UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 19-2875

Honorable Robert B. Kugler

This Order Relates to all Cases

SPECIAL MASTER ORDER NO. 34

IT IS HEREBY ORDERED this 4th day of August, 2021 that the attached Notices of Deposition pursuant to Fed. R. Civ. P. 30(b)(6) directed to Wholesaler Defendants (Ex. A hereto) and Retail Pharmacy Defendants (Ex. B hereto) are approved by the Court and no objections shall be permitted to the notices. The depositions shall be taken in accordance with the Court's scheduling and other Orders.

<u>s/ Thomas I. Vanaskie</u> Hon Thomas I. Vanaskie (Ret.) Special Master Case 1:19-md-02875-RBK-KMW Document 1465 Filed 08/04/21 Page 2 of 16 PageID: 33605

EXHIBIT A

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

All Actions

Civ. No. 19-2875 (RBK/JS)

PLAINTIFFS' NOTICE OF VIDEOTAPED DEPOSITION TO [WHOLESALER] PURSUANT TO FED. R. CIV. P. 30(b)(6)

TO: ADDRESSEE

Counsel for Defendant XXXXX

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this _____ day of ____, 2021

MAZIE SLATER KATZ & FREEMAN, LLC

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By: <u>/s/ Adam M. Slater</u>

Adam M. Slater 103 Eisenhower Parkway, Suite 207 Roseland, New Jersey 07068 Telephone: 973-228-9898

CERTIFICATE OF SERVICE

I, Adam M. Slater, hereby certify that on _____, 2021, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Wholesaler Name, and Defendants' liaison counsel, via email.

DATED this day of ____, 2021.

MAZIE SLATER KATZ & FREEMAN, LLC

By: <u>/s/ Adam M. Slater</u>

Adam M. Slater 103 Eisenhower Parkway, Suite 207 Roseland, New Jersey 07068 Telephone: 973-228-9898

EXHIBIT A

"Active Pharmaceutical Ingredient" ("API") is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

"Manufacturer Defendants" is defined as any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures the active pharmaceutical ingredient (API) for, or the finished dose formulation of, valsartan.

"Communication(s)" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2012 through the December 31, 2019.

"Retail Pharmacy Defendants" refers to any and all entities listed by name as "Retail Pharmacy Defendants" in Plaintiffs' June 17, 2019 Master Personal Injury Complaint (Dkt. No. 121), including any agents, employees, or predecessor entities.

"Valsartan" or **"VCDs"** means any drug with valsartan as an active ingredient. For purposes of these Requests, "Valsartan" or "VCDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Recalled Valsartan" or "Recalled VCDs" means any drug with valsartan as an active ingredient, as well as all finished drug formulations of valsartan, including any valsartan containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Wholesaler Defendant(s) in the ordinary course of business.

"You," "your" or "defendant" shall be used interchangeably and refers to the parties to which these requests are directed.

"Drug Supply Chain Security Act" refers to Pub. L. 113-54 and regulations promulgated thereunder.

"Wholesaler Defendants" refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs' March 13, 2020 Consolidated Second Amended

Economic Loss Class Action Complaint (Dkt. No. 398), including any agents, employees, or predecessor entities.

"Supply/Distribution Agreement" means the agreements between You and any of the Manufacturer Defendants or Retailer Defendants for your purchase or distribution of VCDs, produced by you in this litigation.

It is understood that You are not required to investigate custodial files in order to appropriately prepare for this deposition.

