behalf of cities and state governments.[3]

We ask you to reverse that decision for three reasons. First, as we explained above, the Sacklers' proposal to cloak the OxyContin business in public ownership compromises the proper roles of the private sector and government. Thousands of Americans have died, and it is a top priority of every State to enforce the law against the perpetrators whose misconduct caused the opioid crisis. The last business our States should protect with special public status is this opioid company.

Second, even if DOJ disagrees with the principles that keep government out of the opioid business, DOJ should not impose its view on States, cities, families, and all other stakeholders in the bankruptcy. Instead, the relevant parties in the bankruptcy should be permitted to negotiate without DOJ putting its thumb on the scale.

Third, the States will continue to oppose the Sacklers' plan. When a plan is proposed in the bankruptcy, States and all other creditors can vote against a plan they believe is wrong. Even after that, because the Sacklers seek extraordinary releases of the States' claims for their individual, personal liability, States have powerful arguments to challenge the confirmation of the Sacklers' plan in the Bankruptcy Court and every court above it.[4]

There is no need for DOJ to require a special status for the Sackler's OxyContin business. If DOJ insists that the Sacklers get their way and their OxyContin business is elevated into a public trust, Americans will question whether billionaires bought special treatment in this case, while working families across the country suffered.

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[3] Mike Spector & Jessica DiNapoli, *OxyContin Maker Purdue Nears Guilty Plea Agreement In U.S. Criminal Probe - Sources*, Reuters, Oct. 7, 2020, at https://www reuters.com/article/us-purdue-pharma-investigations-opioids/exclusive-oxycontin-maker-purdue-nears-guilty-plea-agreement-in-u-s-criminal-probe-sources-idUSKBN26S1P2 ("The Justice Department is prepared to waive a large portion of its $2 billion forfeiture claim as long as Purdue meets certain conditions. The first is that Purdue steer significant financial sums for combating the opioid epidemic to U.S. communities suing it over the crisis, two people said. The other is that it receive court approval for a reorganization plan transforming it into a 'public benefit company' run on behalf of those communities and no longer controlled by the Sacklers."). The same article also reported that details of the proposed settlement "remain in flux."

[4] States and the DOJ agree that bankruptcy courts should never force governments to release these claims. *See* Brief for the United States as Amicus Curiae at 12, *Lynch v. Mascini Holdings, Ltd. (In re Kirwan Offices S.a.R.L.)*, Case No. 18-3371 (2d Cir. Oct. 7, 2019) ECF No. 119 ("third-party releases are impermissible"); *id.* at 15 n.3 ("Moreover, the government's view is that, even assuming that releases may be appropriate in certain circumstances, no such releases should ever apply to the government, as its interests are distinct from those of ordinary creditors or other outsiders who may have claims against participants in the bankruptcy process. For example, no bankruptcy court order should release non-debtors from their obligations under criminal laws, tax laws, environmental laws, or other public health and safety laws….").

We ask you to work with us to keep the OxyContin business in the private sector, secure money to abate the crisis, and hold the perpetrators accountable.

Respectfully,

XAVIER BECERRA
California Attorney General

PHILIP J. WEISER
Colorado Attorney General

WILLIAM TONG
Connecticut Attorney General

KATHLEEN JENNINGS
Delaware Attorney General

KARL A. RACINE
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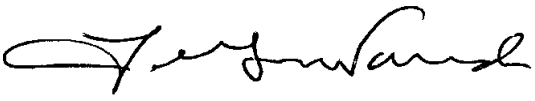
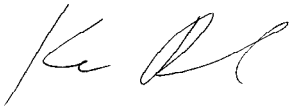


LAWRENCE WASDEN
Idaho Attorney General



KWAME RAOUL
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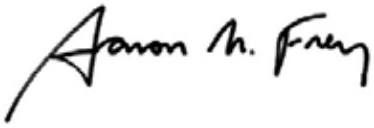
TOM MILLER
Iowa Attorney General



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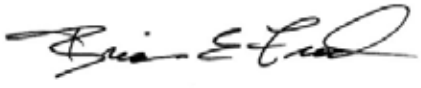

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JANE E. YOUNG
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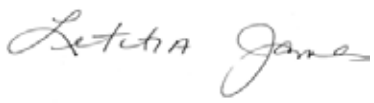

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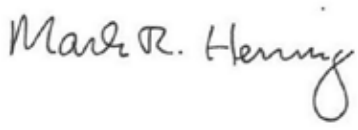

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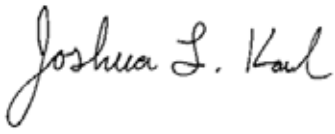

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