IN RE PROTON-PUMP INHIBITOR LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY CASE NO: 631 Civil Action MASTER CASE NO. ATL-L-1259-20 **~~[DRAFT PROPOSED]~~ CASE MANAGEMENT ORDER NO. 7 (Docket Control Order)**

This Case Management Order ("CMO") applies to all Plaintiffs alleging personal injury (and related) claims against Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Merck Sharp & Dohme Corp., Merck & Co., Inc., and Merck & Co. D/B/A Merck Sharp & Dohme Corp. (collectively, the "AstraZeneca and Merck Defendants") who have cases pending against the AstraZeneca and Merck Defendants as of the date this order is entered and are not settling under the voluntary settlement program, and all Plaintiffs with cases alleging personal injury (and related) claims against the AstraZeneca and Merck Defendants that are newly filed in this Court after the entry of this order ("Litigating Plaintiffs").

Consistent with the Court's inherent authority to manage these judicial proceedings, and in light of the Master Settlement Agreement that the AstraZeneca

and Merck Defendants and Plaintiffs' Counsel entered into after over five years of litigation, the Court will exercise its discretion to enter this Docket Control Order to efficiently manage any remaining cases against the AstraZeneca and Merck Defendants, while separately managing the litigation against any remaining defendants that are not subject to settlement agreements and/or a related stay.

Consistent with the directive set forth in New Jersey PPI CMO No. 2 "to promote judicial efficiency between this MCL and other litigations involving PPIs," this Order, which imposes the same requirements as CMO No. 109 entered in In re Proton-Pump Inhibitor Products Liab. Litig., MDL No. 2789 (D.N.J.) ("the MDL"), requires all Litigating Plaintiffs to produce certain specified information regarding their claims and provides for expedited bifurcated discovery on statute of limitations, other time-based defenses, and causation issues, and related dispositive motion practice, prior to any further discovery. Litigating Plaintiffs who represent themselves *pro se* shall be bound by the requirements of this order and shall fully comply with all obligations required of counsel by this order, unless otherwise stated.

A. Background and Status of Proceedings

1. The events leading up to this litigation began in January 2016, when an epidemiological study by Lazarus et al. was published in *JAMA Internal Medicine*, reporting an association between the use of proton pump inhibitors ("PPIs") and chronic kidney disease. The Lazarus study received widespread media coverage in

news outlets such as the New York Times, Washington Post, CBS News, and Fox News. In April 2016, an epidemiological study by Xie et al. was published in the *Journal of the American Society of Nephrology*, reporting a similar association between PPIs and kidney disease. The Xie study generated further publicity in mainstream media outlets including CNN, ABC News, CBS News, and Fox News. In addition, a study by Peng et al. was published in *Medicine* in April 2016 and a study by Arora et al. was published in *BMC Nephrology* in August 2016.

As public awareness of a potential association between PPIs and kidney disease grew, personal injury lawsuits began to be filed. By February 2017, there were nearly 40 lawsuits pending in various federal courts alleging that the use of PPIs resulted in kidney disease. See In re Proton-Pump Inhibitor Prods. Liab. Litig., 273 F. Supp. 3d 1360, 1361 (J.P.M.L. 2017). Over the next several months, more lawsuits were filed, and on August 2, 2017, the JPML established the MDL to centralize cases against several defendants, including the AstraZeneca and Merck Defendants, alleging kidney injuries arising from the use of PPIs. Id. More than 18,600 cases have been filed in, removed to, or transferred to the MDL over the past six years, and of these, approximately 17,950 cases have named one or more of the AstraZeneca and Merck Defendants. In addition, cases have been pending in the New Jersey Superior Court since May 2019. At its height, this consolidated litigation involved 50 cases, all of which named one or more of the AstraZeneca and Merck Defendants.

2. As the Supreme Court of the United States has recognized, "courts possess certain inherent powers, not conferred by rule or statute, to manage their own affairs so as to achieve the orderly and expeditious disposition of cases." Goodyear Tire & Rubber Co. v. Haeger, 581 U.S. 101, 107 (2017) (internal quotations omitted). Likewise, New Jersey courts have recognized "that courts have inherent powers beyond those specifically delegated or confirmed by statute or court rule to do what is reasonably necessary for the orderly and efficient administration of justice within the scope of their jurisdiction." Dziubek v. Schumann, 275 N.J. Super. 428, 439 (App. Div. 1994). Accordingly, the New Jersey Court Rules are "construed to secure a just determination, simplicity in procedure, fairness in administration and the elimination of unjustifiable expense and delay," and "[i]n the absence of rule, the court may proceed in any manner compatible with these purposes," consistent with case/trial management guidelines. R. 1:1-2(a).

