IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA), LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	Civil No. 19-2875 (RBK/JS)

ORDER

The Court having received plaintiffs' July 9, 2020 letter with the parties' final version of the Court-Approved Requests for Production to be answered by the Retailer/Pharmacy defendants (Exhibit A) and the Requests for Production to be answered by the Wholesaler defendants (Exhibit B) [Doc. No. 508]; and accordingly,

IT IS HEREBY ORDERED this 10th day of July 2020, that the attached Requests for Production directed to the Retail/Pharmacy (Exhibit A) and Wholesaler (Exhibit B) defendants are approved by the Court and shall be answered and responded to by August 14, 2020 in accordance with the Court's July 7, 2020 Order [Doc. No. 507].

s/ Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge

Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Judge Honorable Joel Schneider, Magistrate Judge

PLAINTIFFS' SECOND AMENDED SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO RETAIL PHARMACY DEFENDANTS

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, and in accordance with the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order filed on December 13, 2019, as well as the Court's Orders on macro discovery issues filed on November 25, 2019, Plaintiffs propound the following second amended set of requests upon each Retail Pharmacy Defendant. These requests are without prejudice to Plaintiffs' rights to serve other requests consistent with Rules 26 and 34.

Plaintiffs understand and have been advised by the Retail Pharmacy Defendants that the requests that follow represent the Court-Approved Requests for Production to be answered by the Retail Pharmacy Defendants, and are a uniform discovery instrument negotiated by the Retail Pharmacy Defendants at the direction of the Court and follow several rulings by the Court on discovery issues,[1] including but not limited to the Court's ruling on macro discovery following

[1] Each request is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the November 25, 2019 Order on macro discovery issues pertaining to the Manufacturing Defendants (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral and/or written rulings following the December 11, 2019 discovery hearing, the January 15, 2020 discovery hearing, the January 28, 2020 discovery conference, the February 13, 2020 discovery conference, and the July 6, 2020 macro discovery hearing.

argument of the parties on July 6, 2020. The Retail Pharmacy Defendants have advised, and Plaintiffs understand, that there remain differences in the ability of each Retail Pharmacy Defendant to respond to the requests below, including differences in what data is available, and in the type and extent of data that is available in a reasonably accessible format. Following service of these requests for production, each Retail Pharmacy Defendant shall serve its own individual responses to the requests set forth below, including identification of any specific issues that the Retail Pharmacy Defendant has with the requests. The parties will meet and confer in good faith on the substance of any such responses, to the extent necessary, and to address any deficiencies or Plaintiffs' reasonable questions regarding Retail Pharmacy Defendants' responses.

DEFINITIONS:

"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.

"API Manufacturer" is defined as any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures the active pharmaceutical ingredient (API) for valsartan.

"Finished Dose Manufacturer" includes any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

"Manufacturer Defendants" includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

"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.

"Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof.

This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form). Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database. For purposes of these discovery requests, "Documents" shall refer only to centrally stored, non-custodial data maintained by the retailer pharmacy in the ordinary course of business and available via reasonable search of available records and in a reasonably accessible format, and shall not refer to documents or data maintained solely by individual stores or pharmacies, or to emails or custodial data held by individual employees of the Retail Pharmacy Defendants.

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.

"TPP" refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors, and any other health benefit provider in the United States of America and its territories.

"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 Retail Pharmacy 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. 398), including any agents, employees, or predecessor entities, to the extent known to the Retail Pharmacy Defendants.

