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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

How Cos. Can Prepare For Heartburn Drug Cancer Claims

By **Michael Tanenbaum and Kelly Belnick** (February 12, 2020, 3:48 PM EST)

Michael Tanenbaum

Kelly Belnick

Ranitidine medications, including the Zantac brand, may produce a component that plaintiffs counsel allege causes a myriad of cancers. Coordination and consolidation of the claims emerging against the generic and branded form manufacturers is supported by all parties.

This early juncture is an ideal time for considering the likely scale and ramifications of a ranitidine multidistrict litigation. Proactive determinations regarding effective legal strategies can limit corporate exposure and risk; offering decision makers an opportunity to respond from a position of strength.

On Nov. 1, 2019, the U.S. Food and Drug Administration issued a statement advising that "low levels" of N-nitrosodimenthylamine, or NDMA, were detected in ranitidine medications. Prior to the FDA statement, ranitidine medications were among the most commonly prescribed in the United States; in 2017, over 16 million prescriptions were filled.[1]

Following the FDA statement and a wave of recalls, numerous actions were filed in federal and state courts alleging that use of the medication causes cancer. Overnight, a massive media campaign emerged alerting anyone who took ranitidine medications to potential claims against its manufacturers.

On Jan. 30, 2020, the Judicial Panel on Multidistrict Litigation heard arguments on the application to centralize these actions under MDL 2924. There did not appear to be any disagreement among the panel and counsel for both plaintiffs and defendants about the need for a coordinated proceeding.

The only disagreement was related to where the coordinated proceeding should be venued. There appeared to be consensus among plaintiffs counsel seeking coordination that the Southern District of Florida was the appropriate location for the MDL. Arguments in favor included the efficient manner in which the Southern District of Florida handles cases (it has the second fastest docket in the country) and the claim that the Southeast might be the "center of gravity" for plaintiffs.

Defendants advocated for consolidation in the Southern District of New York or New Jersey, noting that many of the judges in those districts have expertise handling complex scientific issues and case management of large MDL dockets. The corporate defendants largely share a nexus to those states, with

many of the already-named pharmaceutical manufacturers headquartered along the Northeast Corridor in New York, New Jersey, Connecticut and Pennsylvania.

The New York metropolitan area will likely be the epicenter for the many years of discovery that will inevitably be sought, and is home to many of the witnesses and documents both parties will wish to access.[2]

Plaintiffs counsel asserted that this litigation is "likely to be the largest MDL in recent history," and "could be larger than the transvaginal mesh litigation."[3] It was argued that this litigation could trigger the biggest medical monitoring class in history. Although the JPML order will only address the ranitidine actions venued in federal courts, state courts will likely also coordinate cases, employing mechanisms at their disposal for consolidating within their respective borders.

Despite the spate of filings and serious injuries alleged, the science regarding NDMA's carcinogenic effect in humans is questionable. There are no reports of NDMA causing cancer in humans.[4]

When rats, mice, hamsters and other animals ate food, drank water or breathed air containing lower levels of NDMA for periods of more than several weeks, liver cancer and lung cancer as well as noncancerous liver damage occurred.[5] NDMA is classified by the International Agency for Research on Cancer as a probable human carcinogen (Group 2A).

Current attorney advertising encourages ranitidine users with an array of cancers, or any cancer, to seek legal advice. Indeed, the personal injury actions already filed against the drug manufacturers involve claims of stomach, colorectal, liver and blood cancers. The lack of signature causation is indicative of the uncertain science upon which plaintiffs are basing their claims.

Although the connection between Ranitidine and cancer is tenuous, at best, the risk of thousands of plaintiffs claiming injury is real. The In re Valsartan litigation, where NDMA exposure is also alleged to have caused a number of injuries, is instructive.

In 2017, 9 million valsartan prescriptions were filled, compared to 16 million for ranitidine. Ranitidine was initially approved by the FDA in 1983, and valsartan approved in 1996. Only certain lots of valsartan were found to contain impurities.[6] Conversely, NDMA was detected in all tested samples of ranitidine from every manufacturer.

Unlike valsartan, ranitidine was also available over the counter until its recent recall. Although the underlying mechanisms of NDMA exposure differ, valsartan plaintiffs claim it was an impurity in the manufacturing process, whereas ranitidine plaintiffs claim it is an inherent defect in the drug's molecular structure, since the detected quantity of NDMA was comparable in all forms tested.

