What starts the avalanche? Earlier triggers for life sciences mass torts in the era of big data and social media

Litigation Alert

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By: Saher Valiani | Matt Holian | Jill Marinoff*

Advertising for pharmaceutical and medical device mass torts has become so pervasive in the media that it is hard to go longer than one commercial break – or more than five minutes on Facebook – without seeing one. With nearly 200 multi-district litigations (MDLs) currently pending, more than 20 percent of which concern product liability claims involving medical devices or pharmaceuticals, mass tort litigation in the life sciences industry shows no signs of slowing down.[1]

In the past, pharmaceutical and medical device product liability litigations typically commenced following major regulatory action by the FDA, such as a label change or a product withdrawal – in other words, only after FDA determined there was a safety concern associated with a medication or medical device – and substantial coverage of that determination in traditional media such as television and print. However, the emergence of new technology and data sources has fundamentally flipped that sequence. Now, with the increasing accessibility of real-world data, social media, and post-marketing adverse event reporting, litigation frequently precedes – and even precipitates – regulatory scrutiny. On top of that, advertising through social media has made it easier for plaintiffs' lawyers to find potential plaintiffs and aggregate their claims into litigations that become mass torts before FDA

can evaluate all the available evidence. Consequently, the bar for safety issues to lead to claims that ultimately result in mass tort litigation has never been lower.

This article explores the impact of big data and social media on the commencement of mass tort litigation by (1) providing background regarding the proliferation of new sources of information and advertising relating to safety issues; (2) analyzing how that trend has hastened the commencement of mass tort litigation; and (3) identifying some of the ways in which the earlier trigger for mass tort litigation has impacted the course of those litigations.

1. The explosion of big data and social media regarding safety issues

In the past decade or so, a number of developments have increased the availability of safety data relating to medications and medical devices. In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA), which expanded safety information in a number of ways:

- First, FDAAA amended the Federal Food, Drug, and Cosmetic Act (FDCA) to require the FDA to "conduct regular, bi-weekly screening of the Adverse Event Reporting System [AERS] database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter."[2] In doing so, FDAAA increased public access to FAERS data and to FDA's investigatory process from the outset, before further scientific study has been conducted to verify any need for concern.
- Second, FDAAA facilitated the creation of databases equipped with analytical tools to monitor further the safety of regulated products. Section 801 of FDAAA implemented new registration requirements for clinical trials through ClinicalTrials.gov, which provides public access to information on clinical study topics, participants, and progress.[3] Additionally, Section 901 of FDAAA led to the creation of the Sentinel System database and the Active Postmarket Risk Identification and Analysis System (ARIA).[4] The Sentinel System pools pre-existing electronic healthcare data, from which the FDA can assess a potential product-related risk using ARIA.
- Finally, FDAAA encouraged consumer reporting of adverse events by requiring manufacturers to print language on advertisements for prescription medications directing consumers to www.fda.gov/medwatch or a toll-free number.[5] From these platforms, patients are prompted to enter details about their adverse events, such as information about the event they experienced, their health histories, and their current prescriptions.

These developments have occurred in parallel with a dramatic growth in real-world data, such as electronic health records and disease registries, as well as real-world evidence, such as ongoing clinical trials and observational studies, from which researchers may identify potential safety concerns.[6] Congress further encouraged the development of health-related big data through the passage of the 21st Century Cures Act, which created a framework for the FDA to use large patient databases to evaluate safety issues.[7]

During the same period, the use of social media has expanded dramatically as well. In a 2012 survey, Pew Research Center determined that 72 percent of internet users searched for health-related information online, and at least 8 percent reported posting a personal health experience or question online within the last 12 months.[8] Because FDA has stated that manufacturers should report adverse events described on social media as spontaneous adverse events in the AERS database,[9] social media content can trigger potential signals when FDA periodically analyzes AERS data and has spurred research into new channels for adverse event monitoring.[10]

Social media also has created a platform for plaintiffs' law firms to identify potential plaintiffs more easily than ever before. Unlike the days when advertising typically involved expensive, relatively inefficiently focused use of television or print media, today mass tort advertisers can pay a nominal fee to sprinkle ads in the Facebook news feed of individuals within a targeted demographic most likely to have been exposed to a particular treatment.[11] Plaintiffs' firms also utilize Facebook and Twitter to identify online networks of potential claimants and promote awareness of purported product side effects through strategic posting.[12] Thus, at the same time there is more information available to identify potential safety issues, there also are easier ways for plaintiffs' lawyers to identify potential plaintiffs who may wish to assert claims.

2. The impact of big data and social media on the commencement of mass tort litigation

The growth in these various sources of information has had a substantial impact on how quickly safety issues result in litigation. Before 2007, it was far more common for FDA to carefully analyze a safety issue and for litigation to follow only after the agency determined a label change or a product withdrawal was warranted, which

typically resulted in substantial traditional media coverage. In the past 12 years, however, safety concerns raised based on big data sources or in social media have prompted litigation *before* FDA has acted – and, in some instances, the adverse event reports that result from litigation have themselves prompted regulatory scrutiny. As a result, the avalanche of claims that characterize mass tort litigations are getting started based on weaker evidence and before the agency entrusted with protecting the public health has had a chance to weigh in on safety issues.

While individual litigations in which we have been involved hint at the shifting influence of big data on mass tort initiation, establishing that our experience reflects a broader trend required a more systematic analysis. To demonstrate the impact of big data and social media on the commencement of mass tort litigations, we performed a comprehensive analysis of the triggers for pharmaceutical product liability MDLs over the past 20 years, as part of a broader project to assemble a database that benchmarks key MDL practices and metrics.

