"Impossibility Preemption" Remains Alive and Well in Missouri for Generic Drug Manufacturers

April 6, 2018 | Leigh Ann Massey

"Impossibility preemption" applies to bar tort claims where it is impossible for a party to comply with both state and federal law. In the recent opinion of Raskas v. Teva Pharms. USA, Inc., No. 4:17-CV-2261 RLW, 2018 U.S. Dist. LEXIS 3507 (E.D. Mo. January 8, 2018), the Eastern District of Missouri reaffirmed application of "impossibility preemption" to generic drug manufacturers on strict liability and negligent defective design and failure to warn claims.

The allegations in the Raskas v. Teva complaint provide the story of a young man, Ralph Raskas, who, after seeking treatment for nausea and vomiting, ingested the medication prescribed by his physician - generic metoclopramide - and allegedly developed pain and restlessness in his legs. After being diagnosed with "drug-induced acute akathisia," he complained of significant pain and eventually committed suicide after two prior attempts. His father filed a wrongful death action against Teva Pharmaceuticals, USA (Teva) and Actavis Elizabeth, LLC (Actavis) - manufacturers of the dispensed generic metoclopramide - alleging that the drug caused his son's neurological injuries and suicide. Plaintiff asserted claims for strict liability and negligent defective design and failure to warn, negligence in identifying risks associated with the drug, as well as what he contended was a failure to update the generic medication's labeling to conform to that of its brand name equivalent. Relying upon PLIVA, Inc. v. Mensing, 564 U.S. 608 (2011), and Mutual Pharm. Co. v. Bartlett, 570 U.S. 472 (2013), Teva and Actavis sought dismissal of all claims against them on federal preemption grounds.

The Raskas court began its analysis of the plaintiff's claims by reviewing the approval requirements of the Food and Drug Administration (FDA) for both brand name and generic drugs. To gain approval of brand name drugs, a manufacturer must submit a new-drug application (NDA) that includes clinical investigative reports and all relevant information to allow the agency to determine whether the drug is safe for use. On the other hand, approval of a generic drug typically requires only that the generic be "bioequivalent" to the branded medication. In fact, a generic may receive FDA approval without any in vivo studies, solely based on in vitro studies that study dissolution of the proposed generic. See 21 C.F.R. §§ 320.24(b)(5) and 320.22(d)(3).

Critically for the generic drug manufacturers in Raskas, 21 C.F.R. Part 314 prohibits generic drug manufacturers from 1) making any unilateral changes to a drug's label, and 2) deviating from the drug's approved formulation. See 21 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10), and 314.70(b)(2)(i). These federal regulatory restrictions are the basis for the "impossibility preemption" found in Raskas.

In rejecting the plaintiff's defective design claims, the court considered Brinkley v. Pfizer, Inc., 772 F.3d 1133 (8th Cir. 2014), in which metoclopramide design defect claims were specifically precluded due to preemption because the only way the manufacturer could avoid liability under Missouri law was by redesigning the product. If a generic drug manufacturer were required to redesign the product to comply with Missouri state law, it would be impossible to comply with federal law, which requires a generic drug's formulation to be bioequivalent to the branded medication and the generic's labeling to be identical to that of the brand name drug. This is the definition, and a descriptive example, of impossibility preemption, which provides that "[w]here state and federal law directly conflict, state law must give way." Mensing, 564 U.S. at 617.

Raskas's failure to warn claims were found to be similarly barred by impossibility preemption, because the warning labels on the generic metoclopramide manufactured by Teva and Actavis were required, under 21 C.F.R. Part 314, to be identical to those of the brand name medication Reglan®. If the failure to warn claims were allowed to proceed, generic drug manufacturers - in order to escape state tort liability - would be required to relabel their products to provide additional information or warnings, which is directly prohibited under federal regulations. The Missouri federal district court in Raskas determined it would be impossible for Teva and Actavis to comply with both state and federal law in this instance, so dismissal of the failure to warn claims against them was appropriate.

Although the plaintiff attempted to distinguish its claims from those presented in controlling legal precedent, the court ultimately concluded that impossibility preemption applied to each of the asserted negligence, strict liability, and wrongful death claims for failure to warn or defective design. The plaintiff was, however, granted leave to amend his complaint to adequately plead an alleged claim against Teva and Actavis for failure to update their labeling to conform to that of Reglan®, the brand name medication.

The Raskas opinion may be found here in its entirety.

Related Services: Pharmaceutical & Medical Device, Product Liability

Attorneys: Leigh Ann Massey

Breaking Up [Plaintiffs] Is [Not] Hard To Do

March 28, 2018 | Megan Sterchi Lammert

While Neil Sedaka may have convinced many that breaking up is hard to do, Judge Stephen N. Limbaugh, Jr. of the United States District Court for the Eastern District of Missouri ("EDMO") has made it clear that breaking up non-Missouri related Plaintiffs from a product liability case is certainly not hard to do in the post-Bristol-Myers Squibb Co. era.

On January 24, 2018, the EDMO added to the split in authority between Missouri and California, two forums favored by Plaintiffs, thereby testing the limits of Bristol-Myers Squibb Co. v. Super Ct. of Cal., 137 S. Ct. 1772 (2017) ("BMS"). In Nedra Dyson, et al., v. Bayer Corporation, et al., No. 4:17CV2584- SNLJ, (E.D. MO Jan. 24, 2018) ("Dyson"), Judge Limbaugh of the EDMO granted Defendants' Motion to Dismiss 92 non-Missouri related Plaintiffs in a product liability lawsuit based on a lack of personal jurisdiction,
finding that a Defendant’s clinical trials and marketing of a product in the state of Missouri does not establish personal jurisdiction for purposes of non-Missouri related Plaintiffs’ claims for that product. This is consistent with other recent EDMO decisions:

- Jordan v. Bayer Corp., No. 4:17cv865(CEJ), 2017 WL 3006993 (E.D. Mo. July 14, 2017);

The Dyson Defendants, who were also not citizens of Missouri, relied on BMS to argue that the EDMO lacked personal jurisdiction over the claims of 92 non-Missouri related Plaintiffs, and should be dismissed. The Defendants argued that dismissal of these Plaintiffs would provide complete diversity between the remaining Plaintiffs and Defendants and the amount in controversy would still exceed $75,000. This quickly became a fight between the parties, with one side trying to persuade the court to decide personal jurisdiction before subject matter jurisdiction and the other side arguing vice-versa. Ultimately, the court determined that personal jurisdiction could and should be decided prior to subject matter jurisdiction, because it provided the more straightforward analysis in light of BMS. Deciding subject matter jurisdiction would involve resolution of notoriously complex issues, reasoned the court.

Quick Recap On BMS: As a brief refresher, BMS involved both California and out of state Plaintiffs who sued in California state court based on alleged injuries caused by Defendant BMS’ drug. The United States Supreme Court, who took the case on a writ of certiorari, overturned the state court, applying “settled principles regarding specific jurisdiction,” finding that state court states fail to retain specific personal jurisdiction over non-resident Defendants for claims asserted by non-resident Plaintiffs that do not arise out of or relate to the Defendant’s contacts with the forum. The Court rejected Plaintiffs arguments for specific personal jurisdiction based on alleged marketing and promotion of the product and clinical trials held in the state of California in the RPM cases. The State Court would also not allow the resident Plaintiffs’ allegations to confer personal jurisdiction over the non-resident Plaintiffs claims. Therefore, the Supreme Court dismissed the claims of the non-resident Plaintiffs.

In Dyson, the non-Missouri related Plaintiffs conceded that the medical device at issue (Essure) was not implanted in Missouri. However, Plaintiffs argued that their allegations concerning Defendant Bayer’s connections with Missouri should support the court’s exercise of personal jurisdiction. Plaintiffs alleged that Bayer’s marketing strategy was developed in Missouri, which was only one of the eight states chosen to conduct pre-market clinical devices on the product (Essure), the original manufacture of the product’s conduct was in Missouri, the sponsoring of biased medical trials was in Missouri, and St. Louis, Missouri was the first city to commercially offer the Essure implant procedure.

Those arguments failed to persuade Judge Limbaugh, who ultimately found that the Dyson Plaintiffs failed to make a prima facie showing for personal jurisdiction and, as such, he denied their motion for jurisdictional discovery to support those arguments. Relying on BMS, Judge Limbaugh rejected Plaintiffs’ marketing campaign arguments, pointing out that the non-Missouri Plaintiffs not only failed to allege they viewed Essure advertising in Missouri, but also failed to allege they purchased, were prescribed or were injured by the product in Missouri. Thus, it was not relevant that Defendant first marketed Essure in Missouri. As for Plaintiffs’ argument regarding clinical trials in Missouri, Judge Limbaugh found such alleged conduct too attenuated to serve as a basis for specific personal jurisdiction over Defendants. In fact, the non-Missouri Plaintiffs failed to allege they even participated in a Missouri clinical study or that they reviewed and relied on the Missouri clinical studies in deciding to use the products.

