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SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
E-MAIL: SAGoldberg@duanemorris.com

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ALLIANCES IN MEXICO
AND SRI LANKA

January 14, 2020

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on January 15.

1. Expansion of the MDL

On December 18, 2019, the Judicial Panel on Multidistrict Litigation entered an order expanding the scope of this MDL to include claims relating to the alleged occurrence of nitrosamines in Losartan and Irbesartan. This Court has since asked whether those drugs may be rolled into the MDL by updating the Valsartan-focused document requests, ESI custodian lists, and ESI search term lists the Court approved in December 2019. The expansion of the MDL to include Losartan and Irbesartan raises a number of complexities, such as those described below,

that may impact the efficient management of the MDL. Accordingly, the parties have agreed to meet and confer to discuss the expansion of the MDL, with the hope of submitting a proposal on issues relating to the management of the expanded MDL in advance of the case management conference on January 28.

(a) Losartan

Losartan Potassium ("Losartan") is an angiotensin II receptor blocker ("ARB") indicated for the treatment of hypertension and diabetic nephropathy. Losartan Potassium Hydrochlorothiazide ("Losartan HCTZ") is a combination of Losartan and Hydrochlorothiazide, a diuretic indicated for the treatment of hypertension.

In 1995, the Food & Drug Administration ("FDA") first approved Losartan for use in oral tablet form under the name brand COZAAR®, and in fixed dose combinations with Hydrochlorothiazide under the brand name HYZAAR®. In 2010, the FDA approved the first of 37 applications for generic pharmaceutical manufacturers to begin marketing their own Losartan and Losartan HCTZ products. By approving these generic applications, the FDA determined that the generic products were safe and effective, contained the same active ingredient and have the same clinical effect and safety profile as COZAAR® and HYZAAR®. The FDA also determined that the generic products' labels, including the warnings, precautions and contraindications sections, were the same as the previously approved labeling for COZAAR® and HYZAAR®.

On November 8, 2018, Sandoz, Inc. issued the first recall (voluntary) of a Losartan product—one lot of Losartan HCTZ Tablets—when it discovered that the tablets contained trace amounts of an impurity, N-nitrosodiethylamine (NDEA). In the ensuing months, there were 16

more Losartan product recalls (505 lots), manufactured by multiple defendants.[1] Of the 17 Losartan recalls totaling 506 lots, 12 were due to the presence of NDEA in the medications and 15 were due to the presence of N-Nitroso N-Methyl 4-Amino Butyric Acid (NMBA) in the medications. There were no Losartan recalls because of NDMA, the impurity alleged in Valsartan.

Underscoring the negligible risk, if any, posed by the trace amounts of NDEA found in the recalled Losartan medications, in its December 11, 2018 announcement, the FDA urged patients to continue taking their recalled Losartan medications. On February 28, 2019, the FDA announced that the interim acceptable daily intake levels of NMBA in finished dose drug products was 0.96 ppm. However, on March 20, 2019, the FDA announced that due the shortage of Valsartan, the agency would allow the temporary distribution of specific lots of Losartan containing NMBA above the interim acceptable intake limit of 0.96 ppm and below 9.82 ppm. In so doing, the FDA stated that its scientists evaluated the risk of exposure to NMBA at levels up to 9.82 ppm and determined that it presented no meaningful difference in cancer risk over a six-month time period.

Six personal injury complaints and two consumer class action complaints have been filed asserting claims arising out of alleged nitrosamine impurities in Losartan. Five of those cases have been transferred to the MDL. The remaining three of these cases require transfer by the JPML.[2]

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[1] Torrent, McLeod's, Camber, Legacy, and Teva have all recalled certain lots of Losartan.

[2] In addition to these actions, there are five Plaintiffs who initially raised, but subsequently dropped, claims related to Losartan or Irbesartan. In four personal injury actions, the initial complaints identified both Valsartan and Losartan, but the Short Form Complaints identified only Valsartan. Similarly, the initial TPP complaint filed by Maine Automobile Dealers Association, Inc. Insurance Trust ("Maine Auto") raised claims related to Valsartan, Losartan, and Irbesartan. Maine Auto's claims have been superseded by the TPP Master Complaint, which raises only Valsartan-related claims.

(b) Irbesartan

Irbesartan is indicated for the treatment of hypertension and high blood pressure associated with diabetic nephropathy. It is an ARB that works to block a substance in the body that causes blood vessels to tighten. Irbesartan works to relax blood vessels in order to reduce blood pressure. Irbesartan and Hydrochlorothiazide ("Irbesartan HCTZ") is a combination of Irbesartan and Hydrochlorothiazide, a diuretic indicated for the treatment of hypertension.

In 2012, the FDA approved the generic version of Irbesartan medication for use under the brand name AVAPRO®, and Irbesartan HCTZ under the brand name AVALIDE®. By approving these generic applications, the FDA acknowledged that the approved generic Irbesartan and Irbesartan HCTZ had the same quality and strength as brand-name drugs and determined that the generic products' labels would include all current safety information and warnings as in the brand drugs' labels. In 2012, the FDA approved the first of 41 applications for generic pharmaceutical manufacturers to begin marketing their own Irbesartan and Irbesartan HCTZ products.

On October 26, 2018, Aurobindo Pharma Limited ("Aurobindo") issued a voluntary recall of Irbesartan due to trace amounts of NDEA. Aurobindo recalled 22 batches of Irbesartan, which were supplied to ScieGen Pharmaceuticals Inc., U.S. ("ScieGen"). On October 30, 2018, Sciegen issued a voluntary recall of Irbesartan tablets at the consumer level due to trace amounts of NDEA contained in Irbesartan API manufactured by Aurobindo. These tablets are labeled as Westminster Pharmaceuticals and Golden State Medical Supply Inc.

On January 18, 2019, Prinston Pharmaceutical Inc. ("Prinston") and Solco Healthcare Inc. ("Solco") issued a voluntary recall of one lot of Irbesartan and seven lots of Irbesartan HCTZ tablets based on information that the Irbesartan API manufactured by Zhejiang Huahai Pharmaceutical ("ZHP") contained trace amounts of NDEA. Prinston announced that it was only recalling lots of Irbesartan that contained NDEA above the approved FDA daily intake levels.

