

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION; STATE  
OF NEW YORK; STATE OF CALIFORNIA;  
STATE OF ILLINOIS; STATE OF NORTH  
CAROLINA; STATE OF OHIO;  
COMMONWEALTH OF PENNSYLVANIA;  
and COMMONWEALTH OF VIRGINIA

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC;  
PHOENIXUS AG; MARTIN SHKRELI,  
individually, as an owner and former officer  
of Vyera Pharmaceuticals, LLC and  
Phoenixus AG (formerly known as Turing  
Pharmaceuticals, LLC and Turing  
Pharmaceuticals, AG); and KEVIN  
MULLEADY, individually, as an owner and  
director of Phoenixus AG and a former  
executive of Vyera Pharmaceuticals, LLC,

Defendants.

Case No.: 1:20-cv-00706-DLC

**STIPULATED ORDER FOR  
PERMANENT INJUNCTION AND  
EQUITABLE MONETARY RELIEF**

Plaintiffs the Federal Trade Commission (“FTC” or “Commission”), by its designated attorneys, and the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia (collectively “Plaintiff States”), by and through their Attorneys General (collectively “Plaintiffs”), pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, Section 342 of the New York General Business Law, Section 63(12) of the New York Executive Law, Sections 16700 *et seq.*, 17200 *et seq.* of the California Business and Professions Code, Section 7 of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*, North Carolina Unfair or Deceptive Practices Act, N.C. Gen. Stat. §75-1 *et seq.*, Chapter 1331 and Section 109.81 of the Ohio Revised Code, Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.* and Common Law Doctrine against Restraints of Trade proceeding under 71 P.S. § 732-204 (c) and the Virginia Antitrust Act, Virginia Code §59.1-9.1 *et seq.*, filed their Amended Complaint for Permanent Injunctive and Other Equitable Relief, against Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, Martin Shkreli, and Kevin Mulleady to remedy and prevent their alleged anticompetitive conduct and unfair methods of competition in or affecting commerce in violation

of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), and state law. The Plaintiffs and Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, and Kevin Mulleady (collectively “Settling Defendants”) have agreed to resolve this case through settlement, without trial or final adjudication of any issue of law or fact, and stipulate to entry of this Stipulated Order for Permanent Injunction and Equitable Monetary Relief (“Order”) to resolve all matters against the Settling Defendants in dispute in this action.

### **FINDINGS**

1. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, as well as under the principles of supplemental jurisdiction codified in 28 U.S.C. § 1367(a).
2. This Court has personal jurisdiction over the Settling Defendants because each has the requisite constitutional contacts with the United States of America pursuant to 15 U.S.C. § 53(b) and with the state of New York pursuant to N.Y. CPLR §§ 301, 302.
3. Venue for this matter is proper in this Court under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 15 U.S.C. § 1391(b) and (c).
4. The Amended Complaint alleges that the Settling Defendants engaged in anticompetitive conduct and unfair methods of competition in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and state law.
5. The Settling Defendants admit the facts necessary to establish the personal and subject matter jurisdiction of this Court in this matter.
6. The Settling Defendants deny the allegations and claims in the Amended Complaint and dispute that Plaintiffs are entitled to obtain relief.
7. The Settling Defendants waive any claim they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.
8. Entry of this Order satisfies the requests for relief made by the Plaintiffs in their Amended Complaint and is in the public interest.

### **STIPULATIONS**

1. The Settling Defendants stipulate that venue for this matter is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, U.S.C. § 53(b).

2. The Settling Defendants waive all rights to appeal or otherwise challenge or contest the validity of this Order.
3. The Plaintiffs and the Settling Defendants have agreed that entry of this Order fully and finally resolves all claims and litigations between them arising from or based primarily on the allegations described in the Amended Complaint and precludes further litigation against Phoenixus, Vyera, and/or Mulleady, as defined herein, arising from or based primarily on the allegations except for purposes of enforcing or modifying this Order.
4. The Plaintiffs and Settling Defendants stipulate that they will each bear their own costs in this matter and shall not make any claims against the other for attorneys' fees or costs.

## **ORDER**

### **IT IS HEREBY ORDERED:**

#### **I. DEFINITIONS**

As used in this Order, the following definitions apply:

- A. "Phoenixus" means Phoenixus AG, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Phoenixus AG, and the respective directors, officers, employees, agents, attorneys, representatives, successors, and assigns of each.
- B. "Vyera" means Vyera Pharmaceuticals, LLC, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Vyera Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, attorneys, representatives, successors, and assigns of each. Vyera Pharmaceuticals, LLC is a subsidiary of Phoenixus.
- C. "Kevin Mulleady" or "Mulleady" means Defendant Kevin Mulleady, an individual defendant. Mulleady was Chairman of the Board of Directors of Phoenixus AG and Chief Executive Officer of Vyera Pharmaceuticals, LLC. Mulleady is also the Executive Chairman and Chief Executive Officer of Prospero Pharmaceuticals, LLC.
- D. "Commission" means the United States Federal Trade Commission.
- E. "Plaintiff States" mean the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.
- F. "API" means any active pharmaceutical ingredient that is used in the manufacture of a Drug Product.
- G. "Biosimilar" means any biologic Drug Product that is highly similar to, and has no clinically meaningful difference from, an existing FDA-approved biologic Drug Product or that otherwise meets the FDA's criteria for classification as a biosimilar.

- H. “Corporate Asset” means any asset of a Corporate Named Defendant or any successor, assign, joint venture, subsidiary, partnership, division, group, or affiliate controlled by a Corporate Named Defendant. Corporate Asset expressly excludes any inventory, goods or products that are sold or to be sold in the ordinary course of business, including without limitation, any APIs, raw materials, or finished product. Corporate Asset also expressly excludes any unissued shares of equity interests, capital stock, partnership interest, membership or limited liability company interest or similar equity right in one or both of the Corporate Named Defendants or any successor, assign, joint venture, subsidiary, partnership, division, group, or affiliate controlled by any of them.
- I. “Corporate Defendants” means Phoenixus and Vyera.
- J. “Corporate Named Defendants” means Phoenixus AG and Vyera Pharmaceuticals, LLC.
- K. “Customer or Supplier” means a counter-party to a distribution, wholesale, resale, API supply, or Drug Product purchase agreement with a Corporate Defendant.
- L. “Daraprim” means any Drug Product authorized for marketing or sale in the United States pursuant to FDA Authorization NDA 008578, and any supplements, amendments, or revisions to this NDA.
- M. “Designated State Representatives” mean the following named individuals or another representative identified by each respective Plaintiff State:
  - 1. Elinor R. Hoffmann, Chief, Antitrust Bureau, Office of the New York State Attorney General, 28 Liberty Street, New York, NY 10005, [elinor.hoffmann@ag.ny.gov](mailto:elinor.hoffmann@ag.ny.gov);
  - 2. Michael D. Battaglia, Deputy Attorney General, California Department of Justice, 455 Golden Gate Avenue, Suite 11000, San Francisco, CA 94102, [michael.battaglia@doj.ca.gov](mailto:michael.battaglia@doj.ca.gov);
  - 3. Richard S. Schultz, Assistant Attorney General, Antitrust Bureau, Office of the Illinois Attorney General, 100 West Randolph Street, Chicago, IL 60601, [richard.schultz@ilag.gov](mailto:richard.schultz@ilag.gov);
  - 4. K. D. Sturgis, Special Deputy Attorney General, North Carolina Department of Justice, 114 West Edenton Street, Raleigh, NC 27603, [ksturgis@ncdoj.gov](mailto:ksturgis@ncdoj.gov);
  - 5. Beth A. Finnerty, Assistant Chief, Antitrust Section, Office of the Ohio Attorney General, 30 East Broad Street, 26th Floor, Columbus, OH 43215, [Beth.Finnerty@ohioAGO.gov](mailto:Beth.Finnerty@ohioAGO.gov);
  - 6. Joseph S. Betsko, Senior Deputy Attorney General, Pennsylvania Office of Attorney General, Strawberry Square, Harrisburg, PA 17120, [jbetsko@attorneygeneral.gov](mailto:jbetsko@attorneygeneral.gov); and
  - 7. Tyler T. Henry, Assistant Attorney General, Office of the Attorney General of Virginia, 202 North Ninth Street, Richmond, VA 23219, [thenry@oag.state.va.us](mailto:thenry@oag.state.va.us).
- N. “Development” means all preclinical and clinical research and development activities related to a Drug Product, including discovery or identification of a new chemical entity, test method development, all studies for the safety or efficacy of a Drug Product, toxicology studies, bioequivalence and bioavailability studies, pharmaceutical

formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, stability testing, statistical analysis and report writing, for the purpose of obtaining any and all FDA Authorizations necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, labeling, distribution, and sale of a Drug Product, and regulatory affairs related to the foregoing.

