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

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THIS DOCUMENT RELATES TO: ALL CASES

PRETRIAL ORDER # 50
Third Census Implementation Order: Generic Manufacturer Production of Product Related Information

This Order applies only to Generic Manufacturer Defendants now or subsequently named and served in the Master Personal Injury Complaint, Consumer Class Action Complaint, or Third Party Class Action Complaint pending in MDL No. 2924.[1]

I. THE CENSUS REGISTRY

In light of the number of complaints likely to be filed in or transferred to MDL No. 2924, as well as the complexity and burden on both sides of filing unique complaints due to the anticipated large number of claimants who may bring claims related to the issues for which the Judicial Panel on Multidistrict Litigation created MDL No. 2924, the Parties and the Special Master developed a unique Census Registry process for the joint investigation of individual claims.

One complexity of this MDL is that Zantac/ranitidine has been manufactured by dozens of Defendants over the years: as brand and generic medicines, in prescription and over-the-counter formulations, in various forms (injectables, capsules, syrup, tablets), and in varying dosages. With

[1] This Order does not apply to Generic Manufacturers not named or previously dropped from the Master Personal Injury Complaint, Consumer Class Action Complaint, or Third-Party Class Action Complaint, but named only in one or more Short Form Complaints.

respect to Generic Manufacturers, Plaintiffs' Co-Lead Counsel indicated that they were using publicly available Abbreviated New Drug Applications ("ANDA") to determine which generic companies manufactured or marketed Zantac/ranitidine and thus could be named in filed cases, until discovery could proceed and retained counsel could narrow their allegations. (The Court entered the Core Discovery Agreement for Generic Manufacturers as Pretrial Order # 34, which sets forth certain categories of documents being provided by those Defendants.)

To expedite this process, this Order sets forth the obligations of the Generic Manufacturers to provide certain product identifying information to the Registry extracted from documents they produce in the litigation. Providing this information as data fields may accelerate the product identification process by many months compared to the traditional litigation process. But equally important, this process permits the Registry vendor, Litigation Management, Inc. ("LMI"), to use data analytics to compare the data submitted in Census Plus Forms to the information provided by each Generic Defendant.

The goal of this process is to help rule out certain Generic Defendants as manufacturers of the product(s) a particular claimant claims to have used, and as possible Defendants in any future complaint that claimant may choose to file, saving substantial time, effort, and costs for all parties. Through this process, the Generic Manufacturers will be eliminated as potential Defendants for any claimant who alleges in a Census Plus Form only branded-product use. Similarly, a Generic Manufacturer will also be eliminated as a potential Defendant for any claimant who alleges formulations that it did not manufacture or who alleges use during a time period during which the manufacturer was not marketing the product in question; thus, for example, an injectable-only manufacturer will be eliminated for all claimants who allege only capsule use.

As the litigation progresses, the Registry will continue to incorporate multiple additional data sets to inform the Census process. Those sources may include: (i) updated or supplemental Census Plus Form information; (ii) medical and pharmacy records; (iii) information provided by brand Zantac manufacturers about their products; (iv) information provided by Generic Manufacturers about their products; and (v) dispensing information maintained by the retailers/pharmacies. This information will allow for an additional subsequent round of narrowing of claims and Defendants that may focus upon information like National Drug Codes ("NDC"), distribution channels, and other more granular inquiries.

When the Registry closes, the parties should have a clearer joint understanding about product identification and alleged injury, together with the available supporting documentation for each potential claimant. This process recognizes it is in the common interest of all parties to have an accurate understanding of which Defendants could be named as to each Filed Plaintiff (or might be as to each Unfiled Claimant), and which Defendants could not, on a timely basis.

This Order addresses Generic Manufacturer production of product-related information for the Registry. This Order was jointly submitted by the parties, through Coordinating Counsel, with the consent of each of the Liaison Counsel, as well as Plaintiffs' Co-Lead Counsel.

II. PRODUCTION OF PRODUCT INFORMATION BY GENERIC DEFENDANTS

A. Phase One

1. On or before October 15, 2020, each Generic Manufacturer as referenced and defined in the introductory paragraph above will identify to Plaintiffs' Co-Lead Counsel the following information:

   i. Each ANDA number under which it commercialized a finished ranitidine drug product in the United States;

   ii. If a Defendant did not itself hold an ANDA for a finished ranitidine drug product, but instead acquired product from an ANDA holder for

repackaging or distribution, the identity of the ANDA holder and the ANDA number under which such product was manufactured;

iii. The dosage of each finished ranitidine drug product commercialized in the United States, by ANDA;

iv. The form (tablet, capsule, syrup, or injection) of finished ranitidine drug product commercialized in the United States, by ANDA;

v. Whether the finished ranitidine drug product commercialized in the United States was a prescription or over the counter drug product, by ANDA; and

vi. Any other special circumstances that define limits on distribution or sales of ranitidine finished drug product in the United States for a particular Generic Manufacturer, if known. This information may be supplemented based on additional investigation and analysis.