Underscoring the negligible risk, if any, posed by the trace amounts of NDEA found in the recalled Irbesartan medications, in its December 11, 2018 announcement, the FDA urged patients to continue taking their recalled Irbesartan medications.

One personal injury complaint and three consumer class action complaints have been filed asserting claims arising out of alleged nitrosamine impurities in Irbesartan. All four of those cases have been transferred to the MDL.

(c) Challenges Concerning the Losartan and Irbesartan Claims

Given differences between Valsartan, Losartan, and Irbesartan, the expansion of the MDL to include claims relating to alleged impurities in Losartan and Irbesartan presents a number of challenges that may affect the rights of parties and impact the management of the MDL, for example:

- Different, and to-be-named, API and/or finished dose manufacturers, wholesalers, distributors, re-packagers, and retailers may be subject to claims relating only to Losartan and/or Irbesartan, and, conversely, some Defendants involved in

Valsartan cases have no connection to or involvement with recalls or litigation concerning Losartan and Irbesartan;[3]

- Class representatives for Irbesartan and Losartan claims must be identified, and Plaintiffs may have to address issues concerning the inclusiveness of Plaintiffs' leadership;
- The scope of the recalls for Valsartan, Losartan, and Irbesartan vary considerably;
- The Valsartan, Losartan, and Irbesartan actions will involve differing and drug-specific design and manufacturing issues;
- Different facilities and ESI/document custodians may be involved in the manufacturing, quality assurance, regulatory, marketing, sales, and distribution functions pertaining to each drug;
- Chronologies for the manufacture, marketing, and recalls of Valsartan, Losartan, and Irbesartan differ, as do each drug's regulatory profile and portfolio;
- The different impurities and permissible levels of impurities allegedly found in Valsartan, Losartan, and Irbesartan respectively potentially involve the consideration of differing risk assessments; and
- Establishing causation and liability in situations where plaintiffs consumed multiple drugs at issue in this MDL creates complexities in the parties' proofs.

[3] Certain potential Defendants are connected to Losartan or Irbesartan products only, and do not currently have any claims against them in the Master Complaints. There are also entities that have produced smaller quantities or only a few lots of Losartan and Irbesartan. It would be prejudicial to involve them in ongoing discovery efforts within the Valsartan context and without any assessment of appropriate scope and/or proportionality.

(d) MDL Management Issues

Complexities involved in managing this MDL are compounded by the expansion to include Losartan and Irbesartan. Given the factual differences between the drugs, the alleged impurities, and the scope of the recalls, lumping the three drugs together may undermine the efficiency of the MDL, and adversely impact the Plaintiffs in prosecuting their claims and the Defendants in defending against those claims. The parties have agreed to meet and confer to discuss the management of the MDL in light of its expansion, with the possibility of discussing the management of the MDL with the Court at the CMC on January 28.

2. Downstream Defendant Discovery

The various tiers of downstream entities have initiated meet and confer discussions with Plaintiffs' counsel regarding the scope of downstream discovery and Defendant Fact Sheet ("DFS") obligations. On January 9 the Retailer/Pharmacy Defendants and Plaintiffs' counsel held a further meet and confer to discuss proposed areas of inquiry for Rule 34 and DFS discovery. To facilitate that discussion, counsel for the Retailer/Pharmacy Defendants provided Plaintiffs with a set of proposed categories for production that, in their view, reflected the guidance provided by the Court regarding the appropriate scope of discovery and the categories of information that the Retailer/Pharmacy Defendants could realistically produce without undue burden. At the conclusion of the discussion, Plaintiffs agreed to confer internally and to respond with written comments; the Retailer/Pharmacy Defendants await that response, and also await comments on the revised DFS to Retailer/Pharmacy Defendants, which was sent to Plaintiffs on October 23. Separately, the Wholesaler/Distributor Defendants are scheduled to continue their meet and confer with Plaintiffs' counsel on Tuesday, January 14.

At this time, the downstream defendants are hopeful that Plaintiffs will agree to narrow their requests in a manner comporting with the Court's directives during the December 18 telephone conference, and we will apprise the Court regarding any areas on which the Court's guidance may be necessary.

3. Manufacturer Defendant Fact Sheets

Now that extensive document requests directed toward the Manufacturer Defendants have been approved by the Court, the Manufacturer Defendants believe that a DFS directed toward their level of the supply chain would be unnecessary, cumulative, and unduly burdensome. All of the information sought through the current draft of the Manufacturer DFS is cumulative of the documents to be produced in response to the finalized document requests. Should the Court find that a Manufacturer DFS is still warranted, the Manufacturer Defendants await Plaintiffs' response to the edits and comments that the Manufacturer Defendants circulated on October 23.

4. Preservation of Recalled Product

On October 25, 2019, counsel for Plaintiffs issued a letter demanding that each Defendant, at every level of the supply chain, preserve and hold "any valsartan API or finished dose products" in its current or future possession, "whether or not they are subject to a recall . . . ." and whether or not newly manufactured and shipped. *See* Exhibit A. Plaintiffs further demanded that each defendant respond in writing to advise Plaintiffs regarding the status of all Valsartan in its possession and to provide details regarding what quantity of product each defendant possesses, when it was received, and where it came from.

Owing to concerns regarding clarity, feasibility, and the impact of Plaintiffs' broad demand, Defendants jointly responded to Plaintiffs on December 20, 2019, advising Plaintiffs that

they were unable to comply with Plaintiffs' demands and identifying a number of concerns including interference with the federal regulatory scheme and duplication of discovery that has already been produced or is being negotiated between the parties. *See* Exhibit B. Counsel for Plaintiffs responded on December 23, writing that they disagreed with Defendants concerns and reiterating their demands.[4] *See* Exhibit C.

For the reasons discussed below, and consistent with Defendants' original letter to Plaintiffs, Defendants submit that Plaintiffs' demands run contrary to and frustrate the federal regulatory scheme, and impose an undue burden on each member of the Valsartan supply chain.