TOPICS

- 1. The VCD testing and testing results of VCDs provided to you, if any, or the VCD testing and testing results of VCDs prepared by or for you, if any.
- 2. Your understanding of the reason(s) for the recall of VCDs.
- 3. Your formal communications with any Manufacturer Defendant, Retail Pharmacy Defendant, or regulatory authority (including but not limited to the FDA) relating to contamination of VCDs with nitrosamines including NDMA.
- 4. Your formal communications with any Retail Pharmacy Defendant, consumer or thirdparty payor, relating to contamination of VCDs with nitrosamines including NDMA.
- 5. The general interpretation of standard Supply/Distribution Agreement representations and warranties provided to you by Manufacturer Defendants regarding VCD quality, purity, content, or contamination issues.
- 6. The general interpretation of standard Supply/Distribution Agreement representations and warranties provided by or passed on by you to Retail Pharmacy Defendants regarding VCD quality, purity, content, or contamination issues.
- 7. Your general process for product recalls applicable to the recall for VCDs, including the retention, sequestration, return, or destruction of product as a result of such recall.
- 8. Your general process for the sourcing of VCDs (e.g., how you choose a supplier, the criteria if any the supplier must meet, whether you retain the right to audit or inspect the supplier or products sourced from them, etc.).
- 9. Your general process for providing to Defendant Retail Pharmacies DCSCA data, package inserts and labeling for VCDs that You sold to Defendant Retail Pharmacies.
- 10. The quantity/units of VCDs sold by you to Defendant Retail Pharmacies in the United States.
- 11. The general interpretation of the purchase and sales data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).
- 12. The general process by which you issue to Retailer Pharmacy Defendants refunds or credits in connection with the return or recall of VCDs sold in the United States, including whether and how any such refunds or credits would be recorded by you. This topic will not include amounts or specifics of any sales, returns or refunds of VCDs.

- 13. The general process by which you receive from Manufacturer Defendants refunds or credits in connection with the return of VCDs purchased or recalled in the United States, including whether and how any such refunds or credits would be recorded by you. This topic will not include amounts or specifics of any purchases, returns or refunds of VCDs.
- 14. The general interpretation of inventory management policies produced by You in this litigation pertinent to Your purchases and sales of VCDs.
- 15. The general interpretation of indemnity and other un-redacted standard provisions of the Supply/Distribution Agreements. It is understood that if there are specific agreements not produced by You or otherwise upon which more detailed testimony is sought, such agreements will be identified and provided to Wholesalers at least fourteen days prior to the deposition, or as soon as reasonably thereafter following the production of such agreement by a Wholesaler or Retail Pharmacy Defendant.
- 16. The existence and general status (whether resolved or still pending) of indemnification requests made by you or to you, to or from Manufacturer Defendants or Retail Pharmacy Defendants in this litigation.
- 17. The organizational charts and other information produced in response to Request for Production No. 8 in Plaintiffs' Second Set of Requests for Production of Documents to Wholesaler Defendants.

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EXHIBIT B

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

All Actions

Civ. No. 19-2875 (RBK/JS)

PLAINTIFFS' NOTICE OF VIDEOTAPED DEPOSITION TO [RETAIL PHARMACY] PURSUANT TO FED. R. CIV. P. 30(b)(6)

TO: ADDRESSEE

Counsel for Defendant XXXXX

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this _____ day of _____, 2021

PLAINTIFFS' CO-LEAD COUNSEL

By: <u>/s/ Adam M. Slater</u> Adam M. Slater 103 Eisenhower Parkway, Suite 207

Roseland, New Jersey 07068 Telephone: 973-228-9898

CERTIFICATE OF SERVICE

I, Adam M. Slater, hereby certify that on ____, 2021, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Pharmacy Name, and Defendants' liaison counsel, via email. DATED this ______ day of ______, 2021.

MAZIE SLATER KATZ & FREEMAN, LLC

By: <u>/s/ Adam M. Slater</u> Adam M. Slater 103 Eisenhower Parkway, Suite 207 Roseland, New Jersey 07068 Telephone: 973-228-9898

EXHIBIT A

"Active Pharmaceutical Ingredient" ("API") is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

"Manufacturer Defendants" is defined as any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures the active pharmaceutical ingredient (API) for, or the finished dose formulation of, valsartan.

"Communication(s)" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2012 through the December 31, 2019.

