

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY
LITIGATION

MDL NO 2924
20-MD-2924

JUDGE ROBIN L ROSENBERG
MAGISTRATE JUDGE BRUCE REINHART

THIS DOCUMENT RELATES TO: ALL CASES

PRETRIAL ORDER # 79
MODIFICATIONS TO REGISTRY TIMELINES

On February 28, 2022, the Court issued Pretrial Order # 72 which set forth a number of provisions related to the continuing existence of the Registry, in light of the progression of this MDL that has occurred over the past two years, including particularly the determination by Plaintiffs' Leadership of which types of injuries it will pursue. This Order now addresses a number of additional matters, which are reflective of this development and the present state of the Registry, as well as modifying certain deadlines set forth in Pretrial Order # 72¹ and Pretrial Order # 15:

1. Defense Mapping. Because Registry Participants allege use of both branded Zantac and generic ranitidine, manufactured over approximately four decades, this MDL includes usage allegations spanning many different dosages and formulations and, in turn, many manufacturers or sellers, each with different dates of manufacture or sale, often across various formulations and dosages. The parties therefore agreed early in this MDL to create a defense mapping feature within the Registry, which would, *inter alia*, assist Registry Participants in excluding certain Defendants from being named in complaints where the Registry Participant's usage pattern as alleged in his

¹ Unless defined herein, capitalized terms have the same meaning as defined in Pretrial Order # 72.

or her Census Plus Form (“CPF”) was inconsistent with such Defendants’ known manufacturing or sale history.

2. The defense map does not serve as a replacement for the obligation of individual Registry Participant’s counsel to make a good faith investigation of any particular claim before filing a lawsuit or listing Anticipated Defendants in their CPF. Rather, the defense map is merely a single tool to be used in conjunction with—not in place of—the diligence of counsel. For example, the CPF does not distinguish between capsules and tablets or certain different formulations, nor does it require entry of the specific National Drug Codes identified in a Registry Participant’s purchase records, and thus the defense map (being derived from the CPF answers) cannot make these distinctions.

3. Modification of Certain Registry Deadlines & Tolling. Pretrial Order # 72 set forth a timeline for Registry Participants who alleged a Designated Cancer to, *inter alia*, determine whether they would elect to become Certified Federal Participants. The deadline for this election was set for June 30, 2022, to permit finality as to those Registry Participants who would ultimately file (if ever) in federal court, in advance of this Court’s upcoming *Daubert* rulings on general causation. Equally important, Pretrial Order # 72 set deadlines for when certain categories of Registry Participants may be exited from the Registry, for example, those alleging Non-Designated Cancers. The deadlines were set to ensure that the 90 days of tolling for any claims exited would expire prior to this Court’s *Daubert* general causation orders, such that any Registry Participant whose statute of limitations would have expired would need to file his/her claim in an appropriate court prior to this Court’s *Daubert* determinations.

4. This MDL was created concurrent with the COVID-19 pandemic and has notably been shaped by that timing, progressing in many ways differently than it otherwise would have. The overhang of the pandemic—now in the form of delays in processing and staffing, impacting

not only the law firms but more notably the medical records retrieval companies and medical offices from whom such records are sought—continues. The parties have jointly recognized the importance of accurate information and of each Registry Participant’s decision to become a Certified Federal Participant or not. The Special Master and Registry Coordinating Counsel, on behalf of the parties, have jointly recommended to this Court that Registry Participants alleging a Designated Cancer be given until Sunday, July 31, 2022, at 5:00 pm Eastern Time to make the election to become a Certified Federal Participant—but that tolling for those who decide not to become a Certified Federal Participant shall be concurrently shortened to 60 days after exit from the Registry (instead of the 90 days set forth in Pretrial Orders # 15 and 72), for all claims exited on or after July 1, 2022.

The Court accepts the recommendation of the Special Master and Registry Coordinating Counsel as follows. The statute of limitations remains tolled for 90 days for all claims exited from the Registry with one limited exception: Registry Participants who exit from the Registry on or after July 1, 2022, who allege a Designated Cancer and do not become a Certified Federal Participant, shall have 60 days in lieu of the 90 days set forth in Pretrial Order # 15. In the interest of clarity and for the avoidance of doubt, the Court sets forth the different categories of Registry Participants below, together with the applicable expiration of tolling.

For all claims exited from the Registry prior to July 1, 2022, tolling expires/expired 90 days after exit from the Registry, consistent with Pretrial Order # 15. For all Non-Designated Cancer claims exited from the Registry at any time, tolling expires 90 days after exit from the Registry, consistent with Pretrial Order # 15. For all Designated Cancer claims exited from the Registry prior to July 1, 2022, tolling expires/expired 90 days after exit from the Registry, consistent with Pretrial Order # 15. For Designated Cancer claims exited from the Registry on or after July 1, 2022, that are also Certified Federal Participants, tolling expires 90 days after exit

from the Registry, consistent with Pretrial Order # 15. Finally, for Designated Cancer claims exited from the Registry on or after July 1, 2022, that are *not* Certified Federal Participants, tolling expires 60 days after exit from the Registry, consistent with this Order and the limited amendment² to Pretrial Order # 15 contained herein.