(a) Plaintiffs' Demands Conflict with the Federal Regulatory Scheme for Product Recall and Undermine FDA's Authority

(i) Product Recall Under the Federal Scheme

The recall of pharmaceutical products is governed by FDA regulations and guidance, which address issues including where to send the recalled product, how to handle recalled product, and how to communicate the recall to patients, healthcare providers and downstream entities responsible for distribution of the product. 21 C.F.R. § 7, *et seq.* FDA regulations require that any recall plan include "specific instructions on what should be done with respect to the recalled products," 21 C.F.R. §7.49(c)(iv), and FDA guidance specifically contemplates that FDA will be involved in the final destruction or disposition of any recalled product. *See, e.g.,* FDA Regulatory Procedures Manual: Chapter 7 – Recall Procedures (April 2019), at 22, 37; FDA Guidance for

[4] Plaintiffs' December 23 letter, unlike the first, specifically referenced "Core Discovery" and addressed issues specific to Manufacturer Defendants, raising questions about precisely which Defendants were the intended targets of Plaintiffs' initial letter.

Industry: Product Recalls, Including Removals and Corrections (Nov. 3, 2003). Any recall protocol ultimately is subject to FDA's final review and approval. 21 C.F.R. § 7.42(a)(2).

Once approved, FDA directs that recalling firms conduct the recall in accordance with the approved recall strategy. *Id.* Each downstream entity responsible for the sale or distribution of the product also is expected to "immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to [their] consignees in accordance with paragraphs (b) and (c) of this section." *Id.* at §7.49(d). It is through this coordinated implementation of the FDA-approved recall protocol that manufacturers can ensure that recalled product is removed from the market and handled in a manner consistent with FDA's guidance and expectations.[5]

Plaintiffs' demand that each defendant who now has or later comes into possession of any Valsartan—recalled or not—hold and preserve any such product. This is objectionable for several reasons.

(ii) Plaintiffs' Demands Conflict with Federal Requirements

Each manufacturer is required to follow its FDA-approved Valsartan recall protocol. *Id.* at §7.42(a)(2). Though they vary by manufacturer, in general terms, these recall protocols mandate quarantine and, in some cases, destruction of recalled Valsartan to ensure that any such product is removed from public circulation. For downstream entities, standard protocol is to return recalled

[5] *See* U.S. Food and Drug Administration, *Guidance for Industry: Product Recalls, Including Removals and Corrections*, *available at* https://www.fda.gov/safety/industry-guidance-recalls/guidance-industry-product-recalls-including-removals-and-corrections ("[T]he cooperation of manufacturers and distributors in expediting recall activities is vital because of the determination that a distributed product is potentially hazardous to the public or animals and/or is in violation of the Federal Food, Drug, and Cosmetic Act (the Act).") (last updated Aug. 1, 2014).

product to the manufacturer so that the manufacturer can quarantine, test, or destroy the recalled product in a manner consistent with FDA's guidance.

Plaintiffs' demands, as drafted, require each pharmacy, retailer, wholesaler and distributor to hold and preserve each tablet of Valsartan now or later in its possession. Complying with Plaintiffs' demands would require each downstream entity to retain and preserve any recalled product in *direct conflict* with the instruction to return recalled product to the manufacturers, in violation of federal law. *See id.* at §7.49(d). Moreover, maintaining pockets of recalled product at countless stores, distribution centers or warehouses across the country, also means that manufacturers may not be able to terminate their recalls, because they cannot reliably account for or destroy the product in the manner necessary to certify that they have executed a proper product "correction." *Id.* at § 7.3(h).

Plaintiffs' attempt to dictate the handling of FDA-regulated drugs conflicts with and undermines the federal scheme, raising significant concerns regarding preemption. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."). Defendants should not be forced to choose between complying with federal requirements and meeting Plaintiffs' broad discovery demands.

(iii) Plaintiffs' Demands Undermine Federal Authority Under the Doctrine of Primary Jurisdiction

Because Plaintiffs' demands undermine the recall procedure envisioned by FDA, they also run afoul of the primary jurisdiction doctrine. Under that doctrine, where an activity is "subject to

an administrative agency's expertise," courts should defer to the "exclusive competence" of that agency. *In re Human Tissue Prods. Liab.*, 488 F. Supp. 2d 430, 432 (D.N.J. 2007) (Martini, J.)

The FDA's primary jurisdiction over the recall process prevents courts from enforcing a request to preserve all recalled products. In *Clark v. Actavis Group HF*, Judge Greenaway considered this same issue. 567 F. Supp. 2d 711 (D.N.J. 2008) (Greenaway, J.). Following an FDA-announced recall of Digitek® based on the presence of the active ingredient in a dose exceeding the amount stated on the label, plaintiffs filed a putative class action against the manufacturers. *Id*. The plaintiffs sought a court order "requiring Defendants to preserve all Digitek® tablets and/or other items returned by consumers as part of the recall." *Id.* at 714. The Court held that the primary jurisdiction doctrine mandated the court's abstention, because Plaintiffs' proposal, if ordered, would interfere with the recall. *Id.* at 718.

As in *Clark*, the doctrine of primary jurisdiction applies here. If the Court were to enforce Plaintiffs' demands and essentially rewrite the recall protocols already implemented by the Defendants it would set a dangerous precedent of interfering with FDA's exercise of its regulatory authority and impeding the coordinated return of recalled product to manufacturers for appropriate handling pursuant to FDA guidance.

(b) Plaintiffs' Request is Unnecessary and Unduly Burdensome

Plaintiffs' ability to prove their case does not hinge on the preservation of each and every tablet of Valsartan in existence. The Manufacturing Defendants already have produced documents in Core Discovery documenting testing of the affected Valsartan lots for the presence of nitrosamine impurities. Further, pursuant to federal law, manufacturers of API and finished dose product also must reserve and retain samples from each batch of product produced. *See* 21 CFR

211.170(a)(1) (requiring retention of reserve samples for at least one year after the expiration date of the last lot containing the active ingredient").