"Retail Pharmacy Defendants" refers to any and all entities listed by name as "Retail Pharmacy Defendants" in Plaintiffs' March 13, 2020 Consolidated Second Amended Economic Loss Class Action Complaint (Dkt. 398), including any agents or predecessor entities.

"Valsartan" or **"VCDs"** means any drug with valsartan as an active ingredient. For purposes of these Requests, "Valsartan" or "VCDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Recalled Valsartan" or "Recalled VCDs" means any drug with valsartan as an active ingredient, as well as all finished drug formulations of valsartan, including any valsartan containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Wholesaler Defendant(s) in the ordinary course of business.

"You," "your" or "defendant" shall be used interchangeably and refers to the parties to which these requests are directed.

"Drug Supply Chain Security Act" refers to Pub. L. 113-54 and regulations promulgated thereunder.

"Wholesaler Defendants" refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs' March 13, 2020 Consolidated Second Amended

Economic Loss Class Action Complaint (Dkt. No. 398), including any agents, employees, or predecessor entities.

"FIFO" means a first-in, first-out inventory method.

"LIFO" means a last-in, first-out inventory method.

"JIT" means just-in-time inventory method.

TOPICS

- 1. The testing of the VCDs for nitrosamines or the results of any such testing, whether performed by you or provided to you, if any.
- 2. Your understanding of the reason(s) for the recall of the VCDs.
- 3. Your communication with any Manufacturer Defendant or Wholesaler Defendant relating to the recall of the VCDs.
- 4. Instructions you received from the Manufacturer and/or Wholesaler Defendants regarding the recall of the VCDs, and the contents of communications directed to pharmacy customers regarding those recalls.
- 5. Representations and warranties, if any, you received from any Manufacturer or Wholesaler Defendants from whom you purchased the VCDs at issue in this litigation. To the extent Plaintiffs intend to rely on any representation or warranty contained in any document produced by any defendant or party other than you during the deposition, Plaintiffs will provide a copy of that document to Counsel no fewer than seven (7) business days prior to the deposition, and the Parties will endeavor to meet and confer as soon as practicable after receipt of the documents to discuss.
- 6. Information including representations and warranties (if any) relating to the VCDs provided by you to pharmacy customers at the point of sale.
- 7. Your retention, sequestration, return or destruction of the VCDs after their recall.
- 8. Your sourcing of the VCDs.
- 9. The information you maintain, if any, regarding NDC, lot, batch, quantity, and expiration date for the VCDs sold by you to consumers in the United States.
- 10. The sales data produced by you in this litigation, including the quantity/units of VCDs sold in the United States.
- 11. The purchase data produced by you in this litigation.
- 12. Your policies and practices for seeking and issuing refunds or credits for any VCDs returned to or returned by you following their recall, including whether you generally sought any such

refunds or credits, whether you generally issued any such refunds or credits, and whether and how any such refunds or credits would be recorded by you.

- 13. Your final inventory management policies, procedures, and practices (e.g., FIFO, LIFO, JIT, turnover ratio, replenishment/re-order triggers), if any, pertinent to the VCDs.
- 14. Those provisions in your purchase and/or supply agreements with the Manufacturing Defendants and Wholesaler Defendants concerning representations and warranties, auditing and inspection rights, recall and return rights or requirements, and stock life and purchasing triggers, if any. To the extent Plaintiffs intend to rely on any agreement produced by any defendant or party other than You during the deposition, Plaintiffs will meet and confer with Your counsel and will provide a copy of that document no fewer than seven (7) business days prior to the deposition.
- 15. The organizational charts or other documents/information produced by you in this litigation in response to Request No. 4 of Plaintiffs' Second Set of Requests for Production of Documents to Retail Pharmacy Defendants [Dkt. 1306].
- 16. Those indemnity provisions produced by you in response to Request No. 21 of Plaintiffs' Second Amended Set of Requests for Production of Documents to Retailer and Dispensing Defendants [Dkt. 508].
- 17. Indemnification requests made by you, or indemnification requests of you, in connection with the VCDs.