- O. “Drug Product” means any product that is the subject of an FDA Authorization.
- P. “Exempted Company” means any Pharmaceutical Company owned or controlled by Mulleady (including Prospero) whose business is limited to a Therapeutic Equivalent of Thiola and/or the PKAN Product.
- Q. “FDA” means the United States Food and Drug Administration.
- R. “FDA Authorization” means any of the following applications:
  - 1. An application filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 *et seq.*, including “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto; or
  - 2. A “Biologic License Application” (“BLA”) filed or to be filed with the FDA pursuant to 21 C.F.R. 601.2, *et seq.*, and Section 351 of the Public Health Service Act, and any NDA deemed to be a BLA by the FDA, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- S. “GPO” means any group purchasing organization, an entity that negotiates prices of Drug Products on behalf of member healthcare providers, including hospitals, ambulatory care facilities, physician practices, nursing homes, and home health agencies.
- T. “Net Proceeds” means proceeds after deducting direct transaction costs paid to Third Parties (i.e., sales commissions, advisor fees, and other costs incurred solely due to the underlying transaction).
- U. “Ownership Interest” means any voting or non-voting stock, share capital, or equity in a Person (other than an individual). Ownership Interest shall not include any unexercised options or other unexercised instruments that are convertible into any voting or non-voting stock.
- V. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- W. “Pharmaceutical Company” means any Person (other than an individual) that is engaged in the research, Development, manufacture, commercialization, or marketing of any Drug Product.

- X. “PKAN Product” means the chemical compound that, as of the date this Order is entered, Prospero is involved in the Development of as a potential treatment for pantothenate kinase-associated neurodegeneration (“PKAN”).
- Y. “Priority Review Voucher” means a voucher issued by the FDA that entitles a Drug Product to receive expedited regulatory review.
- Z. “Prospero” means Prospero Pharmaceuticals, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Prospero Pharmaceuticals, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- AA. “Therapeutic Equivalent” means a Drug Product that is classified by the FDA as being therapeutically equivalent to another Drug Product because, among other criteria, both Drug Products contain identical amounts of an API in the identical dosage form and route of administration, meet compendial or other applicable standards of strength, quality, purity, and identity, and they are classified by the FDA as bioequivalent.
- BB. “Thiola” means the Drug Products authorized for marketing or sale in the United States pursuant to FDA Authorizations NDA 019569 or NDA 211843, and any supplements, amendments, or revisions to these NDAs.
- CC. “Third Party” means any Person that is not a Corporate Defendant or an entity under common management, direction, or control of a Corporate Defendant.

## II. PROHIBITED BUSINESS ACTIVITIES

### Corporate Defendants

- A. The Corporate Defendants, directly or through any Person, are hereby restrained and enjoined from entering into or enforcing any contract, arrangement, mutual understanding, or agreement that prohibits, or in any manner interferes with or restricts the ability of:
  - 1. Any purchaser (including hospitals and pharmacies), reseller, wholesaler, or distributor of a Drug Product to provide that Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of that Drug Product by that Pharmaceutical Company,  
*Provided, however,* this provision does not prohibit the Corporate Defendants from entering an agreement with a distributor that restricts that distributor to certain channels of sale so long as it permits the distributor to sell the Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of the Drug Product;
  - 2. Any manufacturer, seller, supplier, or distributor of an API to sell or provide that API to a Pharmaceutical Company,



*Provided, however,* this provision does not prohibit a Corporate Defendant from entering a contract to purchase all of its needs for a particular API from any Person so long as the contract does not require the Person to supply the API exclusively to the Corporate Defendant or restrict the Person's freedom to sell the API to any other Person, and

*Provided further,* if the Corporate Defendants have no other supply agreement for a particular API, this provision will not apply to any arrangement to obtain API from a Person who has not previously manufactured the API if the Corporate Defendants bear at least 50% of the direct costs of developing the API; or

3. Any distributor, wholesaler, pharmacy, or GPO of a Drug Product to sell or otherwise provide data related to the sales or distribution of any Drug Product, such as sales numbers and volume, or other sales variables such as ordering trends, to a Person engaged in the business of purchasing, aggregating, and selling sales and distribution data on Drug Products.
- B. The Corporate Defendants shall not hire, appoint as an officer or director, or otherwise do business with Mulleady in any manner that violates Paragraph II.C of this Order and shall not hire, appoint as an officer or director, or otherwise do business with Defendant Martin Shkreli in any manner that violates any provision or restriction in an order issued by this Court.

**Defendant Kevin Mulleady**

- C. For a period ending 7 years after this Order is entered, Mulleady is hereby banned, restrained, and enjoined from, directly, or through any other Person:
1. Participating in the research, Development, manufacture, commercialization, distribution, marketing, importation, or sale of a Drug Product or API, including participating in the formulation, determination, or direction of any business decisions of any Pharmaceutical Company;
  2. Exercising control over the activities, conduct, board, or management of any Pharmaceutical Company;
  3. Serving as an officer or director of any Pharmaceutical Company;
  4. Entering into any agreements, whether oral or written, concerning how to vote his shares in any Pharmaceutical Company; and
  5. Calling an Extraordinary General Meeting at Phoenixus or Vyera either on his own or as part of a group doing so,

*Provided, however,* Mulleady may exercise all other rights to which he is entitled as a shareholder of an Exempted Company and/or any Pharmaceutical Company to the extent such shareholding is permitted by Paragraph II.D. Nothing in this Paragraph II.C shall preclude Mr. Mulleady from expressing his own views on his own behalf as a shareholder concerning the business of any such Pharmaceutical Company,

*Provided, further*, it is not a violation of this Paragraph II.C for Mulleady to be employed by, consult with, or act as an officer or director of Phoenixus or Vyera, and in so doing take the actions set forth in Paragraphs II.C.1 to 3, so long as:

- a) Mulleady does not own or control any Ownership Interest in Phoenixus or Vyera, either directly or through any other Person, and
- b) Mulleady provides prior notification to the Commission and the Plaintiff States of any proposed involvement in or engagement with Phoenixus or Vyera pursuant to Paragraph VI.C, and

*Provided, finally*, that it is not a violation of this Paragraph II.C for Mulleady to be employed by, consult with, or act as an officer or director of an Exempted Company and/or take the actions set forth in Paragraphs II.C.1 to 4 at an Exempted Company, so long as:

- a) The Exempted Company's business is limited to (i) a Therapeutic Equivalent of Thiola and/or (ii) the PKAN Product, and the Exempted Company does not have an interest or role in, and is not engaged in any activities related to, any other Drug Product;
- b) The Exempted Company's financial interest in any Therapeutic Equivalent of Thiola is limited to a passive royalty right;
- c) The Exempted Company does not have any authority, control, or other role in, or engage in any activities related to, the commercialization, marketing, sales, distribution, or pricing of any Therapeutic Equivalent of Thiola;
- d) Prior to the filing of an FDA Authorization, the Exempted Company fully divests itself of any control or authority to commercialize, market, sell, distribute, or price any PKAN Product; and
- e) Mulleady complies with the prior notification provisions set forth in Paragraphs VI.D and VIII.B.

- D. Mulleady is hereby restrained and enjoined from acquiring, holding, or voting more than 8% of the Ownership Interest (based on the latest information available to shareholders from the issuer) in any Pharmaceutical Company (other than an Exempted Company), either directly or through any other Person,

*Provided, however*, it shall not be a violation of this Paragraph II.D if Mulleady passively obtains more than 8% of the Ownership Interest in a Pharmaceutical Company through means other than exercising options or otherwise purchasing the Ownership Interest so long as Mulleady (i) reduces his Ownership Interest in such Pharmaceutical Company to 8% or lower within 10 months, and (ii) in the interim only votes up to 8% of the Ownership Interest in the Pharmaceutical Company,

*Provided, further*, this Paragraph II.D does not permit Mulleady to acquire, hold, or vote any Ownership Interest in Phoenixus or Vyera while Mulleady is employed by, consulting with, or acting as officer or director for Phoenixus or Vyera, and



*Provided, finally,* Mulleady may exercise the rights to which he is entitled as a shareholder of a Pharmaceutical Company (other than those prohibited by Paragraphs II.C.4 and 5) so long as his Ownership Interest in such company does not exceed the limits in this Paragraph II.D.