Even if the sheer annual volume of ranitidine prescriptions alone were not enough to drive a mass tort, the availability of private equity and litigation funding to plaintiffs firms is now a powerful driver of mass torts and class actions. The availability of private funding for mass tort law firms provides a cash infusion for far-reaching advertising campaigns and the capital often necessary for the intake of thousands of clients.

The content of these ads is often overreaching, including questions such as, "Have you or a loved one been diagnosed with cancer after using ranitidine or other heartburn medicines for several months?" Considering the number of individuals who could answer this question "yes," and the frequent airing

and posting of these advertisements, it is likely that meritless claims could inundate court dockets.

The time is ripe for companies who might be drawn into ranitidine claims to consider the likely trajectory of the litigation, and strategic pathways for handling it. Reflecting on lessons learned from other large-scale MDLs provides an opportunity for early implementation of cost-effective strategies and technologies to manage, communicate and ultimately efficiently resolve — should resolution be an appropriate strategic choice — this possible behemoth in its nascent stages.

The course of any MDL mass tort action is largely dependent on venue and the transferee judge. There are strategic approaches available that could, at a minimum, narrow the issues and injuries to be litigated. One approach is to aggressively deal with plaintiffs experts at the outset of the litigation.

History demonstrates that litigation supported only by junk science withers away once the court permits the science to be challenged. For example, on Jan. 13, 2020, following a four-day Daubert hearing, U.S. District Judge Richard Seeborg, overseeing the multidistrict litigation over Viagra in the Northern District of California, excluded the plaintiffs' general causation experts, finding that no qualified person, other than those involved in the litigation, concluded that Viagra and Cialis cause melanoma.

Pressing science issues earlier in a litigation, especially where there is no signature injury, creates the opportunity to put an early end to, or at least a limit on, the viable claims, and avoid the flood of meritless ones generated by attorney advertising. Courts are demonstrating a willingness to assess science early.

For example, U.S. District Judge Freda L. Wolfson, who presides over the Johnson & Johnson talcum powder litigation in the District of New Jersey, ordered and held a science day, three months after the JPML coordinated the proceedings. This created a nonadversarial forum for counsel to educate the court on the litigation's scientific and medical issues. More recently, in response to the parties' in limine Daubert motions, Judge Wolfson held a seven-day Daubert hearing, to inform her decision on whether the expert opinions were sufficiently reliable to be admissible.[7]

An oft-overlooked tool in complex mass tort litigation is the appointment of an expert panel under Federal Rule of Civil Procedure 706. Perhaps the most well-known use of this tool was by Chief Judge Sam C. Pointer, Jr., in the silicone gel breast implant litigation. The panel was appointed when pretrial proceedings in the MDL had concluded, and Judge Pointer began remanding cases.

The judge's instructions to the panel were designed to assist the experts in reviewing the scientific literature, producing a written report and providing videotaped testimony for federal and state breast implant trials nationwide. In a 1999 interview with the Federal Judicial Center, Judge Pointer remarked that "the report appeared to have considerable impact on the dynamics of settlement negotiations."[8]

Proactive determinations of scientific evidence admissibility help eliminate meritless claims and generate an early milestone for defendants to evaluate litigation risk. Early trials, without the benefit of such rulings, may include scientific theories that are not fully developed, providing an incomplete assessment of the potential strength of expert testimony.[9]

Another option for assessing the litigation trajectory, when early exits are not available, are bellwether trials. In the context of multidistrict litigation, bellwether trials can accelerate the settlement process without binding the parties. Bellwethers — if properly chosen, which is rare when the parties choose — may highlight the strengths and weaknesses of a case within a trial setting, establishing a framework

where resolution may meaningfully be evaluated.

This mechanism was recently utilized in the transvaginal mesh litigation, in both coordinated state proceedings and the MDL court where, as of June 2018, the total number of filed actions (pending, settled and closed) across all defendants exceeded 100,000.

Complex tort litigation (like the ranitidine actions) confronts in-house and defense counsel with the challenge of not only determining strategy and defending the litigation but managing internal and external business priorities, costs and attendant reporting requirements. Proactive litigation management enables counsel to handle these responsibilities nimbly and quickly — and to stay one step ahead of the litigation.