Moreover, contrary to what Plaintiffs imply in their December 23 letter, the routine destruction of product subject to recall is not unusual and does not raise "serious" questions about product handling. Destruction of recalled products pursuant to an FDA-approved recall plan is common in product liability litigation. *See, e.g., U.S. v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 582, 585 (D.N.J. 2004) (ordering, within 30 days and under FDA supervision, the destruction of "all BeneFin, SkinAnswer, and MGN-3 in Defendant's possession, custody, or control."); *U.S. v. Kasz Enterprises, Inc.*, 862 F. Supp. 717, 723–24 (D.R.I. 1994) (ordering, with 45 days and under FDA supervision, destruction of the "Solutions 109" products.").

Plaintiffs' demands that each Defendant preserve each and every tablet of Valsartan—whether or not recalled—if implemented, would require each Defendant to devote significant resources—in terms of manpower, finances *and* physical storage—in order to comply, and all for a benefit that has yet to be articulated.

(c) Plaintiffs' Demands Unnecessarily Interfere with Patient Access to Valsartan

Finally, Plaintiffs' demands, as drafted, raise serious concerns regarding continued patient access to Valsartan, and whether a pharmacy or wholesaler/distributor must cease distribution or dispensation of Valsartan altogether in order to comply. Plaintiffs' demand is not limited to recalled Valsartan, and is not limited to Valsartan manufactured by the Manufacturer Defendants in this litigation. FDA, however, has explicitly recognized that not all Valsartan is subject to recall, and has instructed patients to continue taking their medication as prescribed, unless instructed

otherwise by their physicians.[6] Implementing Plaintiffs' demands would undermine the FDA's directive and could present serious risk to patients in need of this medication.

Defendants submit that Plaintiffs' attempt to enforce additional discovery burden through their product preservation demands should be denied.

5. Short Form Complaints Not Properly Filed with MDL Centrality

At the November 6, 2019 conference, Defendants raised the issue of improperly filed Short Form Complaints ("SFCs"). *See* Defendants' Position Statement for 11/6/19 CMC (Dkt. 287) at 4–7; *see also* Plaintiffs' Position Statement for 11/6/19 CMC (Dkt. 288) at 3 (agreeing that plaintiffs must comply with orders governing SFCs). The Court requested a list of the improperly-filed SFCs and stated an intention to order those Plaintiffs to re-file their SFCs through the MDL Centrality fillable template by a certain date. *See* 11/6/19 Tr. at 27:19–25. A list of improperly-filed SFCs is attached as Exhibit D.

Defendants have also received a Plaintiff Fact Sheet from Constance Graham Garnes, individually and on Behalf of the Estate of George F. Graham, Civ. A. No. 1:19-cv-15429. That case, however, has been remanded to the New Jersey state court. *See* Civ. A. No. 1:19-cv-15429, Dkt No. 3–4.

6. Plaintiffs' Motions for Extension of Time

The Court raised the issue of counsel from the Golden Law Firm filing motions for extension of time. The Golden Law Firm has not filed such motions in the MDL docket (Civ. A.

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[6] *See, e.g.,* U.S. Food and Drug Administration, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan (last checked Jan. 12, 2020).

No. 1:19-md-02875) as required by Case Management Order 1, ¶ 10 (Dkt. 18) and has not contacted the Defense Executive Committee related to such extensions.

7. Status of Defendants' Ongoing Core Discovery Productions

The Core Discovery Defendants will continue to produce any additional documents falling under the scope of the Court's Core Discovery Order (Dkt. 88) as they become available.

8. Status of Defendants' Compliance with Order Regarding Testing

Following the November briefing and argument on the macro discovery issues, the Court ordered Defendants to "identify the types and purposes of the tests done on Valsartan API and Valsartan." Dkt. 303, ¶ 8. In compliance with that order, in December the Manufacturer Defendants each sent Plaintiffs a letter identifying by Bates number the pages of their DMFs and ANDAs that list the types and purposes of testing performed on valsartan API and valsartan. *See, e.g.*, Exhibit E. On December 6, the ZHP Defendants also met and conferred with Plaintiffs to walk them through the cited documents.

Nevertheless, Plaintiffs continue to request that the Manufacturer Defendants *create* lists of testing, insisting that their letters *citing to* lists are insufficient under the Court's order. Plaintiffs' position is unsupported by the Court's order, which requires Defendants to "identify" the testing, not to recreate existing lists. In addition, Plaintiffs' request would amount to requiring the Manufacturer Defendants to retype the lists contained in these documents, which is an unreasonable and unwarranted request. *See, e.g., Harris v. Advance Am. Cash Advance Ctrs., Inc.,* 288 F.R.D. 170, 172 (S.D. Ohio 2012) (to the extent plaintiff asked defendant to create "list" of specified information, request was denied because party is not required to create documents in response to document requests); *Alexander v. Federal Bureau of Investigation,* 194 F.R.D. 305,

310 (D.D.C. 2000) (denying plaintiff's request for the FBI to create lists of persons whose FBI reports were requested by White House, when list did not exist).

9. Status of Motion to Dismiss filed by Legacy in *Roddey v. Camber, et al.*

Legacy Pharmaceutical Packaging, LLC is a drug repackager in St. Louis, Missouri. Its involvement with Losartan is limited to repackaging bulk product (*e.g.*, 1,000-count containers) into 30-count prescription bottles for Walmart and Kroger, and then returning it to Walmart's or Kroger's distribution centers in States not including New Jersey. Legacy does not buy product from manufacturers or distributors, or sell product to Walmart, Kroger, or direct consumers.

Two Losartan cases filed in federal court have joined Legacy: the *Roddey* case in this Court, No. 1:19-cv-12763; and the *Garrison* case filed in the U.S. District Court for the Eastern District of Michigan, No. 5:19-cv-12536. Legacy was also joined in a Losartan case filed in Cook County Circuit Court, Illinois; Legacy's challenge to personal jurisdiction in that case is pending.