- E. If Phoenixus or Vyera is found in violation of Section II of this Order, it shall be presumed that Mulleady has also violated the terms of this Order, but only if he is employed by, consulting with, or acting as officer or director for Phoenixus or Vyera at the time the violation occurs. Mulleady may rebut this presumption by proving to the Court by a preponderance of the evidence that he did not have any knowledge of, involvement in, or in any manner facilitate, the violation of this Order.
- F. Mulleady, any Exempted Company, and any other company Mulleady controls, is restrained and enjoined from proposing, negotiating, reviewing, entering into, being a party to, or enforcing, either directly or through any other Person, any contract, arrangement, mutual understanding, or agreement that prohibits, or in any manner interferes with or restricts the ability of:
  - 1. Any purchaser (including hospitals and pharmacies), reseller, wholesaler, or distributor of a Drug Product to provide that Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of that Drug Product by that Pharmaceutical Company,  
  
*Provided, however,* this provision does not prohibit Mulleady, any Exempted Company, or any other company Mulleady controls from entering an agreement with a distributor that restricts that distributor to certain channels of sale so long as it permits the distributor to sell the Drug Product to a Pharmaceutical Company or its agent(s) or representative(s) for the purposes of the Development of a Therapeutic Equivalent or Biosimilar of the Drug Product;
  - 2. Any manufacturer, seller, supplier, or distributor of any API to provide that API to a Pharmaceutical Company,  
  
*Provided, however,* this provision does not prohibit Mulleady, any Exempted Company, or any other company Mulleady controls from entering a contract to purchase all of its needs for a particular API from any Person so long as the contract does not require the Person to supply the API exclusively to the company or restrict the Person's freedom to sell the API to any other Person, and  
  
*Provided further,* if Mulleady, any Exempted Company, or any other company Mulleady controls has no other supply agreement for the particular API, this provision will not apply to any arrangement to obtain API from a Person who has not previously manufactured the API if Mulleady, the Exempted Company, or any company he owns or controls bears at least 50% of the direct costs of developing the API; or
  - 3. Any distributor, wholesaler, pharmacy, or GPO of a Drug Product to sell or otherwise provide data related to the sales or distribution of any Drug Product, such as sales numbers and volume, or other sales variables such as ordering

trends, to a Person engaged in the business of purchasing, aggregating, and selling sales and distribution data on Drug Products.

### III. NOTIFICATIONS TO AFFECTED PERSONS

#### **Corporate Defendants**

The Corporate Defendants shall provide, within 21 days of the entry of this Order, written notification in the form of Appendix A to this Order to all their Customers and Suppliers, and going forward shall provide such notification to any Customer or Supplier to whom the Corporate Defendants have not previously provided notification under this Section III,

*Provided, however,* the Corporate Defendants need not provide notice to Customers entering into an agreement to purchase generic prescription drugs so long as the agreement does not also include branded prescription drugs or an API.

### IV. SUPPLY OF DRUG PRODUCTS

#### **Corporate Defendants**

- A. So long as a Corporate Defendant markets a Drug Product, they shall, at the request of a Pharmaceutical Company, sell the Drug Product to that Pharmaceutical Company for use in Development of a Therapeutic Equivalent or Biosimilar of the Drug Product in accordance with the following:
  1. The quantity sold shall be at least as much as the Pharmaceutical Company, in its reasonable judgment, needs to conduct its Development of a Therapeutic Equivalent or Biosimilar of the Drug Product;
  2. The Drug Product is delivered no later than 30 days after the Corporate Defendant receives a purchase order; and
  3. The Corporate Defendants shall charge the Pharmaceutical Company a price that is no greater than the wholesale acquisition cost of the Drug Product.
- B. The Corporate Defendants shall continue to market and sell Daraprim until the earliest to occur of the following:
  1. At least three Pharmaceutical Companies that are Third Parties have obtained FDA Authorization to market and sell a Therapeutic Equivalent of Daraprim and each has made at least one commercial sale of the Therapeutic Equivalent;
  2. At least two Pharmaceutical Companies that are Third Parties have obtained FDA Authorization to market and sell a Therapeutic Equivalent of Daraprim and each of these Pharmaceutical Companies has made uninterrupted commercial sales of the Therapeutic Equivalent for a period of at least 9 months;
  3. The Corporate Defendants exhaust their supply of pyrimethamine API, the API is no longer available, or the API is only available at a cost or in quantities that

make it unprofitable to continue marketing and selling Daraprim, and the Corporate Defendants notify the Commission and the Designated State Representatives of their inability to secure a supply of pyrimethamine and the reasons therefore;

4. An independent auditor, selected by the Corporate Defendants and approved by the Plaintiffs, verifies that the operating expenses (including variable and fixed costs) for Daraprim exceeded net revenues generated through the sale of Daraprim for at least two consecutive quarters;
  5. The Corporate Defendants lose FDA Authorization to continue marketing Daraprim;
  6. Three years after this Order is entered; or
  7. The Corporate Defendants (a) notify the Commission and the Plaintiff States of their intent to discontinue marketing Daraprim; (b) sell their Daraprim business to an acquirer (“Acquirer”) and in a manner that is acceptable to the Commission and the Plaintiff States; (c) maintain the viability, marketability, and competitiveness of the Daraprim business until the sale of the Daraprim business is completed; and (d) provide the Acquirer with the assistance and information necessary to enable the Acquirer to obtain the necessary approvals to manufacture, market, and sell Daraprim in commercial quantities, and to supply the Acquirer with sufficient quantities of Daraprim to meet the Acquirer’s commercial needs until the Acquirer is independently able to manufacture and market commercial quantities of Daraprim.
- C. The Corporate Defendants shall provide notifications required under this Section IV to the Commission and the Plaintiff States by sending electronic copies to the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and to the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov), and by sending electronic copies to each Designated State Representative.

## **V. EQUITABLE MONETARY RELIEF**

### **Corporate Named Defendants**

- A. The Corporate Named Defendants shall pay up to \$40 million to the Settlement Fund (defined below), comprised of a guaranteed payment of \$10 million, and contingent payments of up to \$30 million pursuant to Paragraph V.C.
- B. The Corporate Named Defendants shall pay \$10 million as equitable monetary relief, which shall be used for a settlement fund in accordance with the terms of this Order (“Settlement Fund”). The Corporate Named Defendants will make this payment within 30 business days of the entry of this Order by electronic fund transfer into the Settlement Fund in accordance with instructions provided by the Plaintiff States. The money deposited into the Settlement Fund shall be held in escrow and distributed in the manner prescribed in Paragraph V.D herein.

C. The Corporate Named Defendants are ordered to make additional payments of equitable monetary relief, not to exceed \$30 million in the aggregate, to the Settlement Fund as described below:

1. For any Corporate Asset other than a Priority Review Voucher, Corporate Named Defendants will:
  - a) Pay 20% of the total Net Proceeds from the sale, license, transfer, or other monetization of an asset that results from a transaction that is executed within 5 years after this Order is entered; and
  - b) Pay 20% of the total Net Proceeds from a transaction monetizing the remaining royalty stream related to Ketamine assets that is executed prior to entry of this Order or within 5 years after this Order is entered.

Corporate Named Defendants must transfer monies related to transaction into the Settlement Fund within 30 days of its receipt; for example, in a transaction with an upfront payment and royalty stream, the Corporate Named Defendants would pay 20% of the net upfront payment within 30 days of receiving the upfront payments and would pay 20% of any additional royalties within 30 days of when the royalties are received by either Corporate Named Defendant,

*Provided, however,* the Corporate Named Defendants shall not be required to make payments under this Paragraph V.C.1 after (a) their total payments to the Settlement Fund under this Paragraph V.C.1 equal \$15 million, or (b) their total combined payments to the Settlement Fund under Paragraphs V.C.1 and V.C.2 equal \$30 million.

2. For any Priority Review Voucher that is a Corporate Asset, the Corporate Named Defendants will pay 20% of the Net Proceeds received from the the sale, license, transfer or other monetization of the Priority Review Voucher that results from a transaction executed during the term of this Order,

*Provided, however,* the Corporate Named Defendants shall not be required to make payments under this Paragraph V.C.2 after their total payments to the Settlement Fund under Paragraphs V.C.1 and V.C.2 equal \$30 million.