One way to keep ahead of the litigation is early designation of both litigation and resolution counsel. The two work collaboratively on parallel tracks, implementing an integrated, overarching litigation strategy, and each plays an essential and distinct role in maximizing favorable outcomes in mass tort litigation.

Top-notch trial attorneys are engaged by the defense team to immerse themselves in trial strategy and execution, developing experts, debunking theories of liability and preparing the company story. In tandem, companies benefit from dedicated and experienced resolution counsel who focus on modeling scenarios leading to favorable forms of resolution when confronted with protracted mass tort litigation.

When seeking counsel, the importance of methods and modes of communication is key to managing mass tort legal teams. Utilizing platforms that facilitate communication among legal teams allows in-house, national and local counsel to communicate seamlessly.

Information collaboration is enabled in a secure space where real-time data is made available. From this data, strategies may be developed, assessed and refined throughout the lifetime of any matter. These capabilities are critical to mass tort litigation management.

Communication platforms instituted at the inception of litigation, and refined throughout the life of the lawsuit, permit clients to determine what data related to hundreds or thousands of claimants will be tracked. This data may include information about the nature of liability claims, the extent of damage claims, liens, key documents, procedural status, upcoming events or settlements, to name but a few core data fields. Beyond litigation management, companies have instant access to data for reporting, analysis and disclosure and to assist in setting reserves when necessary.

Equally essential to litigation management is document review, specifically medical records review, which is at the heart of a pharmaceutical mass torts. Traditional approaches to this task are generally slow, costly and inefficient when a defendant is confronted with tens of thousands of claims — let alone hundreds of thousands.

A single plaintiff alleging cancer will likely have over 1,000 pages of medical records associated with his or her diagnosis, treatment and general medical history. Conservatively, an MDL involving 10,000 plaintiffs would confront a defendant and its counsel with tens of millions of pages of documents, most likely electronic, to review.

Confronted with voluminous records, key defenses built on patterns and trends buried within a mass of documents, and documentation of alternate causes for an injury, can be easily overlooked — or, at a

minimum, hard to find. A sophisticated legal team handling the analysis of documents utilizing technology enhanced with machine learning (alternatively known as artificial intelligence) offers a party an avenue of discovery only recently available to the legal profession.

Utilizing sophisticated and evolving technological tools to analyze documents provides early insight concerning core theories and issues that highly skilled lawyers can use to build litigation-wide defenses and defenses to individual claims. Technology, combined with attorneys skilled in its use and application to mass torts, provides parties with cost effective analytical tools not available even five years ago.

With the ranitidine actions still in their infancy, now is the time for companies who might be swept into the litigation to retain experienced mass tort counsel, with sophisticated technological capabilities, to shape the arc of the litigation and produce the best possible outcome. Without such measures, plaintiffs counsel, who utilize their own technologies to develop and share information, have a significant tactical advantage.

Michael A. Tanenbaum is chair of and Kelly A. Belnick is an associate at Tanenbaum Keale LLP.

[1] See ClinCalc DrugStats Database, free U.S. outpatient drug usage statistics, at https://clincalc.com/DrugStats.

[2] To a lesser extent, plaintiffs also advocated for the Central District of California due to the Ninth Circuit's experience and recent decisions regarding innovator liability, which will be a claim in the ranitidine actions.

[3] Robert C. Hilliard of Hilliard Martinez Gonzalez LLP informed the JPML that to date, 14,000 potential plaintiffs have contacted his Corpus Christi, Texas, office alone, 4,000 of whom, he stated, "have cancer caused by NDMA."

[4] U.S. Dept. of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, Toxicology Profile for n-Nitrosodimenthylamine CAS#: 62-75-9. Atlanta, GA 1989.

[5] Id.

[6] It is theorized that certain active pharmaceutical ingredient manufacturers utilized a process that resulted in NDMA contamination.

[7] As of Jan. 14, the decision was still pending.

[8] Laural L. Hooper et al., Fed. Judicial Ctr., Neutral Science Panels: Two Examples of Court-Appointed Experts in the Breast Implants Product Liability litigation (2001).

[9] Barbara J. Rothstein et. al., A Model Mass Tort: The PPA Experience, 54 Drake L. Rev. 621, 624 (2006).