Given the lack of any connection between the *Roddey* claims and New Jersey, Legacy filed a motion to dismiss for want of personal jurisdiction. All five named Plaintiffs live outside the forum (in Florida, California, or Illinois) and none were prescribed, purchased, ingested, or were injured by Losartan in New Jersey. So even if Legacy had purposefully availed itself of New Jersey in some Losartan-related way (it did not), Plaintiffs' claims have no "affiliation with" that activity and there is no jurisdiction over Legacy. *See Bristol-Myers Squibb Co. v. Superior Court of Cal.*, 137 S. Ct. 1773, 1781 (2017) (holding that, absent an "affiliation between the forum and the underlying controversy, . . . specific jurisdiction is lacking regardless of the extent of a defendant's unconnected activities in the State").

Shortly after Legacy filed its motion, the Court terminated the motion to dismiss without prejudice and stayed the case pending a decision by the JPML on an impending motion to expand the MDL to include Losartan. After the JMPL granted that motion in December, Legacy refiled its motion to dismiss in the MDL (Dkt. 333) and cross-filed in the individual case.

Assuming that the Plaintiffs in *Roddey* could show a connection between their claims and New Jersey (by, for example, joining a New Jersey plaintiff), the Court still would lack personal jurisdiction given the absence of any Losartan-related activity by Legacy that targeted New Jersey. Legacy has made this argument in the *Garrison* case in Detroit, for it similarly has no such Losartan-related activity in Michigan. The court ordered the plaintiff (who is pro se) to show cause why the court should not grant Legacy's motion. Plaintiff missed the response deadline but sought an extension until January 16. The JPML's Conditional Transfer Order 16 (for the *Garrison* matter) was entered and stayed January 2, 2020. Legacy's motion to vacate the CTO is due January 21.

Legacy respectfully asks this Court to take up its Motion to Dismiss at the Court's earliest available setting.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
Sarah Johnston, Esq. (*via email*)

Lori G. Cohen, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)

EXHIBIT A

MAZIE SLATER KATZ & FREEMAN, LLC
COUNSELLORS AT LAW
103 Eisenhower Parkway
Roseland, NJ 07068
(973) 228-9898
Fax (973) 228-0303
www.mazieslater.com

David A. Mazie*
Adam M. Slater*°
Eric D. Katz*°
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn°

Karen G. Kelsen°
Cheryll A. Calderon
David M. Estes
Adam M. Epstein°
Michael R. Griffith°
Matthew Tonzola
Christopher J. Geddis

*Certified by the Supreme Court of New Jersey as a Civil Trial Attorney

°Member of N.J. & N.Y. Bars

October 25, 2019

VIA EMAIL
SAGoldberg@duanemorris.com
Seth A. Goldberg, Esq.
Duane Morris LLP
30 South 17th Street
Philadelphia, Pennsylvania 19103-4196

RE: ***In re Valsartan Products Liability Litigation,*** **No. 1:19-md-02875**
Destruction of Valsartan

Dear Counsel:

Plaintiffs request that each Defendant confirm whether it has preserved or destroyed any valsartan API or finished dose products, whether or not subject to a recall. For all preserved product, please identify: (i) from whom the product was returned, if applicable, (ii) where the product is being preserved, (iii) by whom the product is being preserved, (iv) the date(s) on which the product went into preservation, (v) the quantities of product being preserved, and (vi) the lot number, batch number, or any other logical identifier used to identify the product being preserved. To the extent any such product currently exists, Plaintiffs specifically request that Defendants continue to preserve and do not destroy it, in compliance with Defendants' preservation obligations under CMO No. 1 (ECF 5) at ¶ 12, and Federal Rule of Civil Procedure 37(e) as well as common law obligations to preserve potential evidence. Further, to the extent Defendants receive in the future any valsartan API or finished dose products, whether or not they are subject to a recall, and which are not new products you are currently manufacturing, packaging, or shipping for sale, Plaintiffs specifically request that Defendants preserve and do not destroy or otherwise dispose of such product, in compliance with Defendants' preservation obligations under CMO No. 1 (ECF 5) at ¶ 12, and Federal Rule of Civil Procedure 37(e) as well as common law obligations to preserve potential evidence.

For valsartan API or finished dose product that has been destroyed or disposed of (other than through shipping for sale), please identify: (i) from whom the product was returned, if applicable, (ii) where the product was stored prior to destruction, (iii) who had possession of the product prior to destruction, (iv) who destroyed or disposed of the product; (v) how product was destroyed or disposed of, (vi) the date(s) on which product was destroyed or disposed of, (vii) the quantities of product destroyed or disposed of, (viii) the lot number, batch number, or any other logical identifier used to identify the product destroyed or disposed of, and (ix) the identity(ies) of the person or persons who authorized the destruction.

Very truly yours,

ADAM M. SLATER

Cc: Jessica Priselac, Esq.
(to distribute to all counsel of record for all Defendants in the litigation)

EXHIBIT B

NEW YORK
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FIRM and AFFILIATE OFFICES

SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
E-MAIL: SAGoldberg@duanemorris.com

www.duanemorris.com

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OMAN
A GCC REPRESENTATIVE OFFICE OF DUANE MORRIS

ALLIANCES IN MEXICO
AND SRI LANKA

December 20, 2019

VIA EMAIL

Adam M. Slater, Esquire
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068

Re: *In re Valsartan Products Liability Litigation*
Case No. 1:19-md-02875-RBK-JS

Dear Mr. Slater:

We write on behalf of Defendants in this litigation in response to your letter of October 25, 2019. In that letter, Plaintiffs ask a number of questions regarding Defendants' respective recall processes and the status of all valsartan in Defendants' possession. Plaintiffs also demand that each Defendant preserve "any valsartan API or finished dose products" in its possession, "whether or not they are subject to a recall [.]" As we read your request, any defendant would be required to retain and preserve any and all valsartan in, or that may pass through, its possession unless it is a "new product."