INSTRUCTIONS:

Non-privileged information: These Requests seek only information that is not privileged or otherwise protected from disclosure by applicable protection, including but not limited to work product protection or other requirements imposed or protections afforded by applicable law or regulation. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

DOCUMENTS TO BE PRODUCED:

I. SOURCING (UPSTREAM)

1. **Documents sufficient to identify the VCDs purchased by you during the relevant time period, including quantity/units, dates of purchase, NDC, supplier, expiration date, and batch and/or lot number.**

2. **Documents sufficient to identify as exemplar the ordinary-course transactional documents accompanying VCDs purchased by you (e.g., invoices, bills of lading, packing slips, etc.).**

II. SALES (DOWNSTREAM)

3. **Documents sufficient to identify as exemplar the type of manufacturer-included packaging or labeling information for VCDs dispensed by you.**

4. **Documents sufficient to identify your sale of VCDs to consumers, in either of the forms identified in Requests 4(a) and 4(b), below. You need only produce this information in one of these formats.**

   a) **Documents sufficient to identify the quantities/units and number of purchasers of VCDs dispensed by you, by month, state/territory, expiration date, and NDC, as well as by batch and/or lot number.**

   b) **Documents sufficient to identify when and to whom you dispensed VCDs, including quantity/units, NDC, expiration date, and batch, and/or lot number, to be produced in an anonymized manner. You also may redact protected patient information to address any privacy or HIPAA concerns raised by the production of this data, as appropriate.**

5. **The amount paid by consumers for VCDs dispensed by you identified in Request No. 4, to be produced in an anonymized manner. You also may redact protected patient information to address any privacy or HIPAA concerns raised by the production of this data, as appropriate.**

III. WARRANTIES/STATEMENTS (UPSTREAM)

6. **Documents sufficient to show your final written policies or procedures for the types of documents or other information to be provided by a prospective supplier and/or manufacturer of VCDs purchased by you.**

7. **Documents sufficient to show the information provided to you by the Manufacturer Defendants or Wholesaler Defendants from which you actually purchased VCDs.**

IV. WARRANTIES/STATEMENTS (DOWNSTREAM)

8. **Documents sufficient to show your final written policies for the types of documents or other information and materials to be provided by you (whether such materials were created by you or not) when you dispensed VCDs to consumers.**

9. **Documents sufficient to show your final written policies for the types of documents or other information and materials provided to TPPs for VCDs dispensed by you.**

V. TESTING/INSPECTION

10. **Testing (if any) you performed for VCDs, and results thereof.**

VI. DISTRIBUTION CENTERS

11. **Documents sufficient to identify your distribution centers from which VCDs were shipped, including location and state(s) of locations served by each distribution center.**

12. **To the extent available, documents sufficient to identify your distribution centers that would have received or shipped VCDs subject to recall.**

VII. RECALL

13. **Documents sufficient to show the final written policies or procedures specifically governing the VCD recalls, if any.**

14. **Documents sufficient to show the initial VCD recall communications you received from the Manufacturer Defendant or Wholesaler Defendant from whom you purchased VCDs.**

15. **Documents sufficient to show the official notice by which you communicated any VCD recall implemented by you to consumers or TPPs.**

16. **Documents sufficient to identify (by NDC, and by lot and/or batch information to the extent maintained by you in the ordinary course of business) Recalled VCDs: (a) currently on hand; (b) returned by you; or (c) destroyed by you.**

17. **Documents sufficient to show a list of your warehouse and/or distribution facilities involved in any VCD recalls.**

18. **Documents sufficient to show how your retail or other locations of dispensing VCDs de-stock Recalled VCDs.**

VIII. COMPLIANCE WITH THE DRUG SUPPLY CHAIN SECURITY ACT

19. **Documents sufficient to show your final written policies or procedures for the capture and maintenance of the product tracing information for prescription drug transactions pursuant to the Drug Supply Chain Security Act and regulations promulgated thereunder, or internal legacy procedures relating to same prior to the enactment of the DSCSA.**

IX. DOCUMENT PRESERVATION

20. **Produce the final document/data retention or destruction policies, or sections thereof, pertinent to the documents/data called for by the above requests.**

X. INDEMNITY AGREEMENTS

21. **Produce all final written indemnity agreements that you have with any VCD supplier from whom you purchased the VCDs at issue in this litigation. You may redact other competitive or sensitive information from the agreement, including information regarding the pricing and volume of your purchases, provided that the indemnity provision is not redacted.**