Based on that analysis, we determined that for pharmaceutical product liability MDLs initiated between 2000 and 2007, a very small proportion (only 13 percent) arose before or independently of a major regulatory event, such as a label change or product withdrawal. During that time period, Congress had not enacted FDAAA, big data and social media were on the horizon, and the vast majority of the relevant MDLs were initiated following FDA's scientific analysis of a potential safety issue.

In contrast, between 2008 and 2018, the vast majority (approximately 72 percent) of pharmaceutical product liability MDLs were initiated before or independently of a major regulatory event relating to the subject matter of the lawsuits. In other words, in the modern era of big data and social media, plaintiffs no longer wait for FDA to act before filing pharmaceutical product liability actions. Instead, many MDL consolidation motions from this period reference spontaneous adverse event reports, preliminary study findings, and other real-world evidence as the basis for litigation, typically preceding review by FDA.

3. Staying ahead of the avalanche: how earlier triggers for mass torts affect litigation

This fundamental shift in how mass tort litigations are starting has several significant implications for life sciences companies facing product liability claims.

First, the risk of mass tort litigation is higher than ever. Plaintiffs no longer wait for FDA to determine that there is a safety problem before they file claims, and they have access to more sources of information to generate data in support of their lawsuits. In fact, in some instances, they can use adverse event reports from social media or their own lawsuits to attract regulatory scrutiny.

Second, the evidence that forms the basis for product liability claims is typically of a lower caliber than in the past. For example, real world data such as observational studies typically suffer from significant limitations, particularly when compared to randomized clinical trials.[17] And FDA has made clear for years that adverse event reports are anecdotal and do not establish a causal relationship between a reported event and a product.[18] Unfortunately for life sciences companies, that often means plaintiffs' lawyers get ahead of the science, rather than following it, about which some courts have expressed concern.[19]

Third, because plaintiffs are getting ahead of regulators, life sciences companies often are communicating with regulators about safety issues as litigation is ongoing, which can have a significant impact on the scope of discovery, causation defenses, and preemption-based defenses.

The rise of big data and the pervasiveness of social media are here to stay. Life sciences companies facing the possibility of product liability litigation should recognize the earlier triggers for mass tort litigation and be prepared to mitigate these risks.

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**Jill Marinoff, case manager of DLA Piper's Litigation group, is based in Los Angeles.*

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[1] US Judicial Panel on Multidistrict Litigation, Pending MDLs by MDL Number as of October 15, 2019, available at https://www.jpml.uscourts.gov/pending-mdls-0.

[2] FDAAA of 2007, Pub. L. No. 110-85, Tit. XI, § 921.

[3] *Id.* § 801.
[4] *Id.* § 901.
[5] *Id.* § 906 (mandating the inclusion of language on prescription medication advertisements stating, "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.").
[6] *See generally, eg*, Rachel E. Sherman et al., *Real-World Evidence – What Is It and What Can It Tell Us?*, N. ENGL. J. MED. 2016;375(23):2293-2297; Robert M. Califf et al., *Transforming Evidence Generation to Support Health and Health Care Decisions*, N. ENGL. J. MED. 2016;375(24):2395-2400.
[7] 21st Century Cures Act, Pub. L. No. 114-255, Tit. III, § 3022 (2016).
[8] Susannah Fox and Maeve Duggan, *Peer-to-Peer Health Care*, PEW RESEARCH CENTER, January 15, 2013, available at https://www.pewresearch.org/internet/2013/01/15/peer-to-peer-health-care/.
[9] *See* Hesha J. Duggirala, *FDA Perspectives on Social Media for Postmarket Safety Monitoring*, November 15, 2018, available at https://www.fda.gov/media/122897/download at 7 ("For purposes of reporting by companies to FDA, [adverse event] reports from social media should be treated as spontaneous reports.").
[10] *See* Abeed Sarker, et al., *Utilizing Social Media Data for Pharmacovigilance: A Review*, J. BIOMEDICAL INFORMATICS 2015;54:202,212, at 203-204.
[11] *See* Doni Bloomfield and Shanon Pettypiece, *How Law Firms Use Facebook and Other Data to Track Down Medical Victims*, May 27, 2015, available at https://www.bloomberg.com/news/articles/2015-05-27/how-law-firms-use-facebook-and-other-data-to-track-down-medical-victims.
[12] *See* U.S. Chamber Institute for Legal Reform, *Bad For Your Health: Lawsuit Advertising Implications and Solutions*, October 2017, at 17-18, available at https://www.instituteforlegalreform.com/uploads/sites/1/TLA_Advertising-Paper-WEB.pdf
[13] *See* Defendants Pfizer's and Lilly's Motion to Exclude Plaintiffs' Experts' Opinions, *In re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*, Case No. 3:16-md-02691 (Dkt. 840) (Jan. 11, 2019), at 1 (citing Li et al., JAMA INTERN. MED. 2014;174(6):964-70).
[14] Lawyers at DLA Piper, including the authors, are counsel to Pfizer in the litigation.
[15] *See id.* at 1-2, 15-23.
[16] *See id.* at 26-28.
[17] *See* Reference Manual on Scientific Evidence: Third Edition (2011), 217-219, available at https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf.
[18] *See* Questions and Answers on FDA's Adverse Event Reporting System (FAERS), available at https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers. ("[T]here is no certainty that the reported event (adverse event or medication error) was due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event.").
[19] *See, e.g., Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.").

AUTHORS

Saher Valiani
Associate
Boston | T: +1 617 406 6000
saher.valiani@dlapiper.com

Matt Holian
Partner
Boston | T: +1 617 406 6000
matt.holian@dlapiper.com