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 E. REINHART

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ORDER GRANTING THE GENERIC DEFENDANTS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION, GRANTING THE STORE-BRAND RETAILER DEFENDANTS' MOTION TO DISMISS OR STRIKE CONSOLIDATED MEDICAL MONITORING CLASS ACTION COMPLAINT AND CONSOLIDATED AMENDED CONSUMER ECONOMIC LOSS CLASS ACTION COMPLAINT, AND DENYING AS MOOT THE SPECIALLY-APPEARING NON-U.S. GENERIC MANUFACTURER DEFENDANTS' RENEWED MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION

This matter is before the Court on the Generic Defendants' ("Generic Manufacturer Defendants") Rule 12 Motion to Dismiss on the Ground of Preemption [DE 3105], the Store-Brand Retailer Defendants' ("Store-Brand Defendants") Motion to Dismiss or Strike Consolidated Medical Monitoring Class Action Complaint and Consolidated Amended Consumer Economic Loss Class Action Complaint [DE 3113], and the Specially-Appearing Non-U.S. Generic Manufacturer Defendants' ("Specially-Appearing Defendants") Renewed Motion to Dismiss for Lack of Personal Jurisdiction [DE 3108]. The Court held Hearings on the Generic Manufacturer and Store-Brand Defendants' Motions on June 4 and 7, 2021.[1] The Court has carefully considered the Motions, the Responses [DE 3326, 3329, 3409], the Replies [DE 3407, 3422, 3505], the Plaintiffs' Supplemental Filing [DE 3525], the arguments that the parties made during the Hearings, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Generic Manufacturer Defendants' Rule 12 Motion to Dismiss is **GRANTED**, the

[1] The Court also held a Hearing on other motions to dismiss pending in this litigation on June 3, 2021. The Court cites to arguments from all three Hearings in this Order.

Store-Brand Defendants' Motion to Dismiss or Strike is **GRANTED**, and the Specially-Appearing Defendants' Renewed Motion to Dismiss is **DENIED AS MOOT**. The Plaintiffs' claims against the Generic Manufacturer and Store-Brand Defendants are **DISMISSED WITHOUT LEAVE TO AMEND**.

I. Factual Background[2]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980s, first by prescription and later as an over-the-counter ("OTC") medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. AMPIC ¶ 240. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 239. Zantac was a blockbuster—the first prescription drug in history to reach $1 billion in sales. *Id.* ¶ 240.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an OTC form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 243. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 245.

[2] A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor.") (quotation marks omitted). Plaintiffs have set forth their factual allegations in three "master" complaints: the Amended Master Personal Injury Complaint ("AMPIC"); the Consolidated Amended Consumer Economic Loss Class Action Complaint ("ELC"); and the Consolidated Medical Monitoring Class Action Complaint ("MMC") (collectively, the "Master Complaints"). DE 2759, 2835, 2832-1. Unless otherwise noted, all citations will be made to the redacted versions of the Master Complaints.

The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 249-50, 253-55. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 260-62.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 348, 359, 365, 367. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 398-404. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 275, 279. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶ 302.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 322. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 323. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 333. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Five months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 338.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district

litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, approximately 1,400 plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the Southern District of Florida. In addition, this Court has created a Census Registry where tens of thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

The Plaintiffs filed their first Master Complaints on June 22, 2020. DE 887, 888, 889. In those Master Complaints, the Plaintiffs contended that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. DE 887 ¶¶ 1, 6, 19. They alleged that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. The Plaintiffs pursued federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* DE 889.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 36, the Court set a schedule for the filing and briefing of the first round of motions to dismiss under Rule 12 directed to the Master Complaints. DE 1346. The various Defendants filed motions to dismiss. The Court issued rulings on those motions on December 31, 2020, January 8, 2021, and February 23, 2021. *See* DE 2512, 2513, 2515, 2516, 2532, 2840.

Following an amendment to Pretrial Order # 36, the Plaintiffs filed the AMPIC on February 8, 2021. DE 2759. After the Court granted a two-week extension of time [DE 2720], the Plaintiffs filed the MMC [DE 2832-1] and the ELC [DE 2835] on February 22, 2021. In Pretrial Order # 61, the Court set a schedule for the filing and briefing of the second round of motions to dismiss under

Rule 12 directed to the Master Complaints. DE 2968. The Motions addressed herein were filed pursuant to that schedule.

III. The Master Complaints

A. The Amended Master Personal Injury Complaint

All individuals who filed a Short Form Complaint adopt the AMPIC. AMPIC at 2.[3] The Plaintiffs allege that they developed cancers from taking Defendants' ranitidine products. *Id.* at 1. The AMPIC "sets forth allegations of fact and law common to the personal-injury claims" within the MDL. *Id.* at 1-2. Each Plaintiff seeks compensatory damages, punitive damages, restitution, and all other available remedies. *Id.* at 1-2.

The Defendants "are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine." *Id.* ¶ 21. They are categorized into four groups: (1) Brand Manufacturer Defendants; (2) Generic Manufacturer Defendants; (3) Distributor Defendants; and (4) Retailer Defendants. Within each category, the AMPIC combines distinct corporate entities, including parents, subsidiaries, and affiliates, into single named Defendants.[4]

The AMPIC contains 17 counts and numerous state-specific sub-counts: Strict Products Liability—Failure to Warn Through Warnings and Precautions (Count I, 46 sub-counts); Negligence—Failure to Warn Through Warnings and Precautions (Count II, 48 sub-counts); Strict Products Liability—Failure to Warn Through Proper Expiration Dates (Count III, 46 sub-counts); Negligence—Failure to Warn Through Proper Expiration Dates (Count IV, 48 sub-counts); Failure to Warn Through the FDA (Count V, 15 sub-counts); Strict Products Liability—Design Defect Due to Warnings and Precautions (Count VI, 46 sub-counts); Strict Products Liability—Design

[3] Unless noted otherwise, all page number references herein are to the page numbers generated by CM/ECF in the header of each document.

[4] For example, Defendant "Sanofi" refers to five entities: Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Sanofi SA, Patheon Manufacturing Services LLC, and Chattem, Inc. AMPIC ¶¶ 33-39.

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