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August 11, 2025

VIA ECF

The Hon. Renée Marie Bumb
USDJ, District of New Jersey
Mitchell H. Cohen Building
& U.S. Courthouse
4th & Cooper Streets,
Camden, NJ 08101

Special Master the Hon. Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, PA 19103

Re: Defendants' Reproposed Motions *In Limine*:
Gaston Roberts et al. v. Zhejiang Huahai Pharmaceutical Co. Ltd., et al.,
No. 1:20-cv-00946-RMB-SAK (D.N.J.)

Dear Judge Bumb:

Pursuant to the Court's direction at the August 1, 2025 Case Management Conference ("8/1/25 CMC"), defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Princeton Pharmaceutical Inc., and Solco Healthcare U.S., LLC (collectively, "Defendants") have been meeting and conferring with Plaintiff in an effort to narrow the parties' evidentiary disputes. (See 8/1/25 CMC Tr. 47:10-15 (ECF No. 3133).) The parties are very close to reaching stipulated agreements with respect to the admissibility of a number of categories of evidence. It appears at this time, however, that there are certain categories of evidence as to which the parties may not be able to agree. Accordingly, pursuant to the Court's guidance at the 8/1/25 CMC (*id.* 59:2-11), Defendants respectfully request leave from the Court to submit the following proposed motions *in limine* to exclude certain evidence, testimony, or arguments from the trial in the above-captioned matter.

- 1. Motion to exclude evidence related to N-Nitrosodiethylamine ("NDEA"), to which Plaintiff does not contend Mr. Roberts was exposed.**
- 2. Motion to exclude evidence or argument suggesting that Defendants misled the FDA or committed fraud on the FDA.**

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3. **Motion to exclude evidence or argument related to FDA communications or regulatory actions that post-date the valsartan recall and are unrelated to the circumstances or events giving rise to the valsartan recall.**
4. **Motion to exclude evidence, testimony, argument, or references regarding losartan or irbesartan active pharmaceutical ingredient (“API”) or finished dose (“FD”) products used for the purpose of suggesting, inferring or refuting liability, and/or a failure to comply with CGMPs for the at-issue valsartan API or FD products. This motion would not seek to exclude: (1) evidence, testimony, argument or references to the July 27, 2017 ZHP email and related documents pertaining to irbesartan; (2) certain losartan-related documents used to cross-examine Dr. Ali Afnan at the September 18, 2024 *Daubert* hearing (i.e. ZHP02908569 & ZHP02929237); or (3) incidental references to losartan or irbesartan.** (Similar motion agreed to by the parties in connection with the TPP Trial (see Stipulations in Lieu of Motions *In Limine*, at 3 (ECF No. 2639).)
5. **Motion to exclude evidence and arguments about deterring future misconduct by Defendants and others without first informing the Court and establishing that such evidence is relevant to punitive or other alleged damages in the case.** (Similar motion *in limine* granted in connection with TPP Trial (see 7/23/24 Tr. 261:18-264:9 (ECF No. 2791).)
6. **Motion to exclude evidence related to the Parties’ litigation conduct and discovery disputes, including references to document productions, litigation holds, sanctions motions or orders, or confidentiality designations. This motion would not seek to exclude evidence or testimony addressing whether certain documents were included within a witness’s custodial file.** (Similar motion *in limine* granted in connection with TPP Trial (see 7/23/24 Tr. 267:17-268:8).)
7. **Motion to exclude evidence or testimony regarding statements or actions by regulatory agencies outside the United States that were not relied upon by Defendants.** (Similar motion *in limine* granted in connection with TPP Trial (see 7/23/24 Tr. 273:23-276:3).)

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- 8. Motion to exclude evidence or argument related to indemnification requests provided to ZHP by finished dose manufacturers (i.e. ZHP00454953 and TEVA-MDL2875-00324735).** (The parties have agreed to stipulate to the general exclusion of evidence related to cross claims or indemnification agreements among the defendants in valsartan-related litigation, but have not been able to reach agreement with respect to the admissibility of these two documents.)¹

Defendants are happy to provide any additional information that would be helpful to the Court. Thank you for your consideration of this request.

Sincerely,



Nina Rose

¹ In the event that the parties are not able to finalize their proposed agreements with respect to other categories of evidence, Defendants respectfully request the opportunity to seek leave from the Court to file additional motions *in limine* as necessary.