5. In Pretrial Order # 72 this Court also ordered the finalization of Anticipated Defendants contemporaneous with the Certified Federal Participant election period. As such, this deadline is also moved to Sunday, July 31, 2022, at 5:00 pm Eastern Time. Such final designations of Anticipated Defendants are made on the Litigation Management, Inc. (“LMI”) webpage, on the same page on which the mapping of manufacturers/sellers is displayed (“Anticipated Defendant Designation Page”), not in the CPF itself. In the event of a discrepancy between the Anticipated Defendant Designation Page and the CPF answers, the Anticipated Defendant Designation Page is deemed to be the final and binding designation.³ The deadline in paragraph 7 of Pretrial Order # 72 is likewise extended to July 31, 2022.

6. Paragraph 5 of Pretrial Order # 72 contemplated that certain timely-ordered records might not be received sufficiently in advance of the finalization deadline, and that these late-arriving records might impact a Certified Federal Participant’s answer. This provision is hereby modified only as follows: The late-arriving record must be the first record received from any source by the Registry Participant evidencing the information he/she desires to change, whether it is adding a new Anticipated Defendant or modifying the injury (diagnosis or date). If any addition

² This limited modification to the tolling provisions of Pretrial Order # 15 is entered with either the full consent or lack of objection of all parties to the MDL. DE 5769 at 3 n.2. This Order is not intended to alter any agreements that the parties have reached regarding tolling, extension of tolling, or the right of any Defendant to terminate tolling.

³ This provision regarding where in the LMI platform Anticipated Defendant designations are made shall not apply to *pro se* Registry Participants. As set forth in Pretrial Order # 72, the Special Master is granted the authority to create an individualized process for any *pro se* Registry Participant who contacts LMI at zanclaimants@lmiweb.com with his/her name, the name of the Zantac user (if different), and (if applicable) LMI number or docket number.

of a new Anticipated Defendant causes there to no longer be any basis for federal jurisdiction, the Registry Participant may also modify his/her Certified Federal Participant designation. Likewise, if any modification causes the Registry Participant to no longer allege any Designated Cancer, a Certified Federal Participant may withdraw his/her Certified Federal Participant designation; if the modification causes the Registry Participant to now allege a Designated Cancer, he/she may elect to become a Certified Federal Participant. Any modification made pursuant to this paragraph must be made within 45 days of the receipt of the late-arriving record, regardless of when the Registry Participant entered the Registry.

7. Tolling Calculation. Pretrial Order # 74 recognized that there are an increasing number of *pro se* Registry Participants, who need to determine whether to remain in the Registry with its tolling or to opt-out and exit the Registry. The Court therefore takes this opportunity to inform all Registry Participants that the Plaintiffs and the Brand Defendants have agreed how the tolling provision in Pretrial Order # 15 applies, as follows: While a Registry Participant is (or was) in the Registry, all statutes of limitations applicable to his or her claims continue (or continued) to run. However, if any applicable statute of limitations that was tolled under Pretrial Order # 15 would have expired while the Registry Participant is (or was) in the Registry, then (under Pretrial Order # 15) that statute of limitations does not expire (or did not expire) until 90 days after exit from the Registry. Under this Order, this 90-day period is now changed to 60 days for Registry Participants exited from the Registry on or after July 1, 2022, who allege a Designated Cancer and do not become a Certified Federal Participant.

8. In light of these changes, and to avoid any confusion by Registry Participants, the impact on the deadlines set forth in Pretrial Order # 72 are set forth below, together with new deadlines:

- a. May 15, 2022. Generally, medical records, pharmacy records, loyalty records and/or purchase receipts were required to be ordered by May 15, 2022, for the reasons and with the exceptions set forth in paragraph 5 of Pretrial Order # 72. This date, having passed, is not modified by this Order.
 - b. June 15, 2022. Counsel have an obligation to promptly update questions 27 and 28 of the CPF upon notice of a Registry Participant's death, but in particular, a special obligation to ensure that this information is accurate and complete upon this date. (See paragraph 9 of Pretrial Order # 72.) This date remains unchanged.
 - c. June 30, 2022. Registry Participants alleging non-designated injuries (injuries other than the five Designated Cancers) must file a Short Form Complaint by this date if they intend to pursue their injuries/claims in this MDL. (See paragraph 12 of Pretrial Order # 72.) This date remains unchanged.
 - d. July 31, 2022. Registry Participants alleging a Designated Cancer must elect by this date whether to become Certified Federal Participants, with the benefits and obligations extending thereto. Anticipated Defendant elections, where applicable, become final. This is the new date set by this Order, modifying the original June 30, 2022, deadline set in paragraphs 3 and 5 of Pretrial Order # 72.
 - e. Counsel are also reminded that they must notify LMI within 14 days of any change in representation status of any Registry Participant and are encouraged to ensure that LMI has accurate contact information if such a change will cause the individual to become *pro se*. (See Pretrial Order #'s 72 and 74.)
9. Scope of Records Collection. At the outset of this MDL, the parties agreed that identifying potential claimants and their alleged injuries as quickly as possible was important given the anticipated variety of claims being asserted and the breadth of alleged injuries anticipated. The