3. No later than 30 days after any transaction for which the Corporate Named Defendants are required to make additional payments under this Paragraph V.C., the Corporate Named Defendants shall provide notice to the Designated State Representatives of the transaction. The notice shall include a description of the transaction and its financial terms, contact information for each party to the transaction (including the name, phone number and email address of a representative of the party with knowledge of the transaction), and a copy of all agreements regarding the transaction.

D. All money deposited in the Settlement Fund pursuant to this Section V shall be used for equitable relief, including consumer redress and other equitable relief that the Plaintiff States determine to be related to the Corporate Named Defendants' alleged violative practices and injury, any attendant expenses for the administration of such fund, and repayment of out-of-pocket expenses, and to satisfy the amount of any settlement reached

in the related case, *BCBSM, Inc. v. Vyera Pharmaceuticals, LLC, et al.*, No. 21-cv-01884-DLC (SDNY) (the “Class Action”). Any money remaining in the fund after such distributions shall be deposited by the Plaintiff States as disgorgement to be used consistently with their respective state laws. Any interest earned on amounts deposited into the fund will remain in the fund and become a part of the fund.

- E. Within 10 business days of entry of the Order, the Corporate Named Defendants shall submit their Taxpayer Identification Numbers (Employer Identification Numbers) to the Plaintiff States.
- F. The Corporate Named Defendants shall have no right to challenge any actions the Plaintiff States or their representatives may take pursuant to this Section V of this Order.
- G. In consideration for the settlement of this matter and Plaintiff States’ agreement to receive equitable monetary relief over a period of 10 years, one or both Corporate Named Defendants, on behalf of themselves and their successors, and any subsidiaries, and affiliates controlled by them, whether private or publicly-traded, shall sign within 30 days of entry of this Order a collateral agreement (in the form contained in Appendix B or as otherwise agreed to by the Plaintiff States and the Corporate Named Defendants) to secure the contingent debt described in Paragraph V.C as follows: (1) the Corporate Named Defendants give and grant the Plaintiff States a secured interest in all of the assets that are Corporate Assets (other than as set forth in Appendix B and other than any right, title, or interest in any Priority Review Voucher) of the Corporate Named Defendants until the obligation in Paragraph V.C.1 has been fully satisfied or the prescribed period of time has expired; and (2) the Corporate Named Defendants give and grant the Plaintiff States a secured interest in the Priority Review Voucher that is a Corporate Asset until the obligations of Paragraph V.C.2 have been fully satisfied or the prescribed period of time has expired. The Corporate Named Defendants shall promptly provide information requested by a Designated State Representative to facilitate the perfection or enforcement of the security interest granted under the collateral agreement. If Corporate Named Defendants file for bankruptcy protection, within this 10 year period, the Corporate Named Defendants shall not object to the Plaintiff States asserting the appropriate security interest as a Secured Creditor with the appropriate court.

#### **Defendant Kevin Mulleady**

- H. Judgment in the amount of two hundred and fifty thousand dollars (\$250,000) is entered in favor of the Plaintiff States against Mulleady as equitable monetary relief in connection with a negotiated resolution of this action and not as part of any final adjudication of any issue of fact or law. The judgment is suspended unless and until there is a final unappealable judgment of contempt against Mulleady (i.e., all parties have exhausted their rights to appeal the judgment of contempt or the time for all such appeals has lapsed). A final unappealable judgment of contempt against Mulleady shall lift the suspension of the judgment and Mulleady shall be required to pay the judgment within 90 days of delivery of instructions by a Designated State Representative. Neither party will contest the other party’s right to appeal any order or judgment of contempt or other violation of this Order.

## VI. PRIOR NOTIFICATION REQUIREMENTS

### **Corporate Defendants**

- A. The Corporate Defendants shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire from a Third Party:
1. Any Pharmaceutical Company;
  2. Any rights or interest in any Pharmaceutical Company; or
  3. Any exclusive rights to market, distribute, or sell any FDA-approved Drug Product;

without providing prior written notification to the Commission and each of the Designated State Representatives.

The prior notification required by this Section VI shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the “Notification”), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification. Notification shall be filed with the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov), and copies provided to the Compliance Division of the Commission at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov), and each Designated State Representative. Notification need not be made to the Department of Justice. Notification is required only of the Corporate Defendants and not of any other party to the transaction. The Corporate Defendants shall provide Notification to the Commission and to each of the Designated State Representatives at least 30 days prior to consummating any such transaction (hereafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 802.20), the Corporate Defendants shall not consummate the transaction until 30 days after substantially complying with such request. Early termination of the waiting periods in this Paragraph VI.A may be requested by the Corporate Defendants and, where appropriate, granted by a letter from the Commission’s Bureau of Competition,

*Provided, however,* that prior notification to the Commission shall not be required by this Order for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act 15 U.S.C. § 18a; however, notification shall still be made to the Designated State Representatives, and

*Provided further,* that prior notification shall not be required by this Order for a transaction valued at less than \$25 million, as adjusted annually on the anniversary of the date this Order is entered based on the yearly increase or decrease of the Producer Price Index for Pharmaceutical Preparation Manufacturing.

### **Defendant Kevin Mulleady**

- B. If Mulleady, directly or through any other Person, acquires more than 1% of Ownership Interest in a Pharmaceutical Company (other than indirectly through a mutual fund,



exchange-traded fund, or other diversified, investment vehicle that is not specifically focused on Pharmaceutical Companies), Mulleady shall provide written notification to the Commission and to each of the Designated State Representatives within 30 days of acquiring such interest,

*Provided, however,* Mulleady need not provide notice of his Ownership Interest in Phoenixus, Vyera, or Prospero as of the date this Order is entered.

As part of his notification, Mulleady shall describe, by number of shares and percentage of total ownership, based on the latest information available to shareholders from the issuer (which source Mulleady shall identify in the referenced notification), the size of his Ownership Interest in the relevant Pharmaceutical Company before the transaction, and the size of the Ownership Interest he acquired in the transaction.

- C. Mulleady shall not be employed by, consult with, or act as an officer or director for Phoenixus or Vyera pursuant to Paragraph II.C without providing 30 days' prior written notification to the Commission and each of the Designated State Representatives. As part of his notification, Mulleady must identify and describe in detail his position and responsibilities, provide a copy of any employment or consulting agreement, identify and provide contact information for his immediate supervisor, and certify that he has provided a copy of the Order to his immediate supervisor. If, in response to the notification required pursuant to this Paragraph VI.C, representatives of the Commission or the Plaintiff States make a written request for additional information or documentary material, Mulleady will not commence any such work for Phoenixus or Vyera until 30 days after substantially complying with the request.
- D. If Mulleady is employed by, consulting with, or acting as an officer or director of an Exempted Company, then the Exempted Company may not divest itself of control or authority to commercialize, market, sell, distribute, or price the PKAN Product without providing 30 days' advance written notice of the closing of any such transaction to the Commission and the Plaintiff States. The written notification must identify the intended counterparty and value and date of the proposed transaction. No filing fee shall be required for such notification. If, in response to a notification required pursuant to this Paragraph VI.D, representatives of the Commission or the Plaintiff States make a written request for additional information or documentary material, the Exempted Company shall not consummate the transaction until 30 days after submitting such additional information or documentary material. The Commission and Plaintiff States are collectively limited to a single such request for additional information.