In contrast to Dyson, Plaintiffs have tried to rely on the recent California case Dubose v. Bristol-Myers Squibb Co., No. 17-cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017) in support of specific personal jurisdiction over non-forum Defendants. Dubose, however, does not appear to employ the same analysis as BMS or its progeny.

In Dubose, a South Carolina resident Plaintiff sued AstraZeneca, Bristol-Myers Squibb, and McKesson in California federal court, alleging a defect in a prescription diabetes drug. The Dubose court relied upon Walden v. Fiore, 134 S.Ct. 1115 (2014), a 2014 U.S. Supreme Court decision that was in fact a pro-Defendant ruling intended to limit the states’ exercise of personal jurisdiction over non-resident Defendants. The Dubose Court reasoned that because Walden stressed that only the Defendants’ conduct could justify exercise of personal jurisdiction, any jurisdictional analysis should ignore Plaintiff’s residence or place of injury, and focus instead upon conduct that might “tether” the Defendant to the forum state. Ultimately, the Court relied on the Ninth Circuit’s preexisting “but for” test, holding that the pre-approval clinical trials were “part of an unbroken chain of events leading to Plaintiff’s alleged injury” and, therefore, specific jurisdiction existed because Plaintiff’s injuries “would not have occurred but for [Defendants] contacts with California.” Regardless, the Dubose Court ultimately transferred the case to South Carolina, the Plaintiff’s home state.

The judge in Dubose also decided Cortina v. Bristol-Myers Squibb Co., No. 17-cv-00247-JST, 2017 U.S. Dist. LEXIS 100437 (N.D. Cal. June 27, 2017) on the same theories, denying a motion to dismiss but transferring the case to New York, where the Plaintiff was a resident and was prescribed the drug at issue. However, in a footnote, the Court noted that, “[it] does not mean to suggest that even a de minimis level of clinical trial activity would satisfy the requirements of specific jurisdiction.”

While the holdings for the Dubose and Cortina case appear to have relied upon attenuated claims of specific personal jurisdiction, in the EDMO, Judge Limbaugh concluded that the Dyson non-Missouri Plaintiffs’ claims were too attenuated from Missouri to prove specific, case linked personal jurisdiction. For example, the Dubose Plaintiff did not allege that she participated in any of the Defendants’ California clinical trials, but the Dubose court relied on others, not a party to the case, who participated in them. If specific personal jurisdiction exists in every state where a clinical trial occurred, then any Plaintiff who used the subject drug conceivably could sue the manufacturer in any of those states—no matter where the manufacturer is based and no matter where the Plaintiff resides or used the drug. It would be illogical for courts to adopt this rationale, calling that “specific” personal jurisdiction, and would be contrary to the United States Supreme Court’s recent pronouncements on personal jurisdiction, including in BMS.

Other recent cases have held similarly to the EDMO in Dyson, dismissing non-resident Plaintiffs due to a lack of both general and personal jurisdiction. For example, the Southern District of Illinois has been granting dismissal of non-Illinois Plaintiffs and denying remand in pharmaceutical drug, product liability cases. Specifically, those cases held that misjoined, multi-Plaintiff complaints no longer preclude removal, that there was no general personal jurisdiction pursuant to Daimler AG v. Bauman, 134 S. Ct. 756 (2014) and no specific personal jurisdiction existed pursuant to BMS, and/or found that conducting in-state clinical trials is not sufficient contact to support specific personal jurisdiction in suits by non-residents. See: Braun v. Janssen Research & Development, LLC, 2017 WL 4224034 (S.D. Ill. Sept. 22, 2017); Pirtle v. Janssen Research & Development, LLC, 2017 WL 4224036 (S.D. Ill. Sept. 22, 2017); Roland v. Janssen Research &
Bringing this back to Dyson, Judge Limbaugh's decision re-affirms that it really is not that hard to break up Missouri Plaintiffs from non-Missouri Plaintiffs in a product liability lawsuit where the non-Missouri Plaintiffs cannot truthfully allege that their claims arise out of a connection to the state of Missouri (and cannot solely rely on clinical trials occurring in Missouri). This is not to say that non-Missouri Plaintiffs will never find another forum and/or that their claims are foreclosed; rather, those Plaintiffs have a better chance of avoiding a bad break-up by bringing their claims in the forum out of which their claims allegedly arise.

Related Services: Healthcare, Pharmaceutical & Medical Device, Appellate, Personal Injury Defense and Product Liability

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Missouri Supreme Court May Be Signaling a Change in Analysis of Misjoinder of Claims in Multi-Plaintiff Product Liability Cases

October 19, 2017 | Angela Higgins

On October 13, 2017, the Missouri Supreme Court issued a preliminary writ of prohibition directed to Circuit Judge Rex Burlison of the Circuit Court for the City of St. Louis, temporarily staying the talcum case, Valerie Swann, et al. v. Johnson & Johnson, et al. The Supreme Court case number is SC96704. The plaintiffs, on behalf of the trial court, are to answer the writ petition by November 13, 2017.

Plaintiff Michael Blaes is one of 47 plaintiffs in the case, who contend that they or their decedents developed ovarian cancer following use of talcum powder. Johnson & Johnson alleges that Blaes’s decedent did not purchase or use talcum powder in the City of St. Louis. Blaes’s case was set for separate trial from those of the other plaintiffs, but Judge Burlison declined to formally sever his claim such that it could be reassigned and venue assessed. That decision is the subject of Johnson & Johnson’s petition for a writ of prohibition.

Missouri has long had a troubled history with venue analysis. As part of tort reform in 2005, the legislature made significant changes to the venue statute, designed to prevent forum shopping. The recent explosion in “litigation tourism” focused in the City of St. Louis has not been due to any change in, or deficiency of, the venue statute and the joinder rules, but in changes in the application of long-standing principles of venue and joinder.

Refusal to sever unrelated claims is at the core of the problem. Litigation tourism in St. Louis depends upon a single, anchor plaintiff who is a Missouri resident with a plausible jurisdictional claim and basis to claim venue in the City of St. Louis, with dozens of unrelated, out-of-state plaintiffs clinging to that anchor plaintiff’s case to justify pursuit of claims in Missouri against non-residents. The claims are misjoined and should be severed, but to date the Missouri Supreme Court has declined to find that a trial court’s refusal to sever misjoined claims warrants reversal on appeal unless the defendant can establish that the severance decision was prejudicial to the outcome (by establishing that the City of St. Louis is a biased venue). See Barron v. Abbott Labs., Inc., No. SC96151, 2017 Mo. LEXIS 403, at *6 (Sep. 12, 2017).

Severance has not always been this controversial, but reflects a change in the application of Missouri law and procedure in recent years. Rule 52.06 of the Missouri Rules of Civil Procedure is titled “Misdjoiner and nonjoinder of parties,” and provides that “Any claim against a party may be severed and proceeded with separately.” Misdjoinder of claims or parties requires severance of the claims. See State ex rel. Gulf Oil Corp. v. Weinstein, 379 S.W.2d 172, 174 (Mo. App. St. L. 1964).

Rule 52.05 identifies the only circumstances under which the claims of multiple plaintiffs may be properly joined in a single action:

All persons may join in one action as plaintiffs if they assert any right to relief jointly, severally, or in the alternative in respect of or arising out of the same transaction, occurrence or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action.

Mo. R. Civ. P. 52.05(a) (emphasis added). Both tests must be met for plaintiffs to be joined in a single action. Id.; State ex rel. Allen v. Barker, 581 S.W.2d 818, 826 (Mo. banc 1979). If those requirements are not met, the claims are misjoined and severance is required. Even if joinder is permitted, severance is still permissible in the trial court’s discretion, based upon factors related to fairness, economy, and prejudice. See Wilson v. Bob Wood & Associates, Inc., 633 S.W.2d 738, 743 (Mo. App. W.D. 1981).

Rule 52.05(a) is analogous to Fed. R. Civ. P. 20(a), which provides that parties may be properly joined only where claims by or against them arise out of the same transaction or occurrence or present common questions of law or fact. In State ex rel. Allen v. Barker, 581 S.W.2d 818, 826 (Mo.1979) the Missouri Supreme Court discussed the adoption of Rule 52.05(a), recognized that it was patterned after the federal rule, and applied federal cases to interpret it. Id. The federal rule has been extensively construed, and overwhelmingly find that the claims of multiple plaintiffs are misjoined when the only commonality amongst plaintiffs is that they allege damages resulting from using the same product. See, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig., MDL No. 1341, 1995 WL 428683, at *5-6 (E.D. Pa. July 15, 1995). In the bone screw litigation, the only plaintiffs who were allowed to remain joined in a single action were those who underwent surgery by the same doctor or group of doctors, at the same hospital, and who received the same or a similar device by the same manufacturer. Id. at *5. There is no reason in the rule why Missouri should be applying joinder principles in a manner so inconsistent with the federal courts.