3. The Court is aware that, without admission of fault or liability, the AstraZeneca and Merck Defendants have entered into a Master Settlement Agreement to resolve cases alleging personal injury (and related) claims against them related to PPI products. The settlement comes over seven years after the establishment of the MDL and five years after the first filings in this Court. During that time, the parties have engaged in and completed general liability discovery, a robust bellwether selection process, and general and case-specific expert discovery.

4. Docket control orders "have been routinely used by courts to manage mass tort cases." In re Vioxx Prod. Liab. Litig., 557 F. Supp. 2d 741, 743 (E.D. La. 2008) (Fallon, J.); see also N.J. Multicounty Litigation (Non-Asbestos) Resource Book, 7 (4th ed. 2014) (directing courts to promptly develop, update, and modify case management orders "as the litigation unfolds"). Appellate courts regularly uphold such orders in MDL cases.[1]

5. Such docket control orders may be particularly appropriate when a defendant has taken steps to settle a significant portion of the claims pending against it.[2]

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[1] See, e.g., In re Avandia, 687 Fed. App'x at 214; Chauvin, 860 Fed. App'x at 96–97 ("MDL courts are 'given greater discretion to create and enforce deadlines in order to administrate the litigation effectively,' which 'includes the power to dismiss cases where litigants do not follow the court's orders'" (affirming MDL court's dismissal for failure to comply with discovery order that required non-settling plaintiffs to produce an expert report)); Dzik v. Bayer Corp., 846 F.3d 211, 216 (7th Cir. 2017) ("District courts handling complex, multidistrict litigation must be given wide latitude with regard to case management in order to achieve efficiency" (internal quotation marks omitted)) (affirming MDL court's dismissal for failure to comply with discovery order); In re Vioxx Prod. Liab. Litig., 388 Fed. App'x 391 (5th Cir. 2010) ("[I]t is within a court's discretion to take steps to manage the complex and potentially very burdensome discovery that the cases would require" (internal quotations and citations omitted)) (affirming MDL court's dismissal for failure to comply with discovery order that required non-settling plaintiffs to produce a specific-causation expert report); Acuna v. Brown & Root, Inc., 200 F.3d 335, 340 (5th Cir. 2000) (Case management "orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation. In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under Fed. R. Civ. P. 16.").

[2] See, e.g., Case Management Order No. 57, In re 3M Combat Arms Earplug Prods. Liab. Litig., MDL No. 2885 (Case No. 3:19-md-02885) (N.D. Fla. 2023) (in settlement context, requiring non-settling plaintiffs to produce medical records and expert reports); Case Management Order No. 11, Docket No. 12902, In re: Xarelto (Rivaroxaban) Prod. Liab. Litig., MDL No. 2592 (Case No. 2:14-md-02592), (E.D. La. 2019) (in settlement context, requiring non-settling plaintiffs to produce medical and pharmacy records and a specific-causation expert report), available at https://www.laed.uscourts.gov/sites/default/files/xarelto/12902.pdf; Pretrial Order No. 18 at 2, 7-9, Docket No. 758, In re: Fluoroquinolone Prods. Liab. Litig., MDL No. 2642 (Case No. 0:15-md-

6. Moreover, the Court finds it particularly appropriate to enter this Docket Control Order, which mirrors the substantially similar CMO No. 109 entered in the MDL on October 2, 2023, so the Court can efficiently manage this litigation that is proceeding on a settlement front with certain defendants in multiple jurisdictions and coordinate with the MDL as recognized in New Jersey CMO No. 2.