As we explain below, Defendants[1] have concerns regarding the intent and scope of Plaintiffs' directive, and hope that this response can help us reach an understanding on this issue. As should be clear by now, Defendants have been working and continue to work diligently and in good faith

[1] Given the nature of the shared concerns raised in this letter, and in the interest of facilitating a streamlined meet-and-confer process, all Defendants jointly raise these issues for Plaintiffs' consideration, and jointly object to the nature and scope of Plaintiffs' demand. Defendants make this collective attempt at a coordinated meet-and-confer process without prejudice to any Defendant's later right to meet and confer with Plaintiffs separately regarding any individual or unique concerns raised by Plaintiffs' October 25 letter.

to meet their discovery obligations under the Federal Rules of Civil Procedure. Defendants also have been working diligently to adhere to their federally-mandated responsibilities as manufacturers, distributors, re-packagers and pharmacies under and subject to the regulations of the U.S. Food and Drug Administration (the "FDA").

Plaintiffs' October 25 letter is in conflict with those FDA requirements insofar as it demands that Defendants deviate from established, existing drug recall procedures created with the input, assistance and approval of the FDA. Manufacturers of products under the purview of the FDA must follow FDA's regulatory scheme and guidance regarding product recalls, which direct that a recall notice should include "specific instructions on what should be done with respect to the recalled products."[2] Recall instructions are created with the guidance of FDA, and ultimately are subject to the agency's final review and approval. In conducting its review, the FDA reviews "the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate."[3]

The FDA directs recalling firms to conduct the recall in accordance with the approved recall strategy. These recall obligations do not stop with the company initiating the recall. Recipients of a recall notice, including downstream entities, also are directed to "immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to [their] consignees in accordance with paragraphs (b) and (c) of this section."[4]

In light of those regulatory requirements, Defendants object to the scope and substance of Plaintiffs' letter. Because each voluntary recall procedure instructs what manufacturers and downstream entities should do with recalled product, we anticipate that in many circumstances, retaining all recalled valsartan would violate these procedures. Accordingly, we are concerned that compliance with your request raises a conflict with applicable federal law, the purpose of which is to facilitate—not frustrate—FDA's ability to regulate pharmaceutical drugs in furtherance of the public health.[5] Any attempt to impose different, contrary or impeding requirements is preempted by the federal regulatory scheme.

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2 21 C.F.R. §7.49(c)(iv).

3 *Id.* at §7.42(a)(2).

4 *Id.* at §7.49(d).

5 U.S. Food and Drug Administration, *Guidance for Industry: Product Recalls, Including Removals and Corrections*, *available at* https://www.fda.gov/safety/industry-guidance-recalls/guidance-industry-product-recalls-including-removals-and-corrections ("[T]he cooperation of manufacturers and distributors in expediting recall activities is vital because of the determination that a distributed product is potentially hazardous to the

The scope and nature of Plaintiffs' demand also raise significant concerns regarding reasonableness and burden that are not in keeping with the directive under Federal Rule of Civil Procedure 26(b) that discovery be "proportional to the needs of the case" such that "the burden or expense of the proposed discovery [does not] outweigh[] its likely benefit."[6] Specifically, Plaintiffs' demand that each Defendant preserve each and every valsartan tablet, whether or not recalled, if implemented, would require each defendant to devote significant resources—in terms of manpower, finances *and* physical storage—in order to comply. Moreover, because Plaintiffs ask that each Defendant preserve every valsartan tablet in its possession, regardless of whether or not it is "returned" product, Plaintiffs' letter also can be read to demand that current and future distribution and sale of non-recalled valsartan tablets cease so that the product can be warehoused and preserved for Plaintiffs. That is something FDA itself has decided is not appropriate, and which could negatively affect patients' ability to access this important, life-saving medication across the country. In other words, the burden of complying with Plaintiffs' demand is substantial and carries significant consequences. It is unclear—particularly for non-recalled product—why any such effort is necessary or tailored to preserving the information you seek.[7]

Plaintiffs' October 25 letter imposes significant burdens on Defendants that directly conflict with and are an obstacle to the federal regulatory scheme concerning the recall of FDA-controlled products, and the sale and distribution of FDA-approved products that are not the subject of a recall. It also duplicates the substantial discovery already served on the Manufacturing Defendants, who have diligently worked for months to identify and produce core discovery to Plaintiffs.

For the reasons stated above, Defendants reject Plaintiffs' product preservation requests as framed, and they will continue to act pursuant to FDA guidance and regulation, and will continue to implement and follow the procedures for the handling of recalled product as approved by FDA. Defendants reject any attempt by Plaintiffs to impose any different, additional or conflicting obligations on them, or to interfere with the national drug supply chain for non-recalled product. We therefore cannot agree to the demands set forth in Plaintiffs' October 25 letter.

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public or animals and/or is in violation of the Federal Food, Drug, and Cosmetic Act (the Act).") (last updated Aug. 1, 2014).

6 Fed.R.Civ.P. 26(b)(1).

7 Defendants also note that Plaintiffs' letter cites CMO No. 1 (ECF 5) and Rule 37(e) as the basis for Plaintiffs' demand. Both the Court's order and Rule 37(e), however, refer to documents and electronic discovery, and as such do not apply to a request to maintain and store potentially millions of valsartan tablets, regardless of manufacturer, lot number or whether or not recalled. Moreover, even if applicable, both CMO No. 1 and Rule 37(e) invoke reasonableness standards, which are not met for the reasons set forth above.

Defendants submit these objections in good faith and welcome the opportunity to meet and confer further regarding these issues.

Very truly yours,

Seth A. Goldberg

SAG:dmr/DM1\10262928.1
cc: Plaintiffs' Executive Committee (**Via Email**)
Defendants' Executive Committee (**Via Email**)

EXHIBIT C

MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Roseland, NJ 07068
Phone: (973) 228-9898 - Fax: (973) 228-0303
www.mskf.net

David A. Mazie*
Adam M. Slater*°
Eric D. Katz*°
David M. Freeman
Beth G. Baldinger°
Matthew R. Mendelsohn°

*Certified by the Supreme Court of New Jersey as a Civil Trial Attorney

Cheryll A. Calderon
Karen G. Kelsen°
David M. Estes
Adam M. Epstein°
Cory J. Rothbort°
Michael R. Griffith°
Matthew R. Tonzola
Christopher J. Geddis

°Member of N.J. & N.Y. Bars

December 23, 2019

VIA EMAIL
SAGoldberg@duanemorris.com
Seth A. Goldberg, Esq.
Duane Morris LLP
30 South 17th Street
Philadelphia, Pennsylvania 19103-4196

RE: *In re Valsartan Products Liability Litigation,* No. 1:19-md-02875
Core Discovery Deficiencies

Dear Mr. Goldberg:

I am writing in response to your December 20, 2019 letter, responding to Plaintiffs' letter of October 25, 2019 regarding preservation of recalled and potentially contaminated valsartan (all forms) pills. So that there is no ambiguity, Plaintiffs reiterate the demand that all potentially contaminated valsartan pills in defendants' possession be preserved pending further Order of the Court.