Dated: July 9, 2020

/s/ Adam Slater
Adam M. Slater
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068
Tel: (973) 228-9898
aslater@mazieslater.com

Ruben Honik
Golomb & Honik, PC
1835 Market Street
Suite 2900
Philadelphia, PA 19103
(215) 278-4449
rhonik@golumbhonik.com

Daniel Nigh
Levin Papantonio
316 South Baylen Street
Pensacola, FL 32502
Tel.: (850) 435-7013
dnigh@levinlaw.com

Conlee Whiteley
Kanner & Whiteley, LLC
701 Camp Street
New Orleans, LA 70130
(504) 524-5777
c.whiteley@kanner-law.com

CERTIFICATE OF SERVICE

I certify that on the 9th day of July 2020, I electronically transmitted the attached document to counsel of record for all Retail Pharmacy and Wholesaler Defendants.

/s/ Adam M. Slater
Adam M. Slater

Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Judge Honorable Joel Schneider, Magistrate Judge

PLAINTIFFS' SECOND AMENDED SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO WHOLESALER DEFENDANTS

TO ALL WHOLESALER DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, and in accordance with the Court's prior rulings, Plaintiffs propound the following second amended set of requests upon each Wholesaler Defendant. These requests are without prejudice to Plaintiffs' rights to serve other requests consistent with Rules 26 and 34.

Plaintiffs and Wholesaler Defendants agree that the requests for production that follow represent the Court-Approved Requests for Production to be answered by the Wholesaler Defendants in accordance with the Court's ruling on discovery issues following argument of the Parties on July 6, 2020, (D.E. 507), and incorporated herein. The Wholesaler Defendants have advised, and Plaintiffs understand, that there may be differences in the type and extent of data available and the type and extent of data available in a reasonably accessible format. Following service of these requests for production, each Wholesaler Defendant shall serve its own individual responses to the requests set forth below, specifying any issues that the Wholesaler Defendant has with responding to the requests. The Parties will meet and confer in good faith on the substance of any such responses, including to the extent necessary to address Plaintiffs' reasonable questions regarding Wholesaler Defendant's answers.

DEFINITIONS:

"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.

"Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database. For purposes of these discovery requests, "Documents" shall refer only to centrally stored, non-custodial data maintained by the Wholesaler Defendants in the ordinary course of business, and shall not refer to emails or custodial data held by individual employees of the Wholesaler Defendants.

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.

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"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.

INSTRUCTIONS:

Non-privileged information: These Requests seek only information that is not privileged or otherwise protected from disclosure by applicable protection, including but not limited to work product protection or other requirements imposed or protections afforded by applicable law or regulation. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

DOCUMENTS TO BE PRODUCED:

I. SOURCING (UPSTREAM)

1. **For purchases of VCDs by you from Manufacturer Defendants during the time period from January 1, 2012 to December 31, 2019, produce documents sufficient to identify the dates of purchase, the quantities/units purchased, the NDC, batch and lot numbers, and expiration date (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search) for the VCDs purchased, and the name of Manufacturer Defendant from whom the VCDs were purchased.**

II. SALES (DOWNSTREAM)

2. **For sales of VCDs by you to Retail Pharmacy Defendants during the time period from January 1, 2012 to December 30, 2019, documents sufficient to identify the quantities/units sold, the NDC, batch and lot numbers, and expiration date (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search), and purchaser name.**

3. **[Removed]**

III. WARRANTIES/STATEMENTS (UPSTREAM)

4. **Produce documents sufficient to identify your final written policies, if any, that set forth the shipment documents you require be provided to you by a Manufacturer Defendant.**

5. **Produce exemplar documents sufficient to identify the type of manufacturer-included packaging or labeling documents, shipment documents, or similar information which accompany VCDs sold to you by the Manufacturer Defendants.**

IV. WARRANTIES/STATEMENTS (DOWNSTREAM)

6. **Produce documents sufficient to identify your final written policies, if any, that set forth the shipment documents you require be provided by you to Retail Pharmacy Defendant(s) or other retail pharmacies concerning VCDs sold by you.**