Recent jurisprudence in the City of St. Louis and in the Eastern District Court of Appeals, in fact, is inconsistent with those courts’ own past precedent on misjoinder and severance. In Gulf Oil, plaintiffs had purchased fuel oil in unrelated transactions at different times. Id. at 174. These transactions did not constitute the “same transaction nor a series of transactions.” Id. at 175. Moreover, even though the plaintiffs all sustained fires, these occurred on different dates. Id. Accordingly, the plaintiffs’ losses did not constitute the same “occurrence.” Id.

The Gulf Oil court was keenly focused upon what is the “transaction” and what is the “occurrence” that is common to the plaintiffs. Because the issue is joinder of plaintiffs, it is a plaintiff-focused, not defendant-focused analysis. Recent jurisprudence on the eastern side of the state has shifted that focus to the notion that plaintiffs’ claims can arise out of the same transaction or occurrence when they derive from common conduct of the defendant, which has been expanded to include the design, marketing, and sale of the product.
the product. In reaching these decisions, the early trial court orders rely upon cases analyzing the proper joinder of defendants, which is, of course, a defendant-behavior-focused analysis.

Taken to the illogical extreme, the approach of focusing upon the defendants’ business practices and product design to establish joinder would allow any purchaser of a product to join with any single Missouri plaintiff and to pursue their claims in Missouri. It is simply untenable, and seems inevitable that, if the Missouri Supreme Court does not curtail this problem, the U.S. Supreme Court will. Allowing non-residents to sue non-residents for extraterritorial conduct and injuries is not constitutionally defensible.

Personal jurisdiction limitations “are a consequence of territorial limitations on the power of the respective States.” Hanson v. Denckla, 357 U.S. 235, 251 (1958); see also World-Wide Volkswagen Corp v. Woodson, 444 U.S. 286, 292 (1980) (minimum contacts requirement serves the dual functions of protecting defendant against the burden of litigation and ensuring states “do not reach out beyond the limits imposed on them by their status as coequal sovereigns in our federal system”).

There are hopeful signs – the Eastern District Court of Appeals just overturned the first talcum verdict against Johnson & Johnson for lack of personal jurisdiction. See Estate of Fox v. Johnson & Johnson, No. ED104580, 2017 Mo. App. LEXIS 1043 (Mo. App. E.D. Oct. 17, 2017). The dust has not yet settled on these issues, however.

Johnson & Johnson’s writ of prohibition takes a subtly different track from the issue argued in Barron. In its recent writ, Johnson & Johnson does not argue that Judge Burlson erred in denying the original motion to sever based upon misjoinder of the plaintiffs’ claims, but that, when the court ordered separate trial of each of the claims, that the claims of each plaintiff should have been formally severed such that venue (and presumably jurisdiction) would be independently assessed as to each of the severed claims.

Rule 66.02 provides:

The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues.

Rule 52.06 provides that “Any claim against a party may be severed and proceeded with separately.” Missouri law has been somewhat ambiguous as to the relationship between these rules, including whether “proceed[ing] separately” with a claim is the same as severing it.

The 3-judge concurring opinion in Barron, upon which Johnson & Johnson relies for its writ petition, suggested that, when the trial court determines that a plaintiff’s claims should be separately tried, it has effectively “severed” that plaintiff’s claims from the remaining plaintiff(s). Alternatively, where the trial court has determined that the claims should not be tried together, it would ordinarily have no basis to deny a subsequent motion to sever. Because Mo. Rev. Stat. § 508.012 (part of the 2005 tort reform) requires reassessment of venue when a plaintiff is either added to or removed from the petition, and mandates transfer if venue is improper, the trial court’s failure to formally sever a separately-tried claim deprives defendants of the benefit of the statute.

When there has been severance, the normal administrative process would involve the assignment of a new case number to the severed case and, normally, random judicial reassignment. Severance of claims permits the court to render separate judgments which will be deemed final for purposes of appeal. Engel Sheet Metal Equipment, Inc. v. Shewman, 301 S.W.2d 856, 859 (Mo. App. St. L. 1957). The claims, being independent, would be subject to independent venue and jurisdictional analysis, having been unchained from the Missouri anchor plaintiff.

It is interesting that the Supreme Court has issued a preliminary writ in the Blaes matter. Although an order for separate trials is not generally deemed to be equivalent to an order for severance, that general principle must be considered in the context of the venue statute, which does contemplate a reassessment of venue. A court may be required to order severance based upon misjoinder, and the Johnson & Johnson argument seems targeted squarely at overcoming the “lack of prejudice” finding in Barron – the prejudice is in the denial of the rights afforded under Mo. Rev. Stat. § 508.012. Additionally, where the court has discretion to sever based upon judicial economy, fairness, and prejudice, it still appears to be an abuse of discretion to order 47 separate trials but refuse to sever them into independent actions.

Johnson & Johnson’s writ petition may be the hook to pry loose severance orders in these multi-plaintiff cases. Ideally, however, the impropriety of joinder would be assessed at an earlier stage of the litigation, before decisions on trial management have been made. We are hopeful that recent developments in the talc cases indicates a shift away from recent practices in these multi-plaintiff cases.

Related Services: Pharmaceutical & Medical Device, Product Liability

Attorneys: Angela Higgins


August 7, 2017 | Leigh Ann Massey

In Redd v. DePuy Orthopaedics, Inc., the Eighth Circuit Court of Appeals has reminded litigators of the importance of ensuring expert witnesses perform a thorough review of a matter, including apparent alternative causal explanations, prior to issuing their opinions.

In 2008, plaintiff Redd underwent a total hip replacement, receiving an implant supplied by hip manufacturer DePuy Orthopaedics, Inc. At the time of her surgery, Redd suffered from a number of risk factors that placed her at a higher risk for failure of the implant as she took immunosuppressant drugs and was considered morbidly obese. Four years after her initial surgery, the implanted hip stem fractured. During the revision surgery to replace the hip stem, the doctors determined that the stem had not properly grown into the bone at the top of Redd’s hip, which was a known possibility given her risk factors. Two years after her revision, Redd again experienced a hip stem fracture. Plaintiff brought a federal diversity action against DePuy Orthopaedics, alleging negligence and strict liability claims based on product defect and failure to warn. DePuy moved for summary judgment and for exclusion of plaintiff’s expert testimony under Federal Rule of Evidence 702 and the analysis set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).
Plaintiff retained a professor of metallurgy and materials science, Dr. Shankar Sastry, to testify as to the cause of the fracture. In preparing his expert report, Dr. Sastry failed to review records related to the manufacturing process of the hip implant and disregarded consideration of biomechanical factors that could have resulted in failure of the prosthesis. Dr. Sastry concluded that it was the physical state of the implant’s metal that caused the fracture. He further concluded that any individual environmental or biomechanical factors would have been a secondary cause of the fracture.

In granting DePuy’s motion to exclude Dr. Sastry’s testimony, the US District Court for the Eastern District of Missouri concluded that Dr. Sastry lacked a scientific or factual basis to conclude that there was a manufacturing defect or to opine on causation, and that he failed to consider the necessary issues of the forces that were exerted on the implant as it was placed in Redd’s hip. Following exclusion of Dr. Sastry’s testimony, Redd lacked expert testimony on defect or causation and DePuy’s motion for summary judgment was granted.

On appeal, the Eighth Circuit reviewed the district court’s exclusion of Dr. Sastry’s testimony, the propriety of which is governed by Rule 702 and the Daubert standard. Plaintiff argued that the district court erred by requiring Dr. Sastry to exclude other potential causes of the fracture. The Eighth Circuit concluded that, while an expert is not required to rule out all possible causes of an injury, he or she nonetheless should adequately account for obvious alternative explanations. Dr. Sastry did not consider the obvious alternative explanation for the fracture—failure of the hip stem to grow into the patient’s upper hip bone and subsequent failure to properly distribute her weight—which was a known possibility at the time of Redd’s surgery given her risk factors. Because Dr. Sastry failed to consider the individual biomechanical forces placed on the prosthesis in issuing his report, the district court’s decision to exclude the causation testimony was affirmed.

The opinion may be found here.

For more on Missouri’s recent adoption of the expert witness standard set forth in Federal Rules of Evidence 702 and Daubert, see The Daubert Standard – Coming Soon to a Missouri Court Near You.

Related Services: Pharmaceutical & Medical Device, Product Liability

Attorneys: Leigh Ann Massey

FDA - Postmarket Management of Cybersecurity in Medical Devices

June 5, 2017 | Suzanne Billam

It seems almost impossible in today’s world to escape our dependence on technology. From the minute we wake-up in the morning, we access news reports on our tablets, keep track of our health with fitness trackers, receive and respond to e-mails on our mobile phones, and many of us rely upon interconnected medical devices, such as insulin pumps, to safely navigate through a typical day. But such convenience is not without risk.