For the foregoing reasons, and other good cause appearing therefor, it is Ordered as follows:

B. Litigating Plaintiffs' Requirements To Produce Certain Specified Information Regarding Their Claims

02642), (D. Minn. January 2, 2019) (in settlement context, requiring non-settling plaintiffs to produce medical and pharmacy records and causation and liability expert reports and bifurcated discovery on statute of limitations and other time-based defenses), available at https://ecf.mnd.uscourts.gov/doc1/10117574348; Case Management Order No. 126 at 2, 6-8, Docket No. 2716, In re Testosterone Replacement Therapy Prods. Liab. Litig., MDL No. 2545 (Case No. 1:14-cv-01748), (N.D. Ill. June 11, 2018) (in settlement context, requiring non-settling plaintiffs to produce medical and pharmacy records and causation and liability expert reports and bifurcated discovery on statute of limitations and other time-based defenses), available at https://lonepineorders.law.stanford.edu/wp-content/uploads/In-Re-Testosterone-Replacement-Therapy-Products-Liability-Litigation.pdf; In re American Med. Sys., Inc. Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2325, Pretrial Order # 239, ECF No. 4272 (S.D.W. Va. June 7, 2017) (establishing requirements for future claims against a defendant due to "recent settlement developments" of thousands of claims after more than three years of litigation); Case Management Order No. 78 at 5, Docket No. 519, In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig., MDL No. 2385 (Case No. 3:12-md-2385) (S.D. Il. May 29, 2014) (in settlement context, requiring non-settling plaintiffs to produce causation expert reports), available at http://www.ilsd.uscourts.gov/documents/mdl2385/CMO78.pdf; Pretrial Order #28 and #29, Docket Nos. 12962, 12963, In re Vioxx Prods. Liab. Litig., MDL No. 1657 (E.D. La. 2008), available at http://www.laed.uscourts.gov/sites/default/files/vioxx/orders/vioxx.pto28.mdl.pdf and http://www.laed.uscourts.gov/sites/default/files/vioxx/orders/vioxx.pto29.mdl.pdf.

7. **Litigating Plaintiffs' Production Requirements:** Litigating Plaintiffs shall serve the following documents and/or information upon counsel for the AstraZeneca and Merck Defendants, as applicable, by email at xPPI@arnoldporter.com:

a. The Litigating Plaintiff must produce all medical records that document the Litigating Plaintiff's, or if different, the associated PPI user's ("Associated User's"), alleged PPI-related injury/injuries, and pharmacy records/medical records for the Litigating Plaintiff's or the Associated User's PPI prescription(s) and/or samples.

b. **Pharmacy Records:** All pharmacy records and medical records regarding the dispensation of any prescription medication and/or samples to the Litigating Plaintiff or the Associated User for the period from five (5) years prior to the date of the Litigating Plaintiff's or the Associated User's first use of PPIs to the present.

c. **Medical Records:** All medical records relating to the Litigating Plaintiff or the Associated User from health care providers for the period from five (5) years prior to the date of the Litigating Plaintiff's or the Associated User's first use of PPIs to the present.

d. **Record Collection Production**: The Litigating Plaintiff and his/her counsel shall affirmatively collect and produce such Pharmacy and Medical Records from all available sources in the Litigating Plaintiff's possession, custody or control, which includes but is not limited to any relevant Pharmacy and Medical records that can be collected from the Litigating Plaintiff's or the Associated User's medical facilities, health care providers, and/or pharmacies that treated and/or dispensed drugs to, or for, the Litigating Plaintiff or the Associated User. A Litigating Plaintiff and his/her counsel shall not be in compliance with this CMO by producing only records in the Litigating Plaintiff's or his/her counsel's current possession, or by only producing authorizations to allow the AstraZeneca and Merck Defendants to collect such records.

e. **Affidavit:** An affidavit, signed under oath, by the Litigating Plaintiff and his/her counsel attesting to the following:

i. The Litigating Plaintiff has complied with all requirements of this CMO;

ii. Records have been collected from all pharmacies that dispensed drugs to, or for, the Litigating Plaintiff or the Associated User covered by paragraph B.7.b;

iii. All medical records described in paragraph B.7.c. have been collected;

iv. All records collected have been produced pursuant to this CMO;

v. If any of the documents or records described in Sections B.7.a., B.7.b., or B.7.c. do not exist, then the affidavit shall state that fact and the reasons, if known, why such materials do not exist, and shall attach a "No Records Statement" from the pharmacy, medical facilities, and/or other healthcare provider; and

vi. For each prescription PPI product taken by the Litigating Plaintiff or the Associated User, the affidavit shall specify the corresponding FDA National Drug Code ("NDC code") and attach a medical or pharmacy record reflecting that NDC code.

f. **Expert Reports:** Expert reports in compliance with Rule 4:17 as follows:

i. An expert report on general causation concerning the alleged injury/injuries.