## VII. COMPLIANCE REPORTING REQUIREMENTS

### All Settling Defendants

- A. Each Settling Defendant shall submit to the Commission and to each of the Designated State Representatives verified written reports ("Compliance Reports") setting forth in detail the manner and form in which each Settling Defendant intends to comply, has complied, and is complying with this Order, in accordance with the following:

1. Each Settling Defendant shall submit an initial Compliance Report within 60 days of the entry of this Order;
  2. On the first anniversary of the entry of this Order, and annually thereafter for 9 years on the anniversary date of the entry of this Order, each Settling Defendant shall submit an annual Compliance Report; and
  3. Each Settling Defendant shall submit additional Compliance Reports as the Commission or its staff or a Designated State Representative may request.
- B. Each Compliance Report shall contain sufficient information and documentation to enable the Commission and the Plaintiff States to determine whether the Settling Defendants are in compliance with the Order. Conclusory statements that the Settling Defendant has complied with its or his obligations under this Order are insufficient.
- C. The Corporate Defendants shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance with this Order:
1. A full description of the measures the Corporate Defendants have implemented or plans to implement to ensure that they have complied, are complying, or will comply with each paragraph of this Order;
  2. A certified accounting of all proceeds from the sale, license, transfer, or other monetization of any Corporate Asset (other than an asset related to a Priority Review Voucher) and the monetization of the remaining royalty stream related to Ketamine; and
  3. A certified accounting of all proceeds from the sale, license, transfer, or other monetization of any Priority Review Voucher.
- D. Mulleady shall include in his Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance with this Order:
1. A full description of the measures he has implemented or plans to implement to ensure that he has complied, is complying, or will comply with each paragraph of this Order, and
  2. Information that identifies and describes all ballots cast by him, directly or indirectly, in the exercise of his voting interest in any Pharmaceutical Company. Upon request by the Commission or a Designated State Representative, Mulleady shall provide copies of such ballots.
- E. Each Settling Defendant shall retain all material written communications with each party identified in its or his Compliance Report and all internal memoranda, reports, and recommendations concerning fulfilling its or his obligations under this Order, and shall provide non-privileged copies of these documents to Commission staff and the Designated State Representatives upon request.
- F. Each Settling Defendant shall submit its or his Compliance Report to the Commission and the Plaintiff States by submitting the report electronically to the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov), to the Compliance Division of the Commission at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov), and to each Designated State Representative.

## **VIII. CHANGE OF CORPORATE CONTROL**

### **Corporate Defendants**

- A. The Corporate Defendants shall notify the Commission and each Designated State Representative at least 30 days prior to:
1. The dissolution of a Corporate Named Defendant;
  2. Any proposed acquisition, merger, or consolidation of a Corporate Named Defendant; or
  3. Any other change in a Corporate Named Defendant, including assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

### **Defendant Kevin Mulleady**

- B. If Mulleady is employed by, consulting with, or acting as an officer or director of an Exempted Company, then Mulleady shall notify the Commission and each Designated State Representative at least 30 days prior to:
1. The dissolution of the Exempted Company;
  2. The closing of any proposed acquisition, merger, or consolidation of the Exempted Company;
  3. The closing of any proposed change of ownership, control, or authority of the PKAN Product; or
  4. Any other change in the Exempted Company, including assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

## **IX. ACCESS TO INFORMATION**

### **All Settling Defendants**

For purposes of determining or securing compliance with this Order, subject to any legally recognized privilege, upon written request, and upon 10 business days' notice to a Corporate Defendant (made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address), or to Mulleady (if Mulleady is employed at, consulting with, or acting as officer or director of an Exempted Company in accordance with Paragraph II.C), the notified Corporate Defendant or Mulleady shall, without restraint or interference, permit any duly authorized representative of the Commission or of a Designated State Representative:

- A. Access, during business office hours of the Corporate Defendant or the Exempted Company, and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and all other

records and documents (“Books and Records”) in the possession or under the control of that Corporate Defendant or Mulleady related to compliance with this Order, which copying services shall be provided by the Corporate Defendant or Mulleady at the request of the authorized representative(s) of the Commission or of a Designated State Representative and at the expense of the Corporate Defendant or Mulleady,

*Provided, however,* that if the Exempted Company does not have dedicated facilities of its own (including rented office space in a multipurpose building), Mulleady may make such Books and Records available at an alternative location within the Southern District of New York; and

- B. To interview officers, directors, or employees of the Corporate Defendant or the Exempted Company, who may have counsel present, regarding such matters.

## **X. COOPERATION**

### **Corporate Defendants**

- A. In connection with litigation in this matter against Defendant Martin Shkreli, the Corporate Defendants shall:
1. Agree not to object or move to quash service of process of trial subpoenas to Anne Kirby and Nicholas Pelliccione issued by the Commission or the Plaintiff States under Rule 45 of the Federal Rules of Civil Procedure; and agree to seek their authorization to accept service on their behalf; and
  2. Negotiate in good faith with the Commission and a Designated State Representative to provide a declaration, affidavit or, if necessary, a sponsoring witness to establish the authenticity and admissibility of any documents or data that the Corporate Defendants produce or have produced to the Commission or the Plaintiff States.

### **Defendant Kevin Mulleady**

- B. In connection with litigation in this matter against Defendant Martin Shkreli, Mulleady shall:
1. Agree to service of process of a trial subpoena to Mulleady issued by the Commission or the Plaintiff States under Rule 45 of the Federal Rules of Civil Procedure; and
  2. Negotiate in good faith with the Commission and a Designated State Representative to provide a declaration, affidavit or, if necessary, act as a sponsoring witness to establish the authenticity and admissibility of any documents or data as to which he has personal knowledge or can provide evidence as to its reliability.

**XI. RETENTION OF JURISDICTION**

This Court shall retain jurisdiction of this matter for the purposes of construction, modification, and enforcement of this Order.

**XII. EXPIRATION OF ORDER**

This Order shall expire 10 years after the date it is entered.

**XIII. DISMISSAL AND COSTS**


This action is hereby dismissed with prejudice as to the Settling Defendants. Each party to bear its own costs.

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

---

The Honorable Denise Cote

SO STIPULATED AND AGREED:

  
\_\_\_\_\_  
Markus H. Meier  
Assistant Director  
Health Care Division  
Bureau of Competition  
Federal Trade Commission  
FOR PLAINTIFF FEDERAL TRADE COMMISSION

Date: 12/6/21

\_\_\_\_\_  
Elinor R. Hoffmann  
Chief  
Antitrust Bureau  
Office of the New York State Attorney General  
FOR PLAINTIFF STATE OF NEW YORK

Date: \_\_\_\_\_

\_\_\_\_\_  
Michael D. Battaglia  
Deputy Attorney General  
California Department of Justice  
FOR PLAINTIFF STATE OF CALIFORNIA

Date: \_\_\_\_\_

\_\_\_\_\_  
Richard S. Schultz  
Assistant Attorney General  
Antitrust Bureau  
Office of the Illinois Attorney General  
FOR PLAINTIFF STATE OF ILLINOIS

Date: \_\_\_\_\_



SO STIPULATED AND AGREED:

\_\_\_\_\_  
Markus H. Meier  
Assistant Director  
Health Care Division  
Bureau of Competition  
Federal Trade Commission  
FOR PLAINTIFF FEDERAL TRADE COMMISSION

Date: \_\_\_\_\_



\_\_\_\_\_  
Elinor R. Hoffmann  
Chief  
Antitrust Bureau  
Office of the New York State Attorney General  
FOR PLAINTIFF STATE OF NEW YORK

Date: 12/4/2021

\_\_\_\_\_  
Michael D. Battaglia  
Deputy Attorney General  
California Department of Justice  
FOR PLAINTIFF STATE OF CALIFORNIA

Date: \_\_\_\_\_

\_\_\_\_\_  
Richard S. Schultz  
Assistant Attorney General  
Antitrust Bureau  
Office of the Illinois Attorney General  
FOR PLAINTIFF STATE OF ILLINOIS

Date: \_\_\_\_\_


SO STIPULATED AND AGREED:

\_\_\_\_\_  
Markus H. Meier  
Assistant Director  
Health Care Division  
Bureau of Competition  
Federal Trade Commission  
FOR PLAINTIFF FEDERAL TRADE COMMISSION

Date: \_\_\_\_\_

\_\_\_\_\_  
Elinor R. Hoffmann  
Chief  
Antitrust Bureau  
Office of the New York State Attorney General  
FOR PLAINTIFF STATE OF NEW YORK

Date: \_\_\_\_\_

  
\_\_\_\_\_  
Michael D. Battaglia  
Deputy Attorney General  
California Department of Justice  
FOR PLAINTIFF STATE OF CALIFORNIA

Date: 12/5/2021

\_\_\_\_\_  
Richard S. Schultz  
Assistant Attorney General  
Antitrust Bureau  
Office of the Illinois Attorney General  
FOR PLAINTIFF STATE OF ILLINOIS

Date: \_\_\_\_\_

SO STIPULATED AND AGREED:

\_\_\_\_\_  
Markus H. Meier  
Assistant Director  
Health Care Division  
Bureau of Competition  
Federal Trade Commission  
FOR PLAINTIFF FEDERAL TRADE COMMISSION


Date: \_\_\_\_\_

\_\_\_\_\_  
Elinor R. Hoffmann  
Chief  
Antitrust Bureau  
Office of the New York State Attorney General  
FOR PLAINTIFF STATE OF NEW YORK