Medical devices, like all interconnected technology, can be vulnerable to security breaches, which “may compromise the essential clinical performance of a device” and potentially impact patient safety. The Food and Drug Administration (“FDA”) thoroughly understands this benefit v. risk balance, and has issued a number of recommendations that address comprehensive cybersecurity over the lifecycle of medical device products. Most recently, on December 27, 2016, the FDA issued its final Guidance on Postmarket Management of Cybersecurity in Medical Devices. The recommendations apply to medical devices that use software, including programmable logic and software that is regulated as a medical device, including mobile medical apps. You can link to the full text of the Guidance here. This final Guidance closely resembles a draft of the document, issued for comment almost a year prior. For more details on our take of the draft Guidance, see our prior series “FDA Issues Draft Guidance Document for Postmarket Management of Cybersecurity in Medical Devices” posted in four parts here, here, here, and here. This Postmarket Guidance also follows the FDA’s Guidance on medical device premarket cybersecurity, issued in October 2014, discussed in more detail here.

The final Guidance outlines steps that medical device manufacturers and health care systems should take to monitor, identify, understand and address cybersecurity risks once medical devices and mobile medical devices have entered the marketplace. Yet, don’t allow the “guidance” nature of the document fool you into believing its recommendations are optional, as the FDA takes the position that manufacturers are required to ensure the safety and efficacy of their medical devices, and should they choose not to follow this guidance, the device vendor must have in place another similar cybersecurity strategy in order to avoid regulatory scrutiny.

From this Guidance emerges two predominant concepts: 1) the Guidance, like its predecessor draft and the 2014 Premarket Guidance, follows a risk-based approach, i.e., guiding manufacturers to identify, assess, and mitigate risks that emerge after the device has been introduced to market; and 2) medical device cybersecurity and cybersecurity risk management must be proactively addressed throughout the entire lifecycle of a product, and is a shared responsibility among stakeholders including health care facilities, patients, providers, and manufacturers of medical devices.[1] In other words, cybersecurity controls should be incorporated into the design, development and manufacture of a device. But after marketing and during patient use, the device should be continuously monitored, and cybersecurity concerns addressed.

As Suzanne B. Schwartz, the FDA’s associate director for science and strategic partnerships, stated in a blog post concurrent with the issuance of the Guidance itself, “[w]ith this guidance, we now have an outline of steps the FDA recommends manufacturers take to remain vigilant and continually address the cybersecurity risks of marketed medical devices[2].” This approach enables manufacturers to focus on continuous quality improvement, which is essential to ensuring the safety and effectiveness of medical devices at all stages in the device’s lifecycle.[3] Essential to the FDA’s recommendations is the belief that device manufacturers implement comprehensive cybersecurity risk management programs and documentation which emphasizes “addressing vulnerabilities which may permit the unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient, and may result in patient harm. Manufacturers should respond in a timely fashion to address identified vulnerabilities.[4]

Critical components of such a program include:

- Monitoring cybersecurity information sources for identification and detection of cybersecurity vulnerabilities and risk;
Maintaining robust software lifecycle processes that include mechanisms for:

- Monitoring third party software components for new vulnerabilities throughout the device’s total product lifecycle;
- Design verification and validation for software updates and patches that are used to remediate vulnerabilities, including those related to Off-the-shelf software;
- Understanding, assessing and detecting presence and impact of a vulnerability;
- Establishing and communicating processes for vulnerability intake and handling.

Note: The FDA has recognized ISO/IEC 30111:2013: Information Technology – Security Techniques – Vulnerability Handling Processes;

- Using threat modeling to clearly define how to maintain safety and essential performance of a device by developing mitigations that protect, respond and recover from the cybersecurity risk;
- Adopting a coordinated vulnerability disclosure policy and practice. The FDA has recognized ISO/IEC 29147:2014: Information Technology – Security Techniques – Vulnerability Disclosure which may be a useful resource for manufacturers; and
- Deploying mitigations that address cybersecurity risk early and prior to exploitation. [5]

It is further recommended that the program incorporate elements consistent with the National Institute of Standards and Technology’s (NIST) Framework for Improving Critical Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond, and Recover). For more details on these concepts, please see our previous discussion, which can be found here.

Perhaps more important than the shared responsibility of risk mitigation in cybersecurity among all stakeholders, is the concept that, in the FDA’s view, cybersecurity risk management should revolve around assessing the risk to the device’s essential clinical performance, which focuses on assessing the risk of patient harm.[6] As the Guidance explains, “[a] key purpose of conducting the cyber-vulnerability risk assessment is to evaluate whether the risk of patient harm is controlled (acceptable) or uncontrolled (unacceptable). One method of assessing the acceptability of risk involves using a matrix with combinations of “exploitability” and “severity of patient harm” to determine whether the risk of patient harm is controlled or uncontrolled.[7] This focus is achieved by considering:

1. The exploitability of the cybersecurity vulnerability, and
2. The severity of patient harm if the vulnerability were to be exploited.[8]

Such risk is to be assessed according to these two considerations on a sliding scale, which ranges from a controlled risk (low probability of a cybersecurity exploit with little impact on patient health) to an uncontrolled risk (high probability of an exploited vulnerability that seriously threatens patient safety or even patient death). While in some cases the evaluation will yield a definite determination of controlled or uncontrolled, the possibility remains that not all situations will produce such distinct results.[9]

The Guidance provides that manufacturers should have processes for assessing the exploitability of a cybersecurity vulnerability as well as the severity of patient harm. The cybersecurity vulnerability were to be exploited. The FDA suggests using a cybersecurity vulnerability assessment tool or similar scoring system for rating vulnerabilities and determining the need for and urgency of the response, such as the "Common Vulnerability Scoring System," Version 3.0.[10] Many adequate methodologies may be utilized to analyze the potential severity of patient harm, yet the Guidance highlights an approach based on qualitative severity levels as described in ANSI/AAMI/ISO 14971:2007/(R)2010: Medical Devices – Application of Risk Management to Medical Devices.[11] These levels range from Negligible (inconvenience or temporary discomfort) to Catastrophic (resulting in patient death).

The figure below shows the relationship between exploitability and severity of patient harm, and can be used to categorize the risk of patient harm as controlled or uncontrolled.[12]

While the FDA clearly distinguishes between a controlled risk and uncontrolled risk, even its illustrative chart above shows a large gray area of in-between, further acknowledging that it will not always be clear in which category the risk belongs.

The FDA Guidance then sets forth recommended proper responses to controlled and uncontrolled risks. Controlled risk scenarios involve relatively minor issues, where there is sufficiently low (acceptable) risk of patient harm. However, manufacturers are still encouraged to proactively promote good cyber hygiene and reduce cybersecurity risks.
even when residual risk is acceptable[13] Uncontrolled risks, on the other hand, require immediate intervention and remediation, and must be reported under 21 CFR part 806, unless:

1. There are no known serious adverse events or deaths associated with the vulnerability;
2. The manufacturer communicates with its customers and user community regarding the vulnerability, identifies interim compensating controls, and develops a remediation plan to bring the risk to an acceptable level, as soon as possible, but no later than 30 days after learning of the vulnerability;
3. The manufacturer fixes the vulnerability, validates the change, and distributes the deployable fix to its customers and user community within 60 days; and,
4. The manufacturer actively participates as a member of an Information Sharing Analysis Organization or “ISAO.”[14]

Like its draft before it, the final Guidance additionally contains an essential practical element in its Appendix: “Elements of an Effective Postmarket Cybersecurity Program.” The Appendix encompasses the totality of the FDA’s recommendations, in an easy to follow five-prong framework, consistent with the elements of the NIST Framework for Improving Critical Infrastructure Cybersecurity. These prongs are: A) Identify, B) Protect/Detect, C) Protect/Respond/Recover, and D) Risk Mitigation of Safety and Essential Performance[15]

All medical devices come with both risks and benefits. While it may not always be clear whether a particular risk is categorized as controlled or uncontrolled, the FDA has been explicitly clear in both its Premarket and Postmarket Guidelines that comprehensive cybersecurity and risk analysis must be addressed over the lifecycle of medical device products, keeping a primary focus on the risk of patient harm.

[3] Id.

Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach

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Federal Judge Clobbers Claims in a Class III Medical Device Case

May 22, 2017

Talk about a one-two punch. First, federal question jurisdiction kept a medical device case in federal court. And then came the knock-out blow: a federal judge in North Carolina ruled that federal preemption barred all of the state law claims against the medical device companies. In Burrell v. Bayer Corp., U.S Dist. LEXIS 38769 (W.D. N.C. March 17, 2017) (Burrell I), Judge Max O. Cogburn, Jr. retained jurisdiction over the medical device related lawsuit based on federal question jurisdiction. In a subsequent order, Judge

The plaintiff in Burrell alleged she was injured as a result of her use of an Essure birth control device. The Essure device is a Class III medical device approved by the FDA through the pre-market approval process. Plaintiff sued various Bayer entities, as well as local doctors for malpractice to defeat diversity jurisdiction. Bayer removed the case to federal court arguing it belonged there because of federal question jurisdiction. As evidenced by the inclusion of local defendants in her Complaint, plaintiff did not want the case in federal court and, thus, filed a motion to remand.

But the plaintiff’s Complaint was “replete with references to the FDA” and included numerous allegations “that the defendants violated the federal requirements of the Federal Food, Drug & Cosmetic Act (FDCA).” Burrell I, at *4-5. Because plaintiff’s Complaint “necessarily raise[d] federal issues,” Judge Cogburn concluded it was “properly a case that ‘arises from’ federal law, as the MDA was passed by Congress to govern the safety and effectiveness of Class III medical devices.” Id. at *11. He therefore retained jurisdiction over the case and denied plaintiff’s motion to remand. Id.

Just under two months later, Judge Cogburn delivered the knockout punch by granting Bayer’s motion to dismiss. Before delivering the decisive blow, though, Judge Cogburn had to block plaintiff’s counter punch – a motion to reconsider the remand denial order. In Burrell II, plaintiff tried again to convince Judge Cogburn that he should remand the case to state court. Judge Cogburn had no trouble brushing off plaintiff’s reconsideration attempt. For her reconsideration argument, the plaintiff relied on a 2005 Fourth Circuit case for the proposition that:

“[A] preemption defense that raises a federal question is inadequate to confer federal jurisdiction. Again, a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption,” even if the complaint begs the assertion of the defense, and even if the defense is the only question truly at issue in the case. Burrell II, at *8-9 quoting Pinney v. Nokia, Inc., 402 F.3d 430, 446 (4th Cir. 2005).

But Judge Cogburn easily rebuffed the reconsideration wrangle by distinguishing Burrell from Pinney. While federal law “was ‘lurking’ as a question in the background” in Pinney, in Burrell II, “[b]y plaintiff’s own admission,” she alleged violations of the FDCA as part of her state law claims and thus her Complaint met the requirements for federal jurisdiction. Motion for reconsideration denied.

After successfully deflecting plaintiff’s reconsideration left hook, Judge Cogburn led with a little jab about preemption. Usually, when a judge begins a preemption discussion by noting that “Federal law generally recognizes a presumption against preemption,” the defendant can expect a body blow at the end of the discussion. Thankfully, that was not what happened in Burrell II. Instead, Judge Cogburn followed the jab with the express and implied preemption combination by noting that “the task of avoiding express and implied preemption is a difficult one.” Burrell II. He then thoroughly analyzed plaintiff’s claims and concluded federal law preempted all of the claims against the Bayer defendants.

**Negligent Failure to Warn Claims**

Plaintiff alleged the Bayer defendants were negligent by failing to warn of adverse events relating to Essure and that they “were under a continuing duty to comply with requirements” in the FDA’s pre-market approval of Essure. On this point, the court agreed with the plaintiff. Burrell II at *12. But that agreement also meant federal law preempted plaintiff’s negligence claims because “plaintiff’s cause of action is being brought because the Bayer defendants allegedly failed to meet those reporting requirements.” Id. at *12-13.

To insure the negligent failure to warn claims remained knocked out, as an added bonus, Judge Cogburn also ruled that “plaintiff cannot support a finding of causation” for those warnings claims. Id. at *13. Judge Cogburn explained that by the time the plaintiff in Burrell received her device, “the FDA had the related information regarding the adverse event reports mentioned by plaintiff.” Id. Thus, in addition to being a preempted claim, Judge Cogburn found that plaintiff failed to show that the failure-to-warn caused her injuries.” Id.

**Negligent Failure to Train Claims**

In addition to her negligent failure-to-warn claims, plaintiff also asserted claims that the Bayer Defendants failed to train the implanting physician about how “to implant the device, deal with potential complications, and remove the device.”Id. at *14. Judge Cogburn quickly dispensed with plaintiff’s failure-to-train combination. Federal law preempted plaintiff’s negligent training claim because plaintiff’s claim “imposes a duty that is beyond the confines of the MDA.” Id. But on the downside, Judge Cogburn noted that such a claim could survive a preemption attack “to the extent that the manufacturer failed to provide the training required by the MDA.” Id. However, plaintiff’s Complaint did “not provide information as to how the training violated the FDA’s requirements or how her physician was trained.” Id. at *14-15. Due to lack of information on that point, federal law preempted the claim.

As with the negligent warning claims, Judge Cogburn also found plaintiff failed to provide sufficient facts to establish that any training failure caused her injuries. Thus, in addition to being preempted, the negligent training claims failed for lack of causation.

**Manufacturing Defect Claims**

Judge Cogburn also knocked aside plaintiff’s weak attempt at throwing a manufacturing defect punch. Although the plaintiff alleged her Essure was “manufactured improperly,” she did not link “any manufacturing deficiency to the device that [she] received and how it caused the alleged injuries.” Id. at *16. Thus, her manufacturing defect claim failed.

**Design Defect Claim**

Judge Cogburn parried plaintiff’s product liability claim as well. To the extent plaintiff argued that Essure suffered from a design defect, federal law expressly preempted those
claims. In brushing aside the design defect claim, Judge Cogburn simply noted that “The FDA made its determination [about the] safety and effectiveness” of the Essure and therefore “these design defect claims are preempted.” Id. at 17.

Breach of Warranty Claims

Judge Cogburn blasted the breach of warranty claims. The plaintiff alleged the Bayer defendants “expressly warranted Essure to be safe for use by the general public, including Plaintiff” and that the “warranties and representations ‘were untrue in that Essure was unsafe and unsuited for the use for which it was intended.’” Id. at *18. In short, Judge Cogburn noted that “Congress provided the FDA with the authority to regulate the safety and effectiveness of Class III medical devices.” So, he dismissed the breach of warranty claims.

Fraud and Unfair Trade Practices Claims

Finally, with all other claims against Bayer flat on the mat, Judge Cogburn crushed plaintiff’s unfair and deceptive trade practices claims. Judge Cogburn noted that the “allegations largely repackage the allegations” he already dismissed and that “several of the alleged misrepresentations are indistinguishable from FDA-approved labeling statements.” Id. at *19-20. Plaintiff’s allegations of “deviations from the FDA-approved language” were insufficient to “support a claim based on fraudulent behavior or unfair trade practices.” Id. at *20. Federal law preempted those claims.

Medical Malpractice Claims

After knocking out all of the plaintiff’s claims against the Bayer defendants, Judge Cogburn came full circle and turned his attention to the medical malpractice claims against the local defendants. Plaintiff eventually got her wish – the case will not remain in federal court. Judge Cogburn declined to exercise supplemental jurisdiction over the medical malpractice claims and dismissed those claims pursuant to 28 U.S.C. § 1367(c)(3) so plaintiff could reassert those claims in state court.

Post Bout Summary

Under Riegel v. Medtronic, Inc., 552 U.S. 313, 128 S. Ct. 999 (2008), plaintiffs in Class III medical device cases have a “narrow window” through which they must plead when attempting to state “parallel claims.” Judge Cogburn’s orders in this case provide great training roadmaps for knocking out claims in Class III medical device cases when plaintiffs allege violations of the FDCA or FDA regulations. Bayer used a great combination of federal question jurisdiction and preemption arguments to flatten plaintiff’s claims in this Class III medical device case. Bayer made the arguments, and Judge Cogburn delivered the epic knockout.

Indiana Judge Relies on Bausch to Bounce Preemption Motion

May 15, 2017

The old adage “location, location, location” applies as much for medical device preemption as it does for real estate. Despite acknowledging that the plaintiff’s Amended Complaint “would likely not survive a motion to dismiss if this case was pending in a court in the Eighth Circuit (or perhaps the Eastern District of New York),” an Indiana federal judge recently denied Medtronic’s motion to dismiss the Amended Complaint in Cavender v. Medtronic, Inc. (Cavender II), 2017 U.S. Dist. LEXIS 57376 (N.D. Ind. Apr. 14, 2017).

As frequently happens in cases involving pre-market approved medical devices, the court dismissed the initial complaint. He dismissed the initial Complaint because it was “nothing more than the sort of ‘unadorned, the-defendant-unlawfully-harmed-me accusation’ and was ‘still in the ‘assembly required’ stage.” Cavender v. Medtronic, Inc. (Cavender I), 2016 U.S. Dist. LEXIS 154540 *20-21 (N.D. Ind. Nov. 8, 2016). But, just as many other courts do, the judge in this case, Judge William C. Lee, granted the motion to dismiss without prejudice and gave the plaintiff another chance to try to plead a valid claim.

In Cavender I, the plaintiff alleged that her implantable cardioverter defibrillator malfunctioned and injured her. She filed her initial complaint “apparently asserting product liability, breach of warranty and negligence claims against Medtronic.” Cavender I, at *2. Judge Lee’s first task in Cavender I was to determine whether the Indiana Product Liability Act (IPLA) preempted and subsumed plaintiff’s attempted product liability claims. Judge Lee concluded that the IPLA subsumed the negligence and product defect claims.

However, plaintiff’s complaint lacked specifics and was “nothing more than the sort of ‘unadorned, the-defendant-unlawfully-harmed-me accusation’” which was “chock-full of keywords that imply” that the plaintiff was “attempting to assert various product liability claims.” Id. at *20. Because the plaintiff’s complaint “need[ed] work” and was “still in the ‘assembly required’ stage,” Judge Lee gave plaintiff another chance to plead valid claims. Id. at *21-22 and 37.

In his order in Cavender I, Judge Lee offered guidance for what plaintiff needed to do to plead valid claims. For example, in response to Medtronic’s argument that federal law preempts plaintiff’s claims, Judge Lee noted that the Complaint “is completely devoid of any facts whatsoever that would even imply that she is alleging a violation of federal law.” Id. at *28. Judge Lee advised the plaintiff that the “amended complaint will clarify this issue also.” Id. at 29.

Rather than directly clarifying the issue as instructed by Judge Lee, in the Amended Complaint, the plaintiff switched which device she was claiming caused her injury. In the initial Complaint, she vaguely alleged that a defibrillator malfunctioned and injured her. Id. at *2. In the Amended Complaint, she copied allegations from the Master Consolidated Complaint in the Sprint Fidelis Leads Prods. Liab. Litig. MDL and alleged a separate device, a Sprint Fidelis lead, caused her injuries.

By copying the preexisting and previously dismissed complaint, the plaintiff added more detail than in her initial complaint. Judge Lee noted that:

[W]hile the claims contained in her original Complaint were barely discernible, they now jump vividly off the page in full regalia, all because they are clothed in language taken—largely verbatim—from another complaint filled against Medtronic that was summarily dismissed by another district court eight years ago. Id. at *8-9.

Despite the product switcheroo and the blatant copying of a previously dismissed complaint, in Cavender II, Judge Lee concluded that the Seventh Circuit’s decision in Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010), “precludes dismissal of Cavender’s IPLA claim at this point and the motion to dismiss must be denied as to the issue of federal preemption of that claim.” Cavender at *33.

Judge Lee noted that the Seventh Circuit in Bausch agreed with the dissent in the Eighth Circuit’s decision affirming the dismissal of the Master Complaint in the Sprint Fidelis Leads Prods. Liab. Litig. MDL. In short, “the Seventh Circuit took a decidedly different approach to the issue of MDA preemption as it applies to state law claims.” Cavender II at *26-27. Thus, according to Judge Lee, “the Bausch decision mandates that [plaintiff] be permitted, at this juncture, to proceed with that claim notwithstanding the preemption clause in the MDA.” Id. at *38.

One other aspect of Judge Lee’s order is noteworthy. The plaintiff argued that because preemption is an affirmative defense, that she should not have to “defend” against an affirmative defense at this stage, thus the Court should not consider the defense as a basis for dismissal.” Id. at n.5 *21. Medtronic did not take issue with “that statement of the law” and Judge Lee declared that plaintiff was “correct, of course.” Id. Rather than take issue with the statement of law, Medtronic argued that because the plaintiff copied and pasted the very detailed, dismissed MDL complaint relating to this Lead[,]” she has, “[u]nder Seventh Circuit law . . . pled enough facts for the Court to consider the affirmative defense of preemption.” Id. Because Judge Lee concluded that the Bausch decision precluded preemption at the pleading stage in this case, he determined that the issue was “rendered irrelevant.” Id.

Judge Lee’s order is yet another example of how the Bausch decision continues to cause problems for medical device makers at the motion to dismiss phase in cases in the Seventh Circuit. The plaintiff in Cavender II simply copied allegations the Eighth Circuit had already dismissed as preempted. But because of the overly permissive language of Bausch, those same claims survive the motion to dismiss in the Seventh Circuit. Medtronic’s preemption argument may very well prevail at the summary judgment stage, but only after spending on unnecessary litigation expenses.

Rationale Underlying Missouri's Runaway "Supplemental Jurisdiction" Theory to be Tested by U.S. Supreme Court

January 30, 2017 | Angela Higgins

The U.S. Supreme Court has accepted certiorari in Bristol-Myers Squibb Co. v. Superior Court of California, Dkt. No. 16-468, a pharmaceutical product liability case in which some 600 out-of-state plaintiffs sued in a California court, arguing that the defendant had “contacts” with the state even though their individual claims did not arise out of those contacts. This case is straight from the same playbook that has led to dozens of out-of-state plaintiffs suing out-of-state defendants in the plaintiff-friendly jurisdiction of the Missouri long-arm jurisdiction.

A. The California case

In Bristol-Myers Squibb, the question accepted for determination by the Supreme Court is:

The Due Process Clause permits a state court to exercise specific jurisdiction over a defendant only when the plaintiff’s claims “arise out of or relate to” the defendant’s forum activities. Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985) (citation omitted). The question presented is: Whether a plaintiff’s claims arise out of or relate to a defendant’s forum activities when there is no causal link between the defendant’s forum contacts and the plaintiff’s claims—that is, where the plaintiff’s claims would be exactly the same even if the defendant had no forum contacts.

Bristol-Myers Squibb follows a decision of the California Supreme Court affirming denial of the defendant’s motion to dismiss for lack of personal jurisdiction. The drug at issue was not manufactured or designed in California, whose marketing, packaging, and regulatory materials were not prepared in California, and, critically, that was not prescribed to, dispensed to, or ingested by respondents in California. The very concept of 600 unrelated plaintiffs with no contact to the forum state using that state as a friendly forum to maintain their claims against non-resident defendants is blatantly offensive to the concept of personal jurisdiction, and it is encouraging that the Supreme Court has granted certiorari to hear this appeal.

It is commonly accepted amongst practitioners that courts, particularly state courts, struggle with the limitations of personal jurisdiction. Personal jurisdiction can be general or specific. See Daimler AG V. Bauman, 134 S. Ct. 746, 754 (2014). Specific jurisdiction, also known as “contact-based” jurisdiction, refers to personal jurisdiction which derives from a defendant’s actions in the forum state. See id. General jurisdiction refers to a court’s power over a defendant regardless of where those claims arose, based upon a defendant’s overwhelming contacts with the state. See id.

As Bristol-Myers Squibb argues in its petition for writ of certiorari, and amicus Product Liability Advisory Counsel notes in its brief in support of the cert petition, many state courts have “blended” the doctrines of general jurisdiction and contact-based specific jurisdiction to arrive at a hybrid non-standard that effectively subjects any defendant with any type of national commercial presence to jurisdiction anywhere its products are sold. The frequently-expressed test established by the U.S. Supreme Court, and, indeed, the very nature of “contact-based specific personal jurisdiction” is not complex; it is merely flouted because it is in tension with state courts’ desire to afford a forum for cases that they are not constitutionally authorized to hear.

B. Missouri long-arm jurisdiction
The exercise of personal jurisdiction over non-residents is called "long-arm" jurisdiction. The Missouri courts' authority to exercise long-arm jurisdiction is constrained by the Missouri statutes and the U.S. Constitution. Missouri's long-arm statute expressly affords contact-based specific jurisdiction over the person of non-resident defendants. See Shouse v. RFB Const. Co., Inc., 10 S.W.3d 189, 193 (Mo. App. W.D. 1999). Specific jurisdiction is called "contact-based" because such jurisdiction only exists for a cause of action "arising from" certain specified conduct by the defendant within the forum state. See Mo. Rev. Stat. § 506.500.1.

In product liability actions brought in the Missouri courts, plaintiffs commonly rely upon two statutory provisions for long-arm jurisdiction. One is the commission of a tort in Missouri. See Mo. Rev. Stat. § 506.500.1(3). The other is the transaction of business in Missouri. See Mo. Rev. Stat. § 506.500.1(1). Properly applying the jurisdictional test, it is the plaintiff's burden to establish personal jurisdiction. Conway v. Royalite Plastics, Ltd., 12 S.W.3d 314, 318 (Mo. banc 2000).

In order to rely upon the "tortious act" provision of the long-arm statute, a plaintiff is required to show that the non-resident defendant committed a tort in Missouri and that the tortious conduct caused the plaintiff's injuries. Hollinger v. Sifers, 122 S.W.3d 112, 116 (Mo. App. W.D. 2003). In applying the long-arm statute, the Missouri courts in the past have correctly rejected the contention that non-resident defendants should be subject to personal jurisdiction because a plaintiff suffered some "effect" or injuries in Missouri. See Mello v. Giliberto, 73 S.W.3d 669, 678 (Mo. App. E.D. 2002). Instead, the statute is limited to authorizing jurisdiction over non-resident defendants who "committed a tortious act" within the state, and where the plaintiff's cause of action "cause of action arises[es] from the doing of any of such acts." See Mo. Rev. Stat. § 506.500.1. When the defendant is not a resident of the state, it is difficult to imagine how it engaged in tortious conduct directed toward a plaintiff who is also located outside the forum state. Accordingly, if this test were properly applied, it should be difficult for non-resident plaintiffs to establish contact-based specific personal jurisdiction over a defendant based upon the "tortious act" provision of the long-arm statute.

The long-arm statute's grant of personal jurisdiction based upon the "transaction of any business within the state" is intended to confer jurisdiction over nonresidents "who enter into various kinds of transactions with residents of Missouri." Capitol Indemn. Corp. v. Citizens National Bank of Fort Scott, N.A., 8 S.W.3d 893, 904 (Mo. App. W.D. 2000) (emphasis added). The subject matter of that particular transaction must be the one that allegedly caused the plaintiff's alleged injuries. See id.; Mo. Rev. Stat. § 506.500.1(1). The circumstances in which a non-resident plaintiff could successfully argue for personal injury in a product liability case based upon the "business transaction" provision of the long-arm statute should be exceptionally limited.

C. Constitutional due process limitations

The Bristol-Myers Squibb outcome will be significant in Missouri because the Missouri courts' exercise of personal jurisdiction is not only based upon the provisions of our statute, but is also limited by due process requirements found in the U.S. Constitution. For a court to exercise personal jurisdiction over non-resident defendants, the plaintiff's claims must arise out of one or more of the types of conduct identified in Missouri's long-arm statute, and the non-resident defendant must have had sufficient "minimum contacts" with the forum state for the exercise of personal jurisdiction to comport with the defendant's constitutional due process rights. See Conway v. Royalite Plastics, Ltd., 12 S.W.3d 314, 318 (Mo. banc 2000).

The long-arm statute "extend[s] jurisdiction of the courts of this state over nonresident defendants to the extent permissible under the due process clause of the fourteenth amendment of the constitution of the United States." Hollinger v. Sifers, 122 S.W.3d 112, 115 (Mo. App. W.D. 2003) (citing State ex rel. K-Mart Corp. v. Holliger, 986 S.W.2d 165, 167-68 (Mo. banc 1999)). The minimum contacts test is satisfied for due process purposes when a non-resident defendant "purposefully directed" its activities at residents of the forum state, and the litigation results from alleged injuries that "arise out of or relate to" those activities. Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985) (emphasis added); Daimler AG v. Bauman, 134 S. Ct. 746, 754 (2014).

The Missouri courts have held that the commission of an extraterritorial tortious act that produces consequences in Missouri may provide a basis for the exercise of personal jurisdiction, but only where the non-resident defendant "set in motion some course of action which was deliberately designed to move into Missouri and injure the plaintiff." Capitol Indemn. Corp. v. Citizens National Bank of Fort Scott, N.A., 8 S.W.3d 893, 903 (Mo. App. W.D. 2000) (emphasis added). The "purposeful availment" requirement ensures that a defendant will not be hauled into a jurisdiction solely as a result of "random," "fortuitous," or "attenuated" contacts or of the "unilateral activity of another party or third person." State ex rel. William Ranni Associates, Inc. v. Hartenbach, 742 S.W.2d 134, 138 (Mo. 1987).

Because the second half of the test that any plaintiff must satisfy to establish long-arm jurisdiction in Missouri deals with the constitutional due process limitations established by the U.S. Supreme Court and relevant federal authorities, developments in constitutional due process have had a significant effect on the outcome of personal jurisdiction cases in Missouri. Walden v. Fiore, 134 S. Ct. 1115, 1121-22 (2014). The Missouri Supreme Court has previously recognized this, holding that the cause of action must arise out of the particular contact with Missouri. Conway, 12 S.W.3d at 318. Despite clear and binding guidance, however, California, Missouri, and a minority of other jurisdictions have allowed non-residents to take advantage of their states as a forum to litigate disputes that are wholly unrelated to any of the defendants' conduct within the state. Bristol-Myers Squibb argues, correctly, that a Tennessee plaintiff should not be
able to sue a Delaware/New York citizen defendant in California. As the Supreme Court has consistently and repeatedly recognized, there are limitations on a state’s ability to encroach upon jurisdiction that is rightfully placed in another state.

Those states, including Missouri, that fail to strictly apply personal jurisdiction limitations are engaged in an unconstitutional power-grab from their sister states. The restrictions on the courts’ exercise of personal jurisdiction “are more than a guarantee of immunity from inconvenient or distant litigation.” Hanson v. Denckla, 357 U.S. 235, 251 (1958). Rather, “[t]hey are a consequence of territorial limitations on the power of the respective States.” Id.; see also World-Wide Volkswagen, 444 U.S. at 292 (minimum contacts requirement serves the dual functions of protecting defendant against the burden of litigation and ensuring states “do not reach out beyond the limits imposed on them by their status as coequal sovereigns in our federal system”). “Due process limits on the State’s adjudicative authority principally protect the liberty interest of the nonresident defendant – not the convenience of plaintiffs or third parties.” Walden v. Fiore, 134 S. Ct. 1115, 1125 n.9 (2014). “Due process protects [a defendant’s] right to be subject only to lawful authority.” J. McIntyre Machinery Ltd. v. Nicastro, 564 U.S. 873, 887 (2011). The crux of the personal jurisdiction inquiry is whether the defendant ‘reveal[ed] an intent to invoke or benefit from the protection of’ the laws of the forum state. Id. Absent plaintiff’s proof of such intent, the forum state is “without power to adjudge the rights and liabilities” of the foreign defendant. Id.

Missouri courts simply lack the power to hear cases by non-resident plaintiffs against non-resident defendants, and the continued flouting of jurisdictional limitations has created a constitutional crisis in this country and within the state.

D. Each plaintiff must establish personal jurisdiction

Missouri state courts generally fail to appreciate what the federal courts recognize – that each plaintiff in a multi-plaintiff action must independently establish personal jurisdiction over the defendant with respect to his/her claims. See, e.g., Sun World Lines, Ltd. v. March Shipping Corp., 585 F. Supp. 580, 584-85 (E.D. Mo. 1984) (“[P]ersonal jurisdiction must be valid as to each and every cause of action in a complaint. Those causes of action which do not provide a sufficient basis for in personam jurisdiction must be dismissed even if other claims have such a basis.”) (citations omitted). aff’d, 801 F.2d 1066 (8th Cir. 1986); see also Seiferth v. Helicopteros Atuneros, Inc., 472 F.3d 266, 274-75 (5th Cir. 2006) (“Permitting the legitimate exercise of specific jurisdiction over one claim to justify the exercise of specific jurisdiction over a different claim that does not arise out of or relate to the defendant’s forum contacts [is violate[s] the Due Process Clause.”

An MDL court, applying Missouri and federal law, found that “the specific jurisdiction inquiry in this case must be conducted separately for the claims of each individual plaintiff.” In re Testosterone Replacement Therapy Prods. Liab. Litig. (“In re: TRT”), 164 F. Supp. 3d 1040, 1047 (N.D. Ill. 2016)) Thus, “every plaintiff . . . [must] show that his claims arise from, or are related to, defendants’ conduct in Missouri.” Id.

The Missouri state courts, however, have tended toward truly absurd results and unheard-of verdicts in product liability actions maintained by improperly joined out-of-state plaintiffs. The Court of Appeals for the Eastern District recently affirmed a $38 million verdict in favor of a Minnesota plaintiff who sued a Delaware/Illinois citizen defendant. See Slip Opinion, Barron v. Abbott Laboratories, Inc., Case No. ED103508. This is merely the “bellwether” – there are dozens of plaintiffs’ claims still to be tried in that action, which joined unrelated plaintiffs from around the country. Huge verdicts in improperly-joined out-of-state plaintiff actions involving talcum powder have also recently emerged from the City of St. Louis, and are merely the tip of the iceberg if overreach on personal jurisdiction is not reigned in.

Both the Circuit Court for the City of St. Louis and the Court of Appeals for the Eastern District completely glossed over the fundamental jurisdictional problem with the Barron case, and the dozens of others that have followed as out-of-state plaintiffs rush to get a seat at the trough. Each and every one of the Barron plaintiffs was required, by the Missouri long-arm statute and by the U.S. Constitution, to establish personal jurisdiction over the defendant, but neither the trial court nor the Court of Appeals required them to do so. Instead, both courts found that the state’s permissive joinder rules permitted joinder of the unrelated plaintiffs, and simply refused to perform a jurisdictional analysis.

As to joinder, the cases on which the decisions at both levels rely have been misrepresented, and the courts ignored clear and binding authority that prohibits joinder of unrelated product liability plaintiffs. Rule 52.05 identifies the only circumstances under which parties may be properly joined in a single action:

All persons may join in one action as plaintiffs if they assert any right to relief jointly, severally, or in the alternative in respect of or arising out of the same transaction, occurrence or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action.