ii. A case-specific expert report concerning the causation of the Litigating Plaintiff's or the Associated User's alleged injury/injuries. The reports required by Sections B.7.f.i and this B.7.f.ii may be combined in a single report by a single expert.

iii. An expert report on the basis for liability concerning the AstraZeneca and Merck Defendants—*e.g.*, support for allegations that the AstraZeneca and Merck Defendants' warning label(s) were inadequate, that they failed to adequately test and/or monitor the safety of their PPI product(s), and/or that they marketed their PPI product(s) in a manner that would serve as the basis for a claim against the AstraZeneca and Merck Defendants. The requirements of this Section B.7.f.iii apply only to claims alleging kidney disease.

g. **Retention Agreements:** Signed retention agreements between Litigating Plaintiffs' counsel and each expert who submits a report pursuant to Section B.7.f—which shall affirm the expert's intention to attend a deposition, Daubert hearing, and trial, if necessary. These retention agreements shall not be produced to the AstraZeneca and Merck Defendants with the other requirements under Paragraph 7, however, upon the AstraZeneca and Merck Defendants' unilateral request, Litigating Plaintiffs shall provide these retention agreements to this Court, who shall review the retention letters *in camera* to assess their compliance with this Order.

h. **Affidavit:** An affidavit signed by the Litigating Plaintiff and his/her counsel attesting to the following:

(i) the date the Litigating Plaintiff first learned his/her or the Associated User's alleged injury/injuries may be related to PPI use;

(ii) how the Litigating Plaintiff first learned his/her or the Associated User's alleged injury/injuries may be related to PPI use;

(iii) the date the Litigating Plaintiff or the Associated User first spoke to or corresponded with an attorney about potential litigation related to PPI use; and

(iv) the date the Litigating Plaintiff first retained counsel for litigation related to PPI use.

In providing the affidavit required by this paragraph, nothing in this paragraph is intended to infringe or in any way compromise

the attorney-client privilege, or require the production of documents that are protected from disclosure by the attorney client privilege, including, but not limited to attorney-client retainer agreements; as such, in the event that the information required to be included in the affidavit required by this paragraph is protected under the attorney-client privilege, the assertion of that privilege must be set forth in the affidavit.

8. **Deadline to comply:**

a. For each Litigating Plaintiff with personal injury (and related) claims pending against one or more of the AstraZeneca and Merck Defendants as of the entry of this CMO who was eligible to participate in but elects not to settle under the voluntary settlement program, the items required by paragraph B.7 shall be produced no later than 90 days after the date such Litigating Plaintiff elects not to settle his/her claims or the date of this Order, whichever is later.

b. For each Litigating Plaintiff with personal injury (and related) claims newly filed in this Court against one or more of the AstraZeneca and Merck Defendants after the entry of this CMO, the items required by paragraph B.7 shall be produced no later than 90 days after the case is filed, or ninety days after this Order, whichever is later.

9. **Failure to comply:** The Court has established the foregoing deadlines for the purpose of ensuring that pretrial litigation against the AstraZeneca and Merck Defendants will progress as smoothly and efficiently as possible. Accordingly, the Court expects strict adherence to these deadlines. Should any Litigating Plaintiff fail to comply with the obligations of paragraphs B.7 and B.8, or should the AstraZeneca and Merck Defendants deem the Litigating Plaintiff's compliance with this CMO deficient, counsel for the AstraZeneca and Merck Defendants shall notify

the Court of the alleged deficiency and the Court shall issue an "Order To Show Cause Why the Case Should Not Be Dismissed With Prejudice." Litigating Plaintiff's counsel shall have 21 days to respond to said Order To Show Cause. If the Litigating Plaintiff fails to show cause within 21 days of entry of the Court's Order To Show Cause, the Court shall dismiss the Litigating Plaintiff's case with prejudice. See, e.g., Freeman v. Wyeth, 764 F.3d 806, 809-810 (8th Cir. 2014) (affirming MDL court's dismissal of claims for failure to provide medical authorizations); In re Phenylpropanolamine Prods. Liab. Litig., 460 F.3d 1217, 1232-34 (9th Cir. 2006) (finding no abuse of discretion in MDL court's dismissal of claims for failure to comply with discovery and product identification case management orders).