2. Each Generic Manufacturer will provide the information in section II.A.1 in a letter signed by counsel of record ("Phase One Letter") or Affidavit signed by a corporate representative of the Defendant and delivered via email to Plaintiffs' Co-Lead Counsel and the Special Master. If so specified by LMI, the information will also be provided in a format that facilitates application to the Registry.

3. The information provided in the Phase One Letter or Affidavit will be the best available as of the date each Generic Manufacturer makes the disclosure. Each Generic Manufacturer has an ongoing obligation and right to timely update or supplement the information disclosed in its Phase One Letter or Affidavit to the extent new or additional information becomes available.

B. <u>Phase Two</u>

1. On or before December 1, 2020, each Generic Manufacturer as referenced and defined in the introductory paragraph above, will identify, to the extent it is able and subject to sections II.B.2 and II.B.4 of this Order, to Plaintiffs' Co-Lead Counsel the following information:

i. Each NDC under which it commercialized a finished ranitidine drug product in the United States;

ii. Any geographic or commercial limitations on finished ranitidine drug products distributed in the United States, by NDC;

iii. The dates, by NDC, the Generic Manufacturer started and stopped selling, distributing or manufacturing each ranitidine drug product in the United States; and

iv. Any other special circumstances that define limits on distribution or sales of ranitidine finished drug product in the United States for a particular Generic Manufacturer that was unknown at the time Phase One information was due.

2. The information provided by each Generic Manufacturer in section II.B.1 is limited to NDCs representing finished ranitidine drug products sold or distributed to retailers or distributors presently named in and served or previously dropped from the Master Personal Injury Complaint, Consumer Class Action Complaint, or the Third-Party Payer Class Action, to the extent a Generic Manufacturer is aware of limits on the retailers or distributors to whom the product was sold or distributed.

3. Each Generic Manufacturer will provide the information in section II.B.1 in a letter signed by counsel of record ("Phase Two Letter") or Affidavit signed by a corporate representative of the Defendant and delivered via email to Plaintiffs' Co-Lead Counsel and the Special Master. If so specified by LMI, the information will also be provided in a form that facilitates application to the Registry.

4. The information provided in the Phase Two Letter or Affidavit will be the best available as of the date each Generic Manufacturer makes the disclosure. Each Generic Manufacturer has an ongoing obligation and right to timely update or supplement the information disclosed in its Phase Two Letter or Affidavit to the extent new or additional information becomes available.

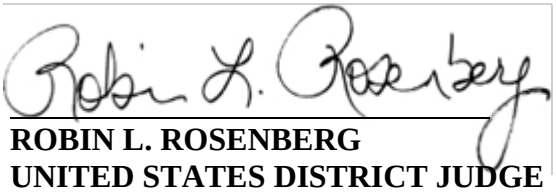
5. It is understood that Plaintiffs' Counsel reserves the right to seek an Affidavit from a Defendant requesting removal or dismissal under Pretrial Order # 52 supporting the request, and that Plaintiff's Counsel may, but will not be obligated to, remove or dismiss that Defendant under Pretrial Order # 52 if the Defendant is unable or unwilling to provide such an Affidavit.

III. DELAYS AND DISPUTES

A. While this Order sets forth the deadlines by which Phase One and Phase Two productions should be completed for each Generic Manufacturer, in the interest of permitting and facilitating early and ongoing analysis of the Registry data, the Court encourages Generic Manufacturers to provide the information outlined herein as soon as practicable.

B. If a Generic Manufacturer anticipates undue delay in its ability to timely produce its Phase One or Phase Two Letter or Affidavits, it shall notify the Plaintiffs' Co-Leads and the Special Master so that an expeditious conferral can occur. If the Plaintiffs' Co-Lead Counsel believe that any Generic Manufacturer has not exercised good faith in meeting its obligations under this Order, they shall notify the Generic Manufacturer, then meet and confer, and seek the participation of the Special Master as necessary. If the matter is not resolved, the Plaintiffs may request a determination by the Court that the Generic Manufacturer has not made a good faith effort to comply with this Order and seek an order compelling compliance and/or requesting appropriate relief.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 9th day of October, 2020.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE