

# 3 LESSONS FOR MEDICAL DEVICE CASES



## The recent Essure litigation imparted significant takeaways for drug and device attorneys to apply in other cases.

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Products liability cases are some of the most complex and difficult cases to litigate. But they are also some of the most important cases you can take on—they often provide the chance to fight against corporate greed, punish gross and outrageous negligence on a national or even international scale, and help scores of innocent people recover from a wrong that never should have happened to them.

Such was the case with the Essure litigation, when thousands of women nationwide were injured by the permanent birth control device designed to take the place of tubal ligation. The first lawsuits were filed in 2014, alleging that significant adverse events<sup>1</sup> associated with the device's use were not properly reported or disclosed, even though the manufacturer knew or should have known that Essure was defective. Plaintiffs claimed that the manufacturer and its domestic and foreign subsidiaries<sup>2</sup> concealed and misrepresented these adverse events until the FDA imposed unprecedented restrictions on the sale and distribution of Essure—including a black-box warning that was added in 2016—that impacted sales to such a degree that it was forced off the market in 2018.<sup>3</sup>

This litigation, while ultimately resolved successfully,<sup>4</sup> posed significant challenges related to personal jurisdiction, e-discovery, relationships between state and federal courts, and the defense of federal preemption. We learned valuable but hard lessons about the changing landscape of litigating such cases on a national scale that can help guide plaintiff attorneys in other complex drug and device cases.



### Intake screening should not gloss over social media.

Client intake is the foundation on which the case is built, so this process should be thorough and include criteria for liability and causation. The screening process should include detailed client interviews, obtaining proof that the device at issue was implanted, reviewing all relevant medical records supporting the injury (and those that don't), background checks,<sup>5</sup> and investigating your clients' social media presence.<sup>6</sup>

In the Essure cases, information about the adverse effects of the device was widely shared on social media, especially Facebook, so our intake screening included a social media review. We reviewed the potential client's social media to look for any posts or online activity that could impact the merits of their case. Most important, we checked to see if the potential client had any prior notice of Essure's problems before they reached out to us, as this could affect the statute of limitations for their claims.

Further, we had to ensure the preservation of our clients' relevant social media information. While some plaintiffs didn't use social media at all, others used it as a form of journaling and means of support following their injuries. As such, we developed routine preservation letters and protocols for social media data. This included advising clients not to post about the case, instructions not to delete or alter existing posts, and instructions on how to download social media to send to us for discovery. While this added time and expense to the beginning

“work-up” phase of our cases, litigating issues related to lost data is also time consuming and expensive. So it is prudent to do this work on the front end and avoid any surprises.



### Research jurisdiction carefully, and have a backup plan.

When choosing where to file, consider jurisdiction issues, which can be one of the most fraught aspects of medical device litigation given the complexity of the companies involved and the geographic diversity of the plaintiffs.

In this litigation, there wasn't a strong push for multidistrict litigation from either side. Instead, cases were filed primarily in California and Missouri state courts and in the Eastern District of Pennsylvania. We also filed in state court in Indiana, eastern Kentucky, and Pennsylvania.

We filed hundreds of cases in state court in St. Louis, Mo. At that time, the law in St. Louis (which has since changed) presented a good joinder opportunity for multi-plaintiff lawsuits, which defeated federal diversity jurisdiction on removal and was economical for our clients. St. Louis was also the location of essential clinical trials, key witnesses, and the commercial release of Essure.

**The Bristol-Myers effect.** Despite all of these factors, however, a change in jurisprudence can turn your entire case upside down. After we filed cases in Missouri, the U.S. Supreme Court decided *Bristol-Myers Squibb Co. v. Superior Court of California*,<sup>7</sup> which,

at least on its face, had similar facts to the St. Louis Essure cases. Although Bristol-Myers was making \$1 billion annually in California on Plavix and had long-standing research facilities and operations in California, the Court held that these “minimum contacts” were insufficient to sustain personal jurisdiction, despite its substantial presence in California.<sup>8</sup>

The Missouri Essure litigation differed from *Bristol-Myers* because Missouri had significant transactions in the state “related to” the nonresident plaintiffs' claims. When Bayer brought its personal jurisdiction challenge in Missouri, we filed expert affidavits asserting that the clinical trials by Conceptus (the original manufacturer of Essure) in Missouri played a significant role in mischaracterizing the safety and effectiveness of the device for nonresident plaintiffs. The state court held that it could exercise personal jurisdiction, and this ruling survived Bayer's writ to the Missouri Supreme Court.<sup>9</sup>

Nevertheless, hundreds of cases filed in St. Louis that had been removed to federal court, but were pending motions to remand, were dismissed en masse as to nonresident claims.<sup>10</sup> Many states have different rules for refiling a case that has been dismissed for personal jurisdiction. For example, Kentucky's “saving statute” tolls the statute of limitations if the case is dismissed for lack of jurisdiction but only allows the plaintiff 90 days to refile in the proper court.<sup>11</sup> Alternatively, Indiana allows a plaintiff to refile their action if “the plaintiff fails in the action from any cause except negligence in the prosecution of the action” and allows the plaintiff up to three years from the dismissal of the action or “the last date an action could have been commenced under the statute of limitations governing the original action” to refile the case, whichever is later.<sup>12</sup>

**Refile when needed.** For every case, always hope for the best but prepare for the worst. After *Bristol-Myers*, it became necessary to think outside of previous assumptions about venue and location of cases and reassess where personal jurisdiction existed under this new case law to ensure our clients' claims could be heard.<sup>13</sup> After extensive jurisdictional research, we decided to refile (most) of the dismissed cases in Indianapolis and Pittsburgh. Bayer Corp. was incorporated in Indiana, and Indiana's saving statute, as previously discussed, allowed three years after the date of dismissal to refile many of our cases there.<sup>14</sup>

No filing is without its challenges, however, and the new venues certainly presented theirs. We filed in state court, but our Pennsylvania cases were removed to federal court in Pittsburgh based on federal question jurisdiction; specifically, that the state law claims were preempted. Fortunately, we were able to remand those cases by establishing that the complaints alleged "parallel claims" that did not conflict with nor were preempted by federal law; therefore, on the face of the complaint there was no federal question requiring removal.<sup>15</sup>

**Prepare for preemption.** Making parallel claims supported with citations against preemption in your complaints is necessary because preemption is a cornerstone of the defense attorney's playbook in drug and device cases.

To plead parallel claims and help set up arguments against preemption, explain that there is a presumption against federal preemption of state laws that operate in traditional state domains.<sup>16</sup> Also assert that claims for failure to warn are not preempted when based on a defendant's "violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device."<sup>17</sup> Finally, cite *Stengel v. Medtronic, Inc.*, in which the U.S. solicitor general explained that only

## Some plaintiffs used social media as a form of journaling and means of support following their injuries—so develop routine preservation letters and protocols for social media data.

device-specific federal requirements have preemptive force while "by contrast FDA's general manufacturing and labeling regulations do not have preemptive force."<sup>18</sup>

In the Essure litigation, Bayer's motion to dismiss based on federal preemption was denied.<sup>19</sup> Subsequent petitions for review on preemption grounds were also denied.<sup>20</sup>

**Personal jurisdiction and foreign defendants.** Even after dealing with preemption arguments, however, challenges to personal jurisdiction for both domestic and foreign defendants are another hurdle you must overcome.

Specifically, in the Essure cases, several significant defendants in the Bayer Group were not located in the United States—they were in France, Germany, and South America.<sup>21</sup> Each of these foreign defendants were integral to the design, manufacture, distribution, and oversight of Essure in America; yet,

Bayer still argued that American courts had no personal jurisdiction over these foreign entities.

Our briefs alleged and provided support for claims that Bayer used an international shell game of domestic and foreign subsidiaries to shield relevant discovery and evade collection of any judgment. For example, we alleged that certain foreign entities controlled the critical due diligence and safety activities of the domestic entities. We further alleged that there was a unity of interest in ownership between the defendants, so any individuality and separateness between them ceased. We argued that adherence to the fiction of a separate existence of certain defendants as any entity distinct from other certain defendants would permit an abuse of corporate privilege and promote injustice.

When faced with foreign entities, scour the internet and get jurisdictional discovery to learn the true relationships between the companies and their affiliates. Generally, the SEC's EDGAR system can provide very useful information on publicly traded corporations, while the Secretary of State websites where the corporate entity is based and permitted to do business may also provide some useful information.<sup>22</sup>

Further, courts should allow the parties to conduct jurisdictional discovery before ruling on a motion to dismiss for lack of personal jurisdiction. In Kentucky, for example, if a trial court rules on a motion to dismiss for lack of personal jurisdiction without conducting an evidentiary hearing on the matter, a nonmoving party "need only make a prima facie showing of jurisdiction."<sup>23</sup> Further, "the court should not grant the motion unless it appears the pleading party would not be entitled to relief under any set of facts which could be proved in support of his claim."<sup>24</sup>

While the boundaries of general personal jurisdiction are usually clearly demarcated for a U.S. corporation to its state of incorporation or its headquarters, this type of jurisdiction is murky for an international defendant that is not incorporated in or has no formal headquarters in the United States.<sup>25</sup> We argued that the Pennsylvania courts had general personal jurisdiction over the foreign defendants because Pittsburgh was the parent company's U.S. headquarters for years. We also argued the courts had specific personal jurisdiction because the foreign defendants had "purposefully availed" themselves of the privilege of conducting activities in the forum state, the plaintiffs' claims arose out of these contacts in the forum state, and exercising jurisdiction would not offend traditional notions of fair play and justice.<sup>26</sup>

Our arguments for specific personal jurisdiction emphasized the foreign defendants' control over U.S. operations.<sup>27</sup> We focused on the domestic "Baby Bayers" in the U.S., arguing that they were obviously designed to be expendable for the protection of the "Mama and Papa Bayers" in Germany. In 2018, the Bayer Group consisted of 420 companies located in 90 countries.<sup>28</sup> We reviewed multiple annual reports, which made the chain of command clear.

For instance, Bayer AG was described as the "parent company" of the Bayer Group that "—represented by its Board of Management—performs the principal management functions for the entire company."<sup>29</sup> The reports also defined Bayer AG's central, ultimate decision-making role for the rest of the Bayer Group: It acted as a strategic management holding company; defined the values, goals, and strategies of the Bayer Group; and was responsible for resource allocation and managerial appointments. Ultimately,

the Pennsylvania courts sided with the plaintiffs, and the cases proceeded onto substantive discovery.<sup>30</sup>



### Fighting burden objections is worth the burden.

Once cases are underway, defendants will do whatever they can to delay and draw out discovery disputes—typically by trying to avoid producing certain discovery and ESI. Challenge unsupported burden objections, because otherwise you may be missing critical information.

**File a motion to compel.** First, we filed motions to compel, based, in part, on Bayer's failure to produce a significant amount of responsive ESI. Bayer objected, claiming undue burden.<sup>31</sup> Based only on the size of the data (which Bayer asserted was 10 terabytes),<sup>32</sup> Bayer's ESI expert opined that it would take nearly \$50 million and approximately two years to complete a privilege review and produce the discovery.<sup>33</sup> The court overruled these objections, finding a "lack of convincing credible evidence presented by [Defendants] that production of clearly relevant information would place upon it a disproportionate burden."<sup>34</sup> Importantly, the court required Bayer to describe the ESI at issue, including what it is, how (in what form) it is kept, where it is, and how it can be accessed.<sup>35</sup>

**Request depositions and an evidentiary hearing.** Be cautious of boilerplate objections concerning burden. The responding party should substantiate their burden objections by making specific disclosures about the

data at issue, such as custodial sources, information about the systems and data sources, data volume, data types, and potentially privileged information. This information should be readily provided because a responding party has a duty to search for and identify sources of potentially relevant information and respond to discovery requests in good faith.

If a responding party withholds this basic information, then they aren't fulfilling their discovery obligations. Importantly, if a responding party attempts to circumvent these disclosures and demonstrate burden by an expert's unsupported assertions, the requesting party should consider moving to exclude the expert's testimony.

In the Essure litigation, many of the defendants' objections were vague and boilerplate. To clarify whether their objections were valid, we requested that the court order depositions of the parties' respective ESI experts and hold an evidentiary hearing.<sup>36</sup> Ultimately, the court entered an order overruling Bayer's burden objections.<sup>37</sup> Significantly, Bayer's expert was excluded on *Daubert* grounds because his opinions were based on hypothetical cost and burden assessments, and not the real data, facts, and orders of the case.<sup>38</sup>

**Consider a search protocol.** Finally, the vast quantities of data are often too large to comb through manually, so a search protocol may be needed. During our e-discovery battles over Bayer's burden objections, the court required Bayer to propose a search protocol using technology.<sup>39</sup> It also ordered "that the information provided by [Defendant] regarding electronically stored information be in sufficient detail for Plaintiffs and their consultants to determine whether [Defendant] is proposing an accurate comprehensive plan for Technology Assisted Review."<sup>40</sup>

The court's ruling here is significant

because it eliminated any unnecessary manual review and forced transparency and cooperation in the discovery process. A transparent search protocol, agreed on by the parties or ordered by the court, may be an effective e-discovery tool to contest burden objections and obtain relevant information.

Drug and device litigation is often challenging, but it is also fulfilling. It serves as a check on corporations to ensure that they are properly designing and testing these products to be safely used. And each litigation imparts lessons that plaintiff attorneys can build on and use for the next one—to ensure that corporate wrongdoers are held accountable. 



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**NOTES**

1. Some of the most prevalent injuries included irregular vaginal bleeding, abdominal pain, migration of the device outside the fallopian tubes, breakage of the device, ectopic pregnancies, and the need to undergo a hysterectomy to remove the device.
2. We filed cases against “Foreign Defendants,” including Bayer AG, Bayer Pharma AG, Conceptus SAS, and Bayer S.A. We also filed cases against “Domestic Defendants,” including Bayer Corporation, Bayer US LLC, Bayer Healthcare LLC, Bayer Essure Inc. (f/k/a Conceptus Inc.), and Bayer Healthcare Pharmaceuticals Inc.
3. See U.S. Food & Drug Admin., *Essure Permanent Birth Control*, Mar. 14, 2022, <https://tinyurl.com/yc29udza>.
4. Our cases were resolved during mediation. Bayer entered a \$1.6 billion settlement in

- August 2020 to resolve virtually all other claims. Christy Bieber, *Essure Lawsuit Update March 2023*, Forbes Advisor, Sept. 9, 2022, <https://tinyurl.com/mrysa9pv>.
5. Background checks can reveal a potential client’s criminal history, any bankruptcy proceedings, and any financial issues that may impact the merits of the case.
6. Some of the women injured by Essure came together on Facebook to create a group called “Essure Problems,” which helped expose Essure as a dangerous and defective device. Through the group, we discovered some of the key injuries, and this information helped to vet our clients and build up the allegations.
7. 137 S. Ct. 1773 (2017).
8. *Id.* at 1782. For more, see Andre M. Mura, *Staying on Track After Bristol-Myers*, Trial, Apr. 2019, at 18; Robert S. Peck, *Constricting Personal Jurisdiction*, Trial, Nov. 2017, at 26; Erwin Chemerinsky, *An Uphill Battle Over Jurisdiction*, Trial, Sept. 2017, at 58.
9. See Petition for Writ of Prohibition, *State ex rel. Bayer Corp. v. Mullen* (Mo. Nov. 1, 2017) (No. SC96765); Order Denying Writ of Prohibition, *State ex rel. Bayer Corp. v. Mullen* (Mo. Dec. 19, 2017) (No. SC96765).
10. See, e.g., *Moore v. Bayer Corp.*, 2018 WL 4144795 (E.D. Mo. Aug. 29, 2018).
11. Ky. Rev. Stat. §413.270; see *D. & J. Leasing, Inc. v. Hercules Galion Prods. Inc.*, 429 S.W.2d 854, 856 (Ky. Ct. App. 1968).
12. Ind. Code §34-11-8-1; see *McGill v. Ling*, 801 N.E.2d 678 (Ind. Ct. App. 2004); *Munoz v. Woroszylow*, 29 N.E.3d 164 (Ind. Ct. App. 2015).
13. Through various tactics, we avoided snap removals. For more info, please contact us.
14. See Ind. Code §34-11-8-1.
15. See, e.g., *Vazquez v. Bayer Corp.*, 2019 WL 3752894 (W.D. Pa. Feb. 11, 2019). On remand, the Bayer Group filed multiple motions in the Court of Common Pleas and in the Pennsylvania appellate courts, focusing again on personal jurisdiction and preemption.
16. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).
17. *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 776 (5th Cir. 2011).
18. U.S. Amicus Br. at 9, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013).
19. See *Vazquez v. Bayer Corp.*, 2019 WL 3753140, at \*2 (W.D. Pa. Feb. 11, 2019).
20. Federal case law holds that federal regulations do not “prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citing *Lohr*, 518 U.S. at 495) (emphasis added); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010). In addition, all the elements of a breach of federal requirements need not be included in state causes of action to be non-preempted “parallel” claims. See *Lohr*, 518 U.S. at 485; *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 447–48 (2005).
21. Service and notice for international defendants can be complicated. For more information on this issue, see HCCH, *Service Section*, <https://tinyurl.com/2dmfzkdv>.
22. For more, see Sophie Zavaglia, *Find the Hidden Ball*, Trial, Nov. 2021, at 26.
23. *Hinners v. Robey*, 336 S.W.3d 891, 895 (Ky. 2011).
24. *Pari-Mutuel Clerks’ Union of Ky. v. Ky. Jockey Club*, 551 S.W.2d 801, 803 (Ky. 1977) (emphasis added).
25. We found one U.S. Supreme Court case that indicated general personal jurisdiction could be exercised over an international defendant: *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437 (1952).
26. See *Bristol-Myers Squibb Co.*, 137 S. Ct. at 1785.
27. Similar arguments were made in *Hammons v. Ethicon, Inc.*, 240 A.3d 537, 556 (Pa. 2020) and *Vaughan v. Olympus Am. Inc.*, 208 A.3d 66, 72–73 (Pa. Super. 2019).
28. Bayer Group’s 2018 Annual Report is available at [https://www.bayer.com/sites/default/files/bayer\\_ar18\\_entire.pdf](https://www.bayer.com/sites/default/files/bayer_ar18_entire.pdf). The entire annual report was filed in the trial court with the plaintiffs-respondents’ papers opposing the foreign defendants’ preliminary objections.
29. *Id.*
30. *Vazquez v. Bayer Corp.*, No. 68 WM 2020 (Pa. Nov. 12, 2020).
31. Order, *Wolford v. Bayer Corp.* (Pa. Pike Cnty. Cir. Ct. Aug. 26, 2020) (No. 16-CI-00907).
32. *Id.*
33. *Id.*
34. Order, *Wolford v. Bayer Corp.* (Pa. Pike Cnty. Cir. Ct. Oct. 16, 2019) (No. 16-CI-00907).
35. *Id.*
36. Order, *Wolford v. Bayer Corp.* (Pa. Pike Cnty. Cir. Ct. Dec. 17, 2019) (No. 16-CI-00907).
37. Order, *Wolford v. Bayer Corp.* (Pa. Pike Cnty. Cir. Ct. Aug. 26, 2020) (No. 16-CI-00907).
38. See *id.*
39. Order, *Wolford v. Bayer Corp.* (Pa. Pike Cnty. Cir. Ct. Oct. 16, 2019) (No. 16-CI-00907).
40. Order, *Wolford v. Bayer Corp.* (Pa. Pike Cnty. Cir. Ct. Aug. 26, 2020) (No. 16-CI-00907).