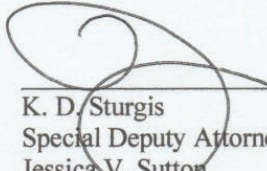
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\_\_\_\_\_  
Michael D. Battaglia  
Deputy Attorney General  
California Department of Justice  
FOR PLAINTIFF STATE OF CALIFORNIA

Date: \_\_\_\_\_

  
\_\_\_\_\_  
Richard S. Schultz  
Assistant Attorney General  
Antitrust Bureau  
Office of the Illinois Attorney General  
FOR PLAINTIFF STATE OF ILLINOIS

Date: 12/6/21

  
\_\_\_\_\_  
K. D. Sturgis  
Special Deputy Attorney General  
Jessica V. Sutton  
Special Deputy Attorney General  
North Carolina Department of Justice  
FOR PLAINTIFF STATE OF NORTH CAROLINA

Date: 12/5/2021

\_\_\_\_\_  
Beth A. Finnerty  
Assistant Chief  
Antitrust Section  
Office of the Ohio Attorney General  
FOR PLAINTIFF STATE OF OHIO

Date: \_\_\_\_\_

\_\_\_\_\_  
Joseph S. Betsko  
Senior Deputy Attorney General  
Pennsylvania Office of Attorney General  
FOR PLAINTIFF COMMONWEALTH OF PENNSYLVANIA

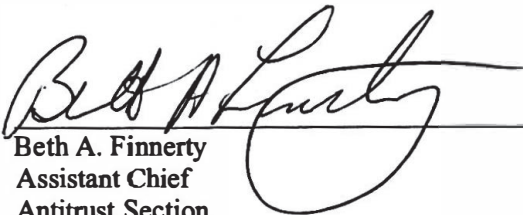
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\_\_\_\_\_  
Tyler T. Henry  
Assistant Attorney General  
Office of the Attorney General of Virginia  
FOR PLAINTIFF COMMONWEALTH OF VIRGINIA

Date: \_\_\_\_\_

\_\_\_\_\_  
K. D. Sturgis  
Special Deputy Attorney General  
Jessica V. Sutton  
Special Deputy Attorney General  
North Carolina Department of Justice  
FOR PLAINTIFF STATE OF NORTH CAROLINA

Date: \_\_\_\_\_

  
\_\_\_\_\_  
Beth A. Finnerty  
Assistant Chief  
Antitrust Section  
Office of the Ohio Attorney General  
FOR PLAINTIFF STATE OF OHIO

Date: 12-6-21

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Senior Deputy Attorney General  
Pennsylvania Office of Attorney General  
FOR PLAINTIFF COMMONWEALTH OF PENNSYLVANIA

Date: \_\_\_\_\_

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Assistant Attorney General  
Office of the Attorney General of Virginia  
FOR PLAINTIFF COMMONWEALTH OF VIRGINIA

Date: \_\_\_\_\_


Date: \_\_\_\_\_

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Special Deputy Attorney General  
Jessica V. Sutton  
Special Deputy Attorney General  
North Carolina Department of Justice  
FOR PLAINTIFF STATE OF NORTH CAROLINA

Date: \_\_\_\_\_

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Antitrust Section  
Office of the Ohio Attorney General  
FOR PLAINTIFF STATE OF OHIO

Date: 12/6/21

  
\_\_\_\_\_  
Joseph S. Betsko  
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Pennsylvania Office of Attorney General  
FOR PLAINTIFF COMMONWEALTH OF PENNSYLVANIA

Date: \_\_\_\_\_

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Special Deputy Attorney General  
North Carolina Department of Justice  
FOR PLAINTIFF STATE OF NORTH CAROLINA


Date: \_\_\_\_\_

\_\_\_\_\_  
Beth A. Finnerty  
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Antitrust Section  
Office of the Ohio Attorney General  
FOR PLAINTIFF STATE OF OHIO

Date: \_\_\_\_\_

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Joseph S. Betsko  
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Pennsylvania Office of Attorney General  
FOR PLAINTIFF COMMONWEALTH OF PENNSYLVANIA

Date: \_\_\_\_\_

  
\_\_\_\_\_  
Tyler T. Henry  
Assistant Attorney General  
Office of the Attorney General of Virginia  
FOR PLAINTIFF COMMONWEALTH OF VIRGINIA

Date: 12/6/2021



Averill Powers

Chief Executive Officer of Phoenixus AG and General Counsel of Vyera Pharmaceuticals, LLC  
FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

Date: \_\_\_\_\_

\_\_\_\_\_  
Steven A. Reed

Morgan, Lewis & Bockius LLP

COUNSEL FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

Date: \_\_\_\_\_

\_\_\_\_\_  
Kevin Mulleady

FOR KEVIN MULLEADY

Date: \_\_\_\_\_

\_\_\_\_\_  
Marc E. Kasowitz

Albert Shemmy Mishaan

Kenneth R. David

Kasowitz Benson Torres LLP

COUNSEL FOR KEVIN MULLEADY

Date: \_\_\_\_\_

\_\_\_\_\_  
Averill Powers

Date: \_\_\_\_\_

Chief Executive Officer of Phoenixus AG and General Counsel of Vyera Pharmaceuticals, LLC  
FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC



\_\_\_\_\_  
Steven A. Reed

Date: 12/4/21

Morgan, Lewis & Bockius LLP

COUNSEL FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

\_\_\_\_\_  
Kevin Mulleady

Date: \_\_\_\_\_

FOR KEVIN MULLEADY

\_\_\_\_\_  
Marc E. Kasowitz

Date: \_\_\_\_\_

Albert Shemmy Mishan

Kenneth R. David

Kasowitz Benson Torres LLP

COUNSEL FOR KEVIN MULLEADY

Date: \_\_\_\_\_

\_\_\_\_\_  
Averill Powers

Chief Executive Officer of Phoenixus AG and General Counsel of Vyera Pharmaceuticals, LLC  
FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

Date: \_\_\_\_\_

\_\_\_\_\_  
Steven A. Reed

Morgan, Lewis & Bockius LLP

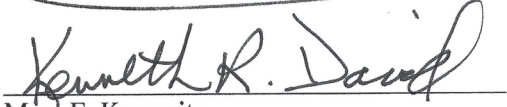
COUNSEL FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

Date: 12/5/21

  
Kevin Mulleady

FOR KEVIN MULLEADY

Date: 12/5/21

  
Marc E. Kasowitz

Albert Shemmy Mishaan

Kenneth R. David

Kasowitz Benson Torres LLP

COUNSEL FOR KEVIN MULLEADY

**APPENDIX A  
NOTICE TO AFFECTED PERSONS**

**Vyera/Phoenixus letterhead]**

**[Name and address of recipient]**

Dear **[Name of recipient]**:

This letter concerns an Order for Permanent Injunction and Equitable Monetary Relief (“the Order”) entered against Vyera Pharmaceuticals, LLC, and Phoenixus AG in Federal Trade Commission, et al. v. Vyera Pharmaceuticals, LLC, et al. Case No. 1:20-cv-00706-DLC. A copy of the Order is attached to this letter. Please read the Order carefully. **To the extent anything in this letter differs from the terms in the Order, the Order supersedes this letter. Further, capitalized terms in this letter have the same meaning as those terms do in the Order.**

The Order bars Vyera and Phoenixus from taking certain actions that can impede the development, manufacture, sale, or marketing of competing Drug Products. Among other things, and subject to certain enumerated exceptions, the Order prohibits and renders unenforceable any agreements where Vyera and Phoenixus interfere with any of the following: (1) providing a Drug Product to a Pharmaceutical Company for the Development of a Therapeutic Equivalent or Biosimilar of that Drug Product; (2) providing any API to a Pharmaceutical Company; and (3) providing data related to sales or distribution of a Drug Product to a data aggregator.

If you have concerns about whether Vyera or Phoenixus is complying with its obligations under the Order, you may contact us at **[contact information for Vyera and Phoenixus]**. You may also contact the Federal Trade Commission at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) or the State Plaintiffs at **[contact information for State Plaintiffs]**.

Sincerely,

**[name and title]**

**APPENDIX B**  
**COLLATERAL ASSIGNMENT AND SECURITY AGREEMENT**

This Collateral Assignment and Security Agreement (“Agreement”) is made by the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia (collectively “Secured Parties”) and Phoenixus AG, Vyera Pharmaceuticals, LLC, successors, and assigns (collectively “Grantors”) on the effective date of \_\_\_\_\_, 2021.