7. **Produce documents sufficient to identify as exemplar the type of manufacturer-included packaging or labeling documents, shipment documents, or similar information which accompany VCDs sold by you to Retail Pharmacy Defendants or other retail pharmacies.**

V. TESTING/INSPECTION

8. **Produce documents sufficient to identify the testing and testing results of VCDs provided to you by the Manufacturer Defendants for VCDs purchased by you during the time period from January 1, 2012 to December 30, 2019.**

9. **Produce documents sufficient to identify the testing, if any, you performed on VCDs purchased by you from Manufacturer Defendants, and results thereof, during the time period from January 1, 2012 to December 30, 2019.**

VI. DISTRIBUTION CENTERS

10. **Produce documents sufficient to identify your distribution centers from which VCDs purchased by you from Manufacturer Defendants were shipped, including location and state(s) served by each distribution center.**

11. **To the extent available, produce documents sufficient to identify your distribution centers that received or shipped VCDs purchased by you from Manufacturer Defendants subject to recall.**

VII. RECALL

12. **Produce documents sufficient to identify your final written policies or procedures specifically governing the VCD recalls, if any.**

13. **Produce documents sufficient to show the initial VCD recall communications you received from the Manufacturer Defendants from whom you purchased VCDs.**

14. **Produce documents sufficient to show the official notice, if any, by which you communicated any VCD recall to any Retailer Defendant.**

15. **Produce documents sufficient to identify by NDC, batch and lot numbers (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search) recalled VCDs: (a) currently on hand; (b) returned by you; or (c) destroyed by you.**

16. **Produce documents sufficient to identify a list of your significant employees involved in managing the recall of VCDs.**

17. **Produce documents sufficient to identify distribution facilities that received any recalled VCD.**

VIII. COMPLIANCE WITH THE DRUG SUPPLY CHAIN SECURITY ACT

18. **Documents sufficient to identify your final written policy(ies) or procedures used by you to track purchases and sales of prescription drugs pursuant to the Drug Supply Chain Security Act and regulations promulgated thereunder,**

and/or final written policy(ies) or procedures used by you to track purchases and sales of prescription drugs after January 1, 2012, and prior to the enactment of the DSCSA.

IX. DOCUMENT PRESERVATION

19. **Produce the final document/data retention or destruction policies, or sections thereof, if any, in effect during the time period from January 1, 2012 to December 31, 2019 and applicable to records of purchases and sales of VCDs, shipment documents accompanying purchases and sales of VCDs, product testing documents accompanying purchases and sales of VCDs, and VCD recall documents.**

X. COMPLAINTS

20. **Produce documents sufficient to show all complaints you received from anyone concerning the purity or contamination of VCDs during the time period from January 1, 2012 to December 31, 2019, excluding litigation generated complaints.**

XI. INDEMNITY AGREEMENTS

21. **Produce final written indemnification agreements applicable to any claims currently pending in MDL 2875 against Wholesaler Defendants.**

Dated: July 9, 2020

/s/ Adam Slater
Adam M. Slater
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068
Tel: (973) 228-9898
aslater@mazieslater.com

Ruben Honik
Golomb & Honik, PC
1835 Market Street
Suite 2900
Philadelphia, PA 19103
(215) 278-4449
rhonik@golumbhonik.com

Daniel Nigh
Levin Papantonio
316 South Baylen Street
Pensacola, FL 32502
Tel.: (850) 435-7013
dnigh@levinlaw.com

Conlee Whiteley
Kanner & Whiteley, LLC
701 Camp Street
New Orleans, LA 70130
(504) 524-5777
c.whiteley@kanner-law.com

CERTIFICATE OF SERVICE

I certify that on the 9th day of July 2020, I electronically transmitted the attached document to counsel of record for all Retail Pharmacy and Wholesaler Defendants.

/s/ Adam M. Slater
Adam M. Slater