Defendants' letter raises serious questions that will need to be answered promptly, as this is an issue that Plaintiffs will be raising with the Court at the mid-January, 2020 conference with the Court. First and foremost, Plaintiffs disagree with and reject the purported preemption issue defendants attempt to create. The preservation of the pills in the context of litigation regarding the contamination issue is not preempted. The suggestion that this request could have had negative impact on the overall availability of medication is not credible either, for example ZHP is still not even permitted to sell valsartan to our knowledge. Moreover, if it was Defendants' position that such an obligation was preempted, or unreasonable, that position should have been disclosed to the Plaintiffs and the Court.

Instead, Defendants waited almost two months to respond to Plaintiffs request, raising serious questions about the status of returned product, and whether Defendants knowingly destroyed evidence (potentially, with the assistance of third-party vendors) during the intervening time period, without notification to Plaintiffs or the Court.

Despite Defendants' suggestion that somehow Plaintiffs' preservation request is "at odds" with ongoing FDA obligations, that does not appear to be the case. For example, in correspondence to the FDA, Mylan indicates that recalled product "***will be in quarantine until approval by the FDA for destruction of the product***." *See* MYLAN MYLAN-MDL2875-00029622 (emphasis added). Mylan has not even requested destruction yet. *See* MYLAN-MDL2875-00030975 ("…we will not request destruction at this time…")

Furthermore, it is unclear whether product subject to this recall could even be destroyed without FDA supervision of the destruction. *See* MYLAN MYLAN-MDL2875-00029622 ("[a]ny destruction…of recalled items may require FDA supervision").

In order to assess next steps, and in preparation of briefing the issue for the Court, Plaintiffs request the following information:

- Status of the recall for each Defendant (i.e., is the recall still ongoing, or closed);
- Names and identities of any and all third parties used to keep and/or destroy recalled products;
    - Plaintiffs have identified the following third parties used by some Defendants in the recall efforts, but request all names of all unidentified third parties being used to destroy pills: Inmar (Teva, Aurobindo); Qualanex (Torrent, Hetero). Plaintiffs understand ZHP utilized a contract warehouse, but have been unable to locate the name of the warehouse in any core discovery produced to date. Plaintiffs cannot discern whether Mylan used a third-party to warehouse and/or quarantine product.
- The dates of any and all destructions, including but not limited to FDA supervised destructions;
- Copies of any and all destruction certifications and/or receipts, including the dates of those destructions, and the manner of destruction (i.e., incineration); and
- Correspondence from the FDA requiring, or confirming approval of, destruction of pills (no such correspondence appears in Core Discovery despite Defendants' continuing obligation to update core discovery pursuant to D.E. 88).

Plaintiffs request this information by January 10, 2019.

Very truly yours,

ADAM M. SLATER

EXHIBIT D

Improperly-Filed Short Form Complaints		
Plaintiff Name	**Law Firm Name**	**Docket Number**
WALTER DILBECK	Hansen, Kohls, Sommer & Jacob, LLP	1:19-cv-15443
DANIEL BAUER	Golden Law Office	1:19-cv-14865
GLENN BAYS	Golden Law Office	1:19-cv-14869
ANTHONY BROWNING	Golden Law Office	1:19-cv-14872
VIRGIE BUCKLEY	Golden Law Office	1:19-cv-14884
ALBERTA BURNS	Golden Law Office	1:19-cv-14886
STEVEN BUTCHER	Golden Law Office	1:19-cv-14888
MARCIA CANTRELL	Golden Law Office	1:19-cv-14891
CHERYL CAUDILL	Golden Law Office	1:19-cv-14900
SHERRI CLOYD	Golden Law Office	1:19-cv-14906
BOBBY COLE	Golden Law Office	1:19-cv-14948
ELIZABETH CORNETT	Golden Law Office	1:19-cv-14950
CHESTER DAVIDSON	Golden Law Office	1:19-cv-14952
LISA DEBORD	Golden Law Office	1:19-cv-14960
CAROL DUVALL	Golden Law Office	1:19-cv-14971
ALAN ERNEST	Golden Law Office	1:19-cv-14974
ROGER GIBSON	Golden Law Office	1:19-cv-14986
JUDY GRIFFITT	Golden Law Office	1:19-cv-14990
TALMADGE HALSEY	Golden Law Office	1:19-cv-14995
CLAYBORNE HAYES	Golden Law Office	1:19-cv-15021
LUCY HOLCOMB	Golden Law Office	1:19-cv-15022
PAUL HOWARD	Golden Law Office	1:19-cv-15024

Improperly-Filed Short Form Complaints		
Plaintiff Name	**Law Firm Name**	**Docket Number**
TONY JUSTICE	Golden Law Office	1:19-cv-15025
SUSAN MEFFORD	Golden Law Office	1:19-cv-15039
WILLIAM LOVE	Golden Law Office	1:19-cv-15030
JAMES MULLINS	Golden Law Office	1:19-cv-15043
LENNY NEEDY	Golden Law Office	1:19-cv-15051
MARION ODANIEL	Golden Law Office	1:19-cv-15087
DENNIS REBER	Golden Law Office	1:19-cv-15101
WILLIAM REYNOLDS	Golden Law Office	1:19-cv-15132
KIM THOMPSON	Golden Law Office	1:19-cv-15135
DARREN WILKERSON	Golden Law Office	1:19-cv-15140
JOE DURBIN	Golden Law Office	1:19-cv-15183
JOYCELYN STEVENS	THE BEASLEY FIRM, LLC	1:19-cv-15711
KEN WISEMAN	THE BEASLEY FIRM, LLC	1:19-cv-15548
CHRISTOPHER BREAUX	Capitelli & Wicker	1:19-cv-19151
JESSIE HAM	Hollis Law Firm, P.A.	1:19-cv-19585
HUNTER NEALY	The Cochran Firm- Dothan, PC	1:19-cv-19609
MELANIE BRODEN	Oliver Law Group P.C.	1:19-cv-18121
RACHAEL HOLLINGSHEAD	Barron & Budd PC	1:19-cv-15336
JAMES TOWNSEND	Gilman & Pastor, LLP	1:19-cv-18407
MIKHAIL LEIMBERG	Colson Hicks Edison	1:19-cv-19967
SUSAN GUITON	Kirtland & Packard LLP	1:19-cv-07145
ALBERT LEE	Golden Law Office	1:19-cv-15027
KAREN MEADE	Kirtland & Packard LLP	1:19-cv-15351

Improperly-Filed Short Form Complaints		
Plaintiff Name	**Law Firm Name**	**Docket Number**
TERRI STINE	Axley Brynelson LLP	1:19-cv-20214
KATHY EDWARDS	The Corchran Firm	1:19-cv-20842
NATALIE CORTEZ	Powell & Roman, LLC	1:19-cv-17454
MICHAEL SVEBEK	Davis & Crump	1:19-cv-20609
DAVID LOOSE	Cohen Placitella & Roth, PC Hendler Flores Law, PLLC	1:19-cv-21327

Plaintiffs Who Failed to File a Timely SFC			
Plaintiff Name	**Law Firm Name**	**Docket Number**	**SFC Deadline**
CHARLESTON PITTMAN	John D. Sileo	1:19-cv-15638	9/19/2019
ROBERT BARBOZA	O'Donnell Law Firm	1:19-cv-06838	9/19/2019
BETTY HEBERT	Damon J. Baldone & Associates	1:19-cv-14647	9/19/2019
AMANDA LOU BABIN	Damon J. Baldone & Associates	1:19-cv-14649	9/19/2019
DAVID NUNNALLY	Law Offices of Kenneth W. DeJean	1:19-cv-15764	9/19/2019
BRYANT BROOKS	Law Offices of Kenneth W. DeJean	1:19-cv-15768	9/19/2019
THERESE FOUGERE	Law Offices of Pius A. Obioha & Associates	1:19-cv-17597	10/4/2019
BEVERLY PATTON	McGrail & Associates	1:19-cv-17609	10/4/2019
DAVID STANO	Gennusa Piacun & Ruli	1:19-cv-18080	10/18/2019

EXHIBIT E

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SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
E-MAIL: SAGoldberg@duanemorris.com

www.duanemorris.com

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A GCC REPRESENTATIVE OFFICE OF DUANE MORRIS

ALLIANCES IN MEXICO
AND SRI LANKA

December 2, 2019

VIA EMAIL TO VALPEC@KIRTLANDPACKARD.COM

Ruben Honik, Esq.
David Stanoch, Esq.
Golomb & Honik, P.C.

Daniel Nigh, Esq.
Levin Papantonio Thomas Mitchell
Rafferty & Proctor, P.A.

Adam Slater, Esq.
Mazie Slater Katz & Freeman, LLC

Conlee Whiteley, Esq.
Kanner & Whiteley, LLC

Re: ***In re Valsartan Products Liability Litigation*, Civ. No. 19-md-2875 (D.N.J.)**
Facility and Testing Information

Counsel:

Pursuant to the Court's November 25, 2019 Order (Dkt. 303), Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") and Prinston Pharmaceutical Co. ("Prinston") provide the following information:

I. Identification of Facilities

As disclosed in a letter to Plaintiffs dated September 16, 2019, ZHP manufactures valsartan API at its Chuannan facility, located at Coastal Industrial Zone, Duqiao, Linhai, Zhejiang, 317016, China; and valsartan finished dose products at its Xunqiao facility located at Linhai, Zhejiang, 317024, China. ZHP began manufacturing valsartan API at the Chuannan facility in 2007, and began manufacturing valsartan finished dose at the Xunqiao facility in 2015.

II. Identification of Testing

The types of testing performed during the valsartan API and finished dose manufacturing processes are identified in Prinston's ANDAs and ZHP's DMF in the documents that begin with the following Bates numbers:

ANDA 204821:

PRINSTON00020754, PRINSTON00020496, PRINSTON00020500, PRINSTON00020504, PRINSTON00020717, PRINSTON00020722, PRINSTON00020726, PRINSTON00020730, PRINSTON00022317, PRINSTON00033450.

ANDA 206083:

PRINSTON00039378, PRINSTON00079310, PRINSTON00079329, PRINSTON00039337, PRINSTON00039341, PRINSTON00039345, PRINSTON00039349, PRINSTON00039354, PRINSTON00039359, PRINSTON00039362.

DMF 023491:

PRINSTON00009342, PRINSTON00017627, PRINSTON00018280, PRINSTON00009363, PRINSTON00010648, PRINSTON00010903, PRINSTON00009782, PRINSTON00011393, PRINSTON00018695, PRINSTON00010529.

DMF 020939:

PRINSTON00078435, PRINSTON00078548, PRINSTON00078700.

In providing this information, ZHP and Prinston expressly reserve all objections to discoverability and admissibility—including their objections to the scope of testing relevant to the issues in these actions—as well as all defenses, jurisdictional or otherwise.

Very truly yours,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Jessica Priselac (jpriselac@duanemorris.com)
Lori G. Cohen (cohenl@gtlaw.com)
Clem C. Trischler (cct@pietragallo.com)
Jessica M. Heinz (Jheinz@c-wlaw.com)
Janet L. Poletto (jpoletto@hkmpp.com)
Alexia Brancato (alexia.brancato@kirkland.com)