C. Expedited Case-Specific Bifurcated Discovery On Statute of Limitations, Other Time-Based Defenses, and Causation Issues And Related Dispositive Motion Practice

10. If the Parties jointly agree that Litigating Plaintiff has complied with the production requirements outlined in paragraphs B.7 and B.8, then the Parties, as applicable, shall submit a proposed Scheduling Order to the Court that: (a) grants the Parties 180 days from the entry of the Scheduling Order to conduct expedited bifurcated discovery on potentially case-dispositive issues, including case-specific statute of limitations, other time-based defenses, and causation issues ("Expedited Discovery"); and (b) sets a briefing schedule that gives the Parties 45 days from the

close of Expedited Discovery for the Parties to submit summary judgment motions and *Daubert* motions, 28 days for oppositions, and 28 days for replies. The briefing schedule required by subsection (b) may not be changed absent agreement of the parties or prior leave granted by the Court upon a showing of good cause.

11. The Parties shall have 180 days to conduct Expedited Discovery on statute of limitations, other time-based defenses, and causation issues. During such Expedited Discovery, the Parties are permitted to: (a) serve written discovery related to statute of limitations, other time-based defenses and/or case-specific affirmative defenses, and causation issues specific to the Litigating Plaintiff; (b) take the depositions of the Litigating Plaintiff, the Litigating Plaintiff's or Associated User's spouse, and any other non-party fact witness specific to the Litigating Plaintiff identified in the Plaintiff Fact Sheet or through other discovery for up to seven hours each, with counsel for the AstraZeneca and Merck Defendants, as applicable, questioning first at each deposition; (c) take the depositions of each of the Litigating Plaintiff's or Associated User's prescribing and treating healthcare providers with the issue of priority of questioning at each deposition to be subject to a meet and confer, and if necessary, resolution by the Court; and (d) take the depositions of the Litigating Plaintiff's experts who submit reports pursuant to Section B.7.f above. If the AstraZeneca and Merck Defendants serve written discovery on Litigating Plaintiffs in accordance with this Paragraph, then Litigating Plaintiffs must respond

to the discovery prior to the AstraZeneca and Merck Defendants' depositions of Litigating Plaintiff or the Associated User and Litigating Plaintiff's or the Associated User's prescribing and treating healthcare providers, provided that Litigating Plaintiff shall have at least 30 days to respond to such discovery. The AstraZeneca and Merck Defendants shall provide Defendant Fact Sheets within sixty (60) days of entry of the Scheduling Order described in Paragraph C.10. If a Litigating Plaintiff serves any additional written discovery against the AstraZeneca and Merck Defendants pursuant to clause (a) above beyond a request for the Defense Fact Sheet, the Parties shall meet and confer about an appropriate deadline for responding to such discovery, provided Defendants shall have at least 30 days to respond to such discovery. The Court's use of the term "specific to the Litigating Plaintiff" is intended to express the Court's prohibition of additional "generic" discovery against the AstraZeneca and Merck Defendants during the Expedited Discovery period. No other depositions, including depositions of current and former sales representatives and managers of the AstraZeneca and Merck Defendants, may be taken during the Expedited Discovery period.

12. If the AstraZeneca and Merck Defendants' summary judgment motions are denied in any case, as applicable, the Court will set a Case Management Conference to determine whether any non-duplicative additional discovery is necessary and to discuss other case management issues. For any claims alleging

non-kidney injuries, the parties shall meet and confer regarding an appropriate deadline by which Litigating Plaintiffs must produce an expert report in compliance with Rule 4:17-4(e) on the basis for liability concerning the AstraZeneca and Merck Defendants. The filing and briefing of summary judgment motions and *Daubert* motions after the Expedited Discovery discussed above shall not prejudice or otherwise foreclose the opportunity for the Parties to file later, non-duplicative summary judgment and *Daubert* motions after completing full fact and expert discovery. The Court's use of the term "non-duplicative" is intended to express the Court's intention not to permit later summary judgment motions concerning topics addressed in summary judgment motions filed at the conclusion of the Expedited Discovery period or *Daubert* motions concerning witnesses addressed in *Daubert* motions filed at the conclusion of the Expedited Discovery period.

IT IS SO ORDERED this 14th day of November, 2025.

Danielle J. Walcoff

~~Hon. Michael J. Blee, A.J.S.C.~~

Danielle J. Walcoff, J.S.C.