parties therefore created a process that mandated that claimants elect to enter the Registry, and complete their CPF, within weeks of retention. The parties further created a process for the joint collection of certain medical records, recognizing the importance of this information to ensuring the accuracy of the information provided in the CPF. However, as it became clear that many of the claimants alleged injuries that would not be pursued by Plaintiffs' Leadership Counsel, the parties deferred such records collections in most instances as a cost-savings measure until Plaintiffs' Leadership Counsel had completed their assessment.

10. In January 2022, Plaintiffs' Leadership Counsel identified the five Designated Cancers that they seek to pursue in this MDL (from over 100 injuries alleged in the Registry), and the bellwether selection process is likewise limited to these five Designated Cancers. In Pretrial Order # 72, this Court began the process of determining whether any additional injuries should be addressed in the MDL. While any active (non-deficient and not exited) Registry Participant may utilize Lexitas to obtain medical records, cost-sharing for Lexitas's services is limited at present to those alleging a Designated Cancer. Also, a Registry Participant may not seek to utilize cost-sharing for any costs that come due after exit from the Registry.

11. CPF Data Access. Pursuant to Pretrial Order #'s 53 and 55, Plaintiffs' Co-Lead Counsel were granted the authority to access individual CPFs, but, as a temporary measure, each Defendant was permitted access only to the CPF of current and former Registry Participants who mapped to that Defendant or listed that Defendant as an Anticipated Defendant. At this point in the MDL, balancing the needs of the litigation as well as concerns with ensuring the security of the Registry data, and at the recommendation of the Plaintiffs, the Brand Defendants, and the Special Master, the Court now orders that up to two attorneys for each of the four Brand Defendants, at their option, shall be given access to all CPFs in the Registry. All other Defendants participating in Pretrial Order # 15 shall continue to have access to the CPFs of Registry

Participants who map to that Defendant or who list that Defendant as an Anticipated Defendant. The parties are reminded that CPFs are protected information under Pretrial Order #'s 26 and 45.


12. For numerous reasons, no Defendant has been permitted to download (or have LMI export) information from the Registry beyond certain limited fields of data for those CPFs that map to that Defendant. Nothing in this Order modifies that restriction. Defendants remain able to request aggregated data reports, and individual Defendants may continue to request customized aggregated data reports at their own cost. Special Master Dodge shall continue to be copied on any such request.

13. Proof of Use/ Proof of Injury Records Access. In creating the Registry, the parties determined that identifying which Registry Participants had documentation of their alleged use of the products at issue and their respective alleged injuries would be beneficial. However, given the short time period between the initial allegations regarding the product and the creation of the MDL, it was anticipated that there would be many individuals investigating potential claims beyond those Registry Participants. The Retailer Defendants anticipated the challenges of having one-off records requests submitted, versus a consolidated and streamlined process for reviewing these records requests. Likewise, the parties determined that it would be mutually beneficial to collect certain limited medical records designed to identify use and injury records, which the parties would then have joint access to through the Registry.

14. The Court now orders that the Special Master, in consultation with Registry Coordinating Counsel, shall work with LMI to provide access to all records collected and provided by Lexitas and the Retailer Defendants, as well as any records uploaded by the Registry Participant or his/her counsel. Access to these records shall mirror the access to the individual Registry Participant's CPF.

15. Data Analytics. The Court and the parties have made use of data analytics throughout the MDL, as has been noted during many of this Court's case management conferences. On July 30, 2022, certain CPF data of Certified Federal Participants will be finalized; the remaining data will become final 45 days after this Court's *Daubert* order(s) are entered. In parallel with this data true-up, the bellwether selection process is moving forward. It is anticipated that Registry Coordinating Counsel and Bellwether Coordinating Counsel⁴ will have an increased interest in data analytics to understand the contours of the MDL as the data finalization progresses. The Special Master shall work with LMI to determine whether additional analytics tools may be provided to Registry Coordinating Counsel and Bellwether Coordinating Counsel. If requested to do so by Registry Coordinating Counsel or Bellwether Coordinating Counsel, the Special Master may implement such data analytics tools on behalf of and without further order of this Court.

DONE AND ORDERED in Chambers, West Palm Beach, Florida, this 29th day of June, 2022.


ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

⁴ Adam Pulaski, Esq. and Andrew Bayman, Esq.