

**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 # 53  
Fifth Census Implementation Order:  
Access to Census Plus Forms and Aggregated Data**

Under the deadlines set forth in various prior Pretrial Orders, including Pretrial Order #'s 15, 23, 38, and 42, the initial tranche of Filed Plaintiffs and Unfiled Claimants submitted Census Plus Forms (CPFs) to the Census vendor, Litigation Management, Inc. (LMI), on or before September 30, 2020. As a result, it is now appropriate for the Court to address the parties' respective access to CPFs and to reports generated by LMI concerning the data extracted from CPFs.

As stated in Pretrial Order # 15, the Census was created to enable "the parties and the Court to have a robust and timely understanding of the scope and size of the litigation" and "to facilitate early case management decisions." One of the core purposes of the CPF is to provide the Court and the parties critical information about the claims that have been filed, or that might be filed after further investigation, in this MDL, including what ranitidine product(s) an individual asserts he or she used, during what years, and for what purposes; where the individual allegedly purchased the ranitidine product(s); the type of injury the individual claims; whether the individual has documents reflecting the asserted use and/or injury; and other information that would permit the

census records collection vendor, Lexitas, to obtain such documents. This information is especially important in this MDL, where the product at issue was on the market for almost forty years, in both prescription and over-the-counter versions and in various different formulations and doses, and was manufactured or sold by dozens of different manufacturers (including branded and generic), retailers, and distributors. Among other things, the CPFs should allow the Court and the parties to determine in an efficient manner which products and injuries are at issue, which Defendants could have manufactured or sold the product(s) allegedly used by each individual who submitted a CPF, and which individuals have medical/pharmacy records or other documents that reflect their alleged use and injury.

The original Pretrial Order on Procedures for Implementing Census, Pretrial Order #15, contemplated that Plaintiffs' Co-Lead Counsel and the Defendants would have access to the CPFs and aggregated data extracted from the CPFs in an orderly fashion and with appropriate controls. The Court now provides guidelines for such access. No party shall have access to either the CPFs or the aggregated data outside of the process set forth in this Order. Nothing in this Order shall be interpreted to limit the application of Pretrial Order #'s 15, 23, 38, or 42, to restrict the ability of a Filed Plaintiff or his/her counsel to access or update his/her own census data and accompanying records at any time, or to restrict a Filed Plaintiff's counsel from authorizing other plaintiff's counsel to have access to that Filed Plaintiff's data/records.

#### **I. AGGREGATED DATA EXTRACTED FROM CPFs**

The Court and the parties have a keen interest in reports of aggregated data based on information LMI can extract from CPFs. This data analytics feature is a major benefit of the Census process. "Aggregated data" refers to data and information extracted from CPFs that does not identify any particular individual who submitted a CPF—in other words, anonymized data that

does not contain personal identifying information. As a simple example, LMI can generate a report of how many CPFs allege use of prescription ranitidine versus over-the-counter ranitidine and, within those two categories, what is the distribution of dates of alleged use. The parties, through their appointed Lead or Liaison Counsel, should have reasonable access to this type of aggregated data to assist them in their overall conduct of the litigation.

For Plaintiffs, only Plaintiffs' Co-Lead Counsel may request that LMI generate reports of aggregated data. For Defendants, Defendants' Co-Lead Counsel and Defense Liaison Counsel only may request that LMI generate reports of aggregated data; any Defendant that seeks such reports may make its request through the Co-Lead or Liaison Counsel appointed for the defense group with which it is associated. The Special Master, Co-Lead Counsel for Plaintiffs, and Co-Lead Counsel for Defendants, in consultation with LMI, will establish a process for LMI to provide such reports and will inform Defense Liaison Counsel of the process. The Special Master shall be copied on any party's request for aggregated data but, to protect the work product of counsel, no other party shall be informed of such a request. The Special Master shall ensure that the volume and scope of requests from either side is reasonable.

The parties may request reports of aggregated data beginning the day after entry of this Order.

## **II. FILED PLAINTIFF CPFs**

A Filed Plaintiff who submits a CPF, and that Filed Plaintiff's counsel, have access to the Plaintiff's own CPF. No Filed Plaintiff or Filed Plaintiff's counsel (other than Plaintiffs' Co-Lead Counsel) may access the CPF submitted by any other individual or counsel, absent authorization delivered to LMI by the Filed Plaintiff or his/her counsel. Access to these CPFs will be available

to an individual Plaintiff, his/her counsel, and Plaintiffs' Co-Lead Counsel the day after entry of this Order.

Any Defendant named in a filed action shall have the right to access the CPF (and any amendments thereto) submitted by the Plaintiff(s) in that action, for as long as that Defendant remains a party in the action. Within seven (7) days of the entry of this Order, LMI shall provide a list to Defense Coordinating Counsel of all Filed Plaintiffs who have submitted a CPF as of that date, along with each Plaintiff's unique LMI identification number. Defendants may request access to the CPFs for each case in which they are named as Defendants, using the LMI identification number from the LMI list. LMI is directed and has agreed to make access available to the named Defendants within seven (7) days of such request.

The parties anticipate that there will continue to be additional Filed Plaintiff CPFs submitted and that some Filed Plaintiffs will be filing amended Short Form Complaints pursuant to Pretrial Order # 52, which may impact the composition of named Defendants. As such, LMI shall provide, by agreement, an updated Filed Plaintiff CPF list on the 15<sup>th</sup> of each month and shall make newly-filed CPFs available to requesting Defendants within seven (7) days of a Defendant's request.

If any dispute arises regarding the status or access of a party, Adam Pulaski (on behalf of Plaintiffs' Co-Lead Counsel) and Joe Petrosinelli (as Defense Coordinating Counsel), or their delegates, shall meet and confer to resolve the matter, and may request the assistance of the Special Master. The Special Master may extend any deadline in this section in her discretion.

### **III. UNFILED CLAIMANT/REGISTRY CPFs**

An Unfiled Claimant who submits a CPF, and that claimant's counsel, have access to the claimant's own CPF. No claimant or claimant's counsel (other than Plaintiffs' Co-Lead Counsel)

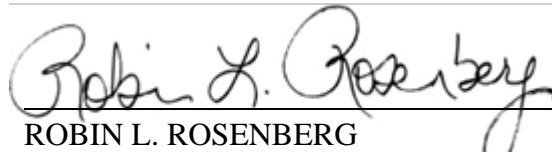
may access the CPF submitted by any other individual or counsel, absent authorization delivered to LMI by the Unfiled Claimant or his/her counsel.

The Court understands that a substantial number of CPFs from Unfiled Claimants have been submitted. For that reason, the parties have requested, and the Court grants, additional time to meet and confer about the process and timing for access to these CPFs. The parties shall promptly consult with the Special Master on this subject, and the Court may enter a subsequent Pretrial Order to address this issue.

#### **IV. CONFIDENTIALITY OF CPFs**

A CPF is considered “protected health information” as defined in Pretrial Order # 26 and 45 C.F.R. § 160.103 and shall be treated as Confidential Information and subject to the provisions relating to confidentiality set forth in Pretrial Order # 26.

**DONE and ORDERED** in Chambers, West Palm Beach, Florida, this 21st day of October, 2020.



ROBIN L. ROSENBERG  
UNITED STATES DISTRICT JUDGE