**PRELIMINARY STATEMENT**

WHEREAS, the Grantors, have entered into a settlement agreement with Secured Parties to resolve all claims against the Grantors entitled *Federal Trade Commission, et al. v. Vyera Pharmaceuticals, LLC, et al.*, Case No. 20-cv-00706 pending in the Federal Court of the Southern District of New York (the “Action”), the terms of which are set forth in the Stipulated Order for Permanent Injunction and Equitable Monetary Relief dated \_\_\_\_\_, 2021 in the Action (“Stipulated Order”).

WHEREAS, the Grantors have agreed to make certain contingent payments in an aggregate amount not to exceed \$30 million over a period of up to 10 years based on sales of certain assets of the Grantors, as set forth in the Stipulated Order and as further described herein; and

WHEREAS, subject to the terms set forth in this Agreement, the Grantors have agreed to grant a security interest in the Collateral (as defined below) to the Secured Parties, as security for the Secured Obligations (as defined below);

NOW, THEREFORE, in consideration of the foregoing premises and other good and valuable consideration, the receipt of which are hereby acknowledged, the parties hereto agree as follows:

**DEFINITIONS**

1. **Terms Defined in Agreement.** All capitalized terms used herein and not otherwise defined shall have the meanings assigned to such terms in the Agreement.
2. **Terms Defined in New York UCC.** Terms defined in the New York UCC which are not otherwise defined in this Security Agreement are used herein as defined in the New York UCC.
3. **Definitions of Certain Terms Used Herein.** As used in this Agreement, in addition to the terms defined in the Preliminary Statement, the following terms shall have the following meanings:

“**Collateral**” means any and all Corporate Assets of Phoenixus AG and Vyera Pharmaceuticals, LLC, in which a security interest may be created under Article 9 of the New



York UCC, including but not limited to Priority Review Vouchers and any Corporate Asset not related to a Priority Review Voucher, in which the Grantors now have, or hereafter acquire any right or interest in, as well as any monetized royalty stream owed to Phoenixus related to any Corporate Assets regarding the treatment of intranasal racemic ketamine, even if such transactions was entered prior to the entry of this Agreement. Collateral shall expressly exclude (a) any inventory, goods or products, including without limitation, any active pharmaceutical ingredients, raw materials or finished product sold or produced in the ordinary course of business, (b) any unissued shares of equity interests, capital stock, partnership interest, membership or limited liability company interest or similar equity right in one or both of the Corporate Named Defendants (as defined in the Stipulated Order) or any other Grantor or any successor, joint venture, subsidiary, partnership, division, group, or affiliate controlled by any of them, (c) any property to the extent that such grant is prohibited by any requirement of law of a governmental authority or constitutes a breach or default under or results in the termination of or requires any consent not obtained under, any contract, license, agreement, instrument or other document evidencing or giving rise to such property, except to the extent that such requirement of law or the term in such contract, license, agreement, instrument or other document providing for such prohibition, breach, default or termination or requiring such consent is ineffective under Section 9-406, 9-407, 9-408 or 9-409 of the UCC (or any successor provision or provisions) of any relevant jurisdiction or any other applicable law or principles of equity; provided, however, that such security interest shall attach immediately at such time as such requirement of law is not effective or applicable, or such prohibition, breach, default or termination is no longer applicable or is waived or any required consent has been obtained, and to the extent severable, shall attach immediately to any portion of the Collateral that does not result in such consequences; or (d) United States intent-to-use trademark or service mark application to the extent that, and solely during the period in which, the grant of a security interest therein would impair the validity or enforceability of such intent-to-use trademark or service mark application under Federal United States law; provided, however, after such period, each Grantor acknowledges that such interest in such trademark or service mark application shall be subject to a security interest in favor of the Secured Parties shall be included in the Collateral, or (e) leasehold interests in real property, or (f) motor vehicles and assets subject to certificates of title, or (g) or other assets to the extent the costs or burden of obtaining or perfecting a security interest therein is excessive in relation to the benefit of the collateral security provided to the Secured Parties, as reasonably determined by the Collateral Agent in consultation with the Grantors.

**“Corporate Asset”** has the meaning assigned to such term in the Stipulated Order.

**“Event of Default”** means that Grantors have:

- a. Failed to make payments in accordance with the requirements of Paragraph V.C of the Stipulated Order unless promptly cured; or

- b. Commenced a case, proceeding or other action seeking to adjudicate it as bankrupt or insolvent or seeking reorganization, arrangement, adjustment, winding up, liquidation, dissolution, composition or other relief with respect to it or its debts.

“**New York UCC**” means the New York Uniform Commercial Code as in effect in the State of New York as of the date of this Agreement.

“**Secured Parties**” Means the states or commonwealths of New York, California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia.

### **GRANT OF SECURITY INTEREST**

1. **Grantors’ Pledge.** The Grantors hereby pledge, assign, and grant to Secured Parties, a security interest in all of such Grantors’ rights title and interest, whether now owned or hereinafter acquired, in and to the Collateral to secure the prompt and complete payments and performance of the Secured Obligations. The Grantors agree to promptly file such documents and to enter into any such agreements in order to perfect the Secured Parties security interest in the Collateral which may not be considered located in the United States. The Grantors shall take any other actions reasonably requested by the Secured Parties from time to time to cause the attachment and perfection of, and the ability of the Secured Party to enforce, the security interest of the Secured Party in any and all of the Collateral.

### **REPRESENTATIONS AND WARRANTIES**

Grantors represent and warrant that:

1. **Authority to Act.** The execution, delivery and performance of this Agreement are within its corporate or other organizational powers have been duly authorized by all required organizational action and do not and will not contravene its charter or other organizational documents or any law or any agreement or undertaking to which it is a party or by which it may in any way be bound..

2. **Title, Validity and Enforceability.** The Grantors are the rightful legal owners of the Collateral, and have good and valid rights in or the power to transfer the Collateral and title to the Collateral with respect to which it has purported to grant a security interest hereunder, free and clear of all liens. No other creditor has the right to ownership of the Collateral that may interfere with the Secured Parties’ ability to take and profit from the sale of said assets in the event that the above-listed contingent equitable monetary relief is not paid.

3. **Change of Office.** The Grantors shall not change their chief executive office or mailing addresses or organizational identification number unless the Secured Parties shall have received not less than 30 days' prior written notice from Grantors of such proposed change, which notice shall set forth such information with respect thereto as the Secured Parties may require.

4. **Change of Name.** The Grantors shall not change their names unless each of the following conditions is satisfied: (i) the Secured Parties shall have received not less than 30 days prior written notice from the Grantors of such proposed change in their names, which shall accurately set forth the proposed new name; and (ii) the Secured Parties shall receive a certified copy of the amendment to the charter documents providing for the name change as soon as it is available.

5. **Change of Structure.** The Grantors shall not change their type of organization, jurisdiction of organization or other legal structure unless each of the following conditions is satisfied: (i) the Secured Parties shall have received not less than 30 days prior written notice from the Grantors of such proposed change in it their names, which shall accurately set forth the proposed new name; and (ii) the Secured Parties shall receive a certified copy of the amendment to the charter documents providing for the change of structure as soon as it is available.

#### **EVENT OF DEFAULT/REMEDIES**

**Grantors' Obligations upon the Event of Default.**, Upon the occurrence of an Event of Default, the Secured Parties shall have the right to exercise all rights and remedies available to them under applicable law.

#### **GOVERNING LAW**

1. **Governing Law.** This Agreement shall be construed in accordance with and governed by the law of the State of New York.

2. **Submission to Jurisdiction.** The Grantors hereby irrevocably and unconditionally submit, for their selves and their property, to the nonexclusive jurisdiction of the United States District Court of the Southern District of New York, , and any appellate court from any appeal thereof, in any action or proceeding arising out of or related to this Agreement, or for recognition or enforcement of any judgment, and the Grantors, hereby irrevocably and unconditionally agree that all claims in respect of any such action or proceeding may be heard and determined in such Federal Court. The Grantor agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

3. **Waiver of Inconvenient Forum.** The Grantors hereby irrevocably and unconditionally waive, to the fullest extent they may legally and effectively do so, any objection

which they may now or hereinafter have to the laying of venue of any suit, action or proceeding to enforce this Agreement in any court referred to in Paragraph 2 above.

4. **Waiver of Jury Trial.** The Grantors hereby irrevocable and unconditionally waive, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any legal proceeding directly or indirectly arising out of or relating to this Agreement.

### **GENERAL**

1. **Successors and Assigns.** This Agreement shall be binding upon Grantors and each of their successors and assigns and inure to the benefit of and be enforceable by Secured Parties, for the purpose of protecting the Secured Parties' interest in the satisfaction of the Grantors' obligation to make certain payments to the Settlement Fund as set forth in Paragraph V.C of the Stipulated Order.

2. **Amendments.** Neither this Agreement nor any provision hereof shall be amended, modified, waived or discharged orally or by course of conduct, but only by a written agreement signed by the Secured Parties and the Grantors. The Secured Parties shall not, by any act, delay, omission or otherwise be deemed to have expressly or impliedly waived any of their respective rights, power and/or remedies unless such waiver shall be in writing and signed by all Secured Parties. Any such waiver shall be enforceable only to the extent specifically set forth therein. A waiver by Secured Party of any right, power and/or remedy on any one occasion shall not be construed as a bar to or waiver of any such right, power and/or remedy which the Secured Party would otherwise have on any future occasion, whether similar in kind or otherwise.

3. **Survivability.** If any provisions of this Agreement is held to be invalid or unenforceable, such invalidity or unenforceability shall not invalidate this Agreement as a whole, but this Agreement shall be construed as though it did not contain the particular provision held to be invalid or unenforceable and the rights of the parties shall be construed and enforced only to such extent as shall be permitted by applicable law.

4. **Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of this Agreement by facsimile or other electronic method of transmission shall have the same force and counterpart of any such agreement by facsimile or other electronic method of transmission shall also deliver an original executed counterpart, but the failure to do so shall not affect the validity, enforceability or binding effect of this Agreement.

5. **Collateral Agent.** Each Secured Party, on behalf of itself [and any of its affiliates] hereby irrevocably appoints [\_\_\_\_\_] (in such capacity, the "Collateral Agent") to serve as collateral agent under this Agreement and with respect to the liens, encumbrances, pledges and security interests granted hereunder, for the purpose of

protecting the Secured Parties' interest in the satisfaction of the Grantors' obligation to make certain payments to the Settlement Fund as set forth in Paragraph V.C of the Stipulated Order. Each Secured Party authorizes the Collateral Agent to take such actions as agent on its behalf and the Secured Parties and to exercise all powers under this Agreement related to the administration, validity, perfection and enforcement of the liens, encumbrances, pledges and security interests granted herein, including without limitation, the granting of any consent with respect to the Collateral and liens, encumbrances, pledges and security interests hereunder, and to exercise such powers as are reasonably incidental thereto. In addition, to the extent required under the laws of any jurisdiction each Secured Party hereby grants to the Collateral Agent any required powers of attorney to execute and enforce this Agreement governed by the laws of such jurisdiction on such Secured Party's behalf. Without limiting the foregoing, each Secured Party hereby authorizes the Collateral Agent to execute and deliver, and to perform its obligations under this Agreement and to exercise all rights, powers and remedies that the Collateral Agent may have under this Agreement. No Secured Party shall have any right individually to realize upon any of the Collateral, it being understood and agreed that all powers, rights and remedies under this Agreement may be exercised solely by the Collateral Agent on behalf of the Secured Parties in accordance with the terms thereof. In its capacity, the Collateral Agent is a "representative" of the Secured Parties within the meaning of the term "secured party" as defined in the New York UCC, as applicable. The Secured Parties irrevocably authorize the Collateral Agent, at its option and in its discretion, to subordinate any lien, encumbrance, pledge or security interest on any property granted to or held by the Collateral Agent under this Agreement. The Secured Parties hereby irrevocably authorize the Collateral Agent, at its option and in its sole discretion, to release any Liens granted to the Collateral Agent on any Collateral.

## **6. Release.**

A. The Collateral, other than any right title and interest in any Priority Review Voucher (the "Non PRV Collateral") shall be automatically released from the liens, encumbrances and security interests in favor of the Secured Parties created hereby upon the earlier of (i) the date the Grantors' aggregate payments to the Settlement Fund pursuant to Paragraph V.C.1. of the Stipulated Order equal \$15 million (ii) the five (5) year anniversary of the date the Stipulated Order is entered in the Action, or (iii) the date the Grantors' aggregate payments to the Settlement Fund pursuant to Paragraph V.C.1 and V.C.2 of the Stipulated Order equal \$30 million. Concurrently with such release, this Agreement shall terminate with respect to such Non PRV Collateral, and all obligations of each Grantor to the Secured Parties hereunder with respect to such Non PRV Collateral shall terminate, all without delivery of any instrument or performance of any act by any party. The Secured Parties shall promptly deliver such documents as such Grantor may reasonably request to evidence the termination of this Agreement and the related liens, encumbrances and security interest with respect to such Non PRV Collateral.

B. All Collateral constituting any Priority Review Voucher shall be automatically released from the liens, encumbrances and security interests in favor of the Secured Parties created hereby upon the earlier of (i) the date the Grantors' aggregate payments to

the Settlement Fund pursuant to Paragraphs V.C.1 and V.C.2 of the Stipulated Order equal \$30 million or (ii) the ten (10) year anniversary of the date the Stipulated Order is entered in the Action. Concurrently with such release, this Agreement shall terminate, and all obligations of each Grantor to the Secured Parties hereunder shall terminate, all without delivery of any instrument or performance of any act by any party. The Secured Parties shall promptly deliver such documents as such Grantor may reasonably request to evidence such termination in full of the interests hereunder.

**7. Notices**

All notices, requests and demands to or upon the respective parties hereto to be effective shall be in writing (including by electronic mail), and, unless otherwise expressly provided herein, shall be deemed to have been duly given or made when delivered, or three (3) business days after being deposited in the mail, postage prepaid, or, in the case of electronic mail notice, when received, addressed as follows in the case of the Grantors and each of the Secured Parties, or to such other address as may be hereafter notified by the respective parties hereto:

[Add notice information for each party below]

[\_\_\_\_\_]

[\_\_\_\_\_]

[Remainder of Page Intentionally Left Blank]

[Signature Pages to Follow]



IN WITNESS WHEREOF, the Grantors and Secured Parties have hereunto set their hands this \_\_\_\_\_ day of December, 2021.

\_\_\_\_\_  
Elinor R. Hoffmann  
Chief  
Antitrust Bureau  
Office of the New York State Attorney General  
FOR PLAINTIFF STATE OF NEW YORK

Date: \_\_\_\_\_

\_\_\_\_\_  
Michael D. Battaglia  
Deputy Attorney General  
California Department of Justice  
FOR PLAINTIFF STATE OF CALIFORNIA

Date: \_\_\_\_\_

\_\_\_\_\_  
Richard S. Schultz  
Assistant Attorney General  
Antitrust Bureau  
Office of the Illinois Attorney General  
FOR PLAINTIFF STATE OF ILLINOIS

Date: \_\_\_\_\_

\_\_\_\_\_  
K. D. Sturgis  
Special Deputy Attorney General  
Jessica V. Sutton  
Special Deputy Attorney General  
North Carolina Department of Justice  
FOR PLAINTIFF STATE OF NORTH CAROLINA

Date: \_\_\_\_\_

\_\_\_\_\_  
Beth A. Finnerty  
Assistant Chief  
Antitrust Section  
Office of the Ohio Attorney General  
FOR PLAINTIFF STATE OF OHIO

Date: \_\_\_\_\_

\_\_\_\_\_  
Joseph S. Betsko  
Senior Deputy Attorney General  
Pennsylvania Office of Attorney General  
FOR PLAINTIFF COMMONWEALTH OF PENNSYLVANIA

Date: \_\_\_\_\_

\_\_\_\_\_  
Tyler T. Henry  
Assistant Attorney General  
Office of the Attorney General of Virginia  
FOR PLAINTIFF COMMONWEALTH OF VIRGINIA

Date: \_\_\_\_\_

\_\_\_\_\_  
Averill Powers  
Chief Executive Officer of Phoenixus AG and General Counsel of Vyera Pharmaceuticals, LLC  
FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

Date: \_\_\_\_\_

\_\_\_\_\_  
Steven A. Reed  
Morgan, Lewis & Bockius LLP  
COUNSEL FOR PHOENIXUS AG AND VYERA PHARMACEUTICALS, LLC

Date: \_\_\_\_\_