Mo. R. Civ. P. 52.05(a) (emphasis added). Both tests must be met for plaintiffs to be joined in a single action. Id.; State ex rel. Allen v. Barker, 581 S.W.2d 818, 826 (Mo. banc 1979)). Misjoinder of claims or parties requires severance of the claims. See State ex rel. Gulf Oil Corp. v. Weinstein, 379 S.W.2d 172, 174 (Mo. App. St. L. 1964). In Gulf Oil, plaintiffs had purchased fuel oil in unrelated transactions at different times. Id. at 174. These transactions did not constitute the “same transaction nor a series of transactions.” Id. at 175. Even though the plaintiffs all sustained fires, these occurred on different dates. Id. Accordingly, the plaintiffs’ losses did not constitute the same “occurrence.” Id.

The Barron court did a 180 from its prior analysis in Gulf Oil, rejecting the defendant’s argument that “the Court should look solely from the perspective of the particular circumstances of each plaintiff’s mother’s use of Depakote as constituting the relevant ‘transactions’ and not from the perspective of Appellant’s nationwide promulgation and marketing of Depakote.” Slip Op. at 7. Of course, the “same transaction” test in a product liability action is a plaintiff-based test, as the court had previously found in Gulf Oil and as regularly found under the federal rules. In State ex rel. Allen v. Barker, 581 S.W.2d 818, 826 (Mo.1979) the Missouri Supreme Court discussed the adoption of Rule 52.05(a), recognized that it was patterned after Fed. R. Civ. P. 20, and applied federal cases to interpret it. Id. There is abundant federal authority disapproving the joinder of unrelated plaintiffs in pharmaceutical and medical device actions, which cuts against the dubious rationale of Barron.

Commentators have lamented Barron and remarked upon the liberal joinder rule in Missouri, but the statute is derived from and intended to be applied in the same manner as the corresponding federal rule. The fault is not in the text of the rule, it is in its mistaken application, and the failure of the Missouri courts to conduct any meaningful jurisdictional analysis. Barron has been accepted by the Missouri Supreme Court for further review, and the judgment may not stand, but the myriad of errors in the underlying case makes it doubtful that a clear ruling on personal jurisdiction will emerge from that appeal.
The argument that numerous unrelated out-of-state plaintiffs may be joined under Missouri’s Rule 52.05 with one plaintiff who properly asserts contact-based specific personal jurisdiction is a type of “pendent” or “supplemental” theory of specific personal jurisdiction. Liggins v. Abbvie Inc. (In re Testosterone Replacement Therapy Prods. Liab. Litig.), 164 F. Supp. 3d 1040, 1048 (N.D. Ill. 2016). However, “[t]here is no such thing as supplemental specific personal jurisdiction; if separate claims are pled, specific personal jurisdiction must independently exist for each claim and the existence of personal jurisdiction for one claim will not provide the basis for another claim.” Seiferth v. Helicopteros Atuneros, Inc., 472 F.3d 266, 275 n.6 (5th Cir. 2006) (emphasis added).

It is hoped that the resolution of Bristol-Myers Squibb will put to rest the runaway “supplemental personal jurisdiction” argument that has been adopted in Missouri. With Republican domination of the state legislature and governor’s office, tort reform to address the litigation abuses that have garnered national attention is imminent, and may also provide corrective measures on this issue.

Related Services: Pharmaceutical & Medical Device, Product Liability

Attorneys: Angela Higgins

Effectively Addressing Cybersecurity Breaches in Medical Devices (Part 3 of 3)

January 24, 2017 | Suzanne Billam and Megan Sterchi Lammert

The Inherent Risks, Impacts of Security Decisions, and Practical Approaches – Best Practices to Prepare, Mitigate, and Otherwise Manage Vulnerabilities and Potential Cybersecurity Attacks

Continuing from our two prior posts in this three-part series on effectively addressing cybersecurity breaches in medical devices, this third and final post will focus on best practices to prepare, mitigate and otherwise manage vulnerabilities and potential cyber-attacks.

Best practices to prepare, mitigate, and otherwise manage vulnerabilities and potential cybersecurity attacks

The FDA has issued both pre-market considerations[i], which consists of proactively addressing vulnerabilities, and post-market considerations[ii], which consists of mitigation, remediation, and other risk management strategies, to aid in addressing today’s issues of medical device vulnerabilities and potential cybersecurity attacks on those devices. For more details on the FDA’s post-market guidance, see our prior series “FDA Issues Draft Guidance Document for Postmarket Management of Cybersecurity in Medical Devices” posted in four parts here, here, here, and here.

The pre-market considerations include, (1) identifying assets, threats, and vulnerabilities; (2) assessing the impact of threats and vulnerabilities on device functionality and end users/patients; (3) assessing the likelihood of a threat and of a vulnerability being exploited; (4) determining risk levels and suitable mitigation strategies; and (5) assessing the residual risk and risk acceptance criteria[iii]. The manufacturer’s pre-market submission effectively includes the pre-market considerations that have been brainstormed thus far, such as all hazard analysis, mitigation and design considerations associated with the potential cybersecurity risks of a specific medical device, summary of plan for cybersecurity updates and patches, a matrix and summary showing and discussing cybersecurity controls and the risks they face, and device instructions for the specific product as to recommendations on how to properly use and secure the device[iv]

Even after rigorous testing and risk assessment in the pre-market consideration and submission phase, given the rapid pace of technology today, medical device manufactures and companies should never stop evaluating the potential vulnerability of their devices or considering how to mitigate and remediate the same[v]. Mitigation is a risk management strategy used to minimize the impact of a cybersecurity attack on medical devices and the systems to which they are connected or networked, which takes into consideration the risk is the outcome of an attack and the aspect of security it affect[v]. Remediation consists of an action or actions that are taken to reduce the risk to the medical device’s essential clinical performance to an acceptable level, including, but not limited to finding an official fix or solution to remove a cybersecurity vulnerability, using a compensating control, such as notifying the consumer base about a temporary fix or other work-around solution), to adequately mitigate the risk[vii]. One remediation strategy is to engage in cybersecurity “routine updates and patches,” which involves updates or enhancements or patches to a medical device. These updates and patches provide an increase in the medical device’s security and help to remediate the device’s vulnerabilities linked to the device’s controlled risk, while also not reducing the risk to a patient’s health. Such updates and/or patches included, but are not limited to, software, firmware, and hardware updates.

Other post-market considerations issued by the FDA include as follows: (1) monitoring cybersecurity information sources for identification and detection of cybersecurity vulnerabilities and risk, which may require auditing of the network and immediately reporting any security breach,[viii] (2) understanding, assessing and detecting presence and impact of a vulnerability; (3) establishing and communicating processes for vulnerability intake and handling; (3) clearly defining essential clinical performance to develop mitigations that protect, respond and recover from the cybersecurity risk; (4) adopting a coordinated vulnerability disclosure policy and practice; and (5) employing mitigations that address cybersecurity risk early and prior to exploitation.

Other all-around best practices[x] discussed by the FDA have been to:

1. Limit access to only trusted users through the use of such things as passwords, usernames, smartcards, biometrics, automatic timers, and physical locks.[x]
2. Ensure that only trusted content is within the device and/or system by such means as restricting updates to the same or using encryption[x]
3. “Detect, respond, and uncover,” which can be accomplished by using procedures and features that alert security compromises, educate the end user(s) on detections of security breaches, and provide methods for retention and recovery of device[xi]

a. These elements are consistent with the National Institute of Standards and Technology Framework for Improving Cybersecurity Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond and Recover)[xiii]
4. Create a structured and systematic approach to risk management and quality management systems consistent with 21 CFR part 820, which would include methods to identify, characterize, and assess a cybersecurity vulnerability and methods to analyze, detect, and assess threat sources[xiv]

5. Be proactive! Practice good cyber hygiene and reduce cybersecurity risks even when residual risk is acceptable;

6. Remediate by finding an official and/or temporary fix to cybersecurity vulnerabilities to reduce the risk of compromise to essential clinical performance to an acceptable level;

7. Keep in contact and maintain a solid, formal business relationship with any software vendors to ensure they are providing you timely information about any quality and/or security problems that you can correct and/or prevent; and [xv]

8. Incorporate elements consistent with the National Institute of Standards and Technology Framework for Improving Cybersecurity Infrastructure Cybersecurity (i.e., Identify, Protect, Detect, Respond and Recover).

Conclusion

The threat that a pacemaker will be hacked by foreign terrorists may be low, but the risk of devastating and life-threatening cybersecurity attacks in medical devices and healthcare is significant. To ensure the future protection of medical devices in a networked world, device manufacturers, regulatory bodies, healthcare providers and patients must engage in a coordinated proactive approach that includes standard cybersecurity assessment and control, together with specific medical device data and workflow considerations.

Read part one of this series on navigating the medical device field and vulnerabilities of medical devices here and part two on cybersecurity and attacks on medical devices here.

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[i] U.S. Food and Drug Administration, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, October 2, 2014.


[iii] Supra, note 1.

[iv] Id.


[vi] Id.

[vii] Supra, note 2.

[viii] Williams, Woodward, supra note 5.


[x] Supra note 1.

[xi] Id.

[xii] Id.


[xiv] Supra note 2.


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Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach and Product Liability
Effectively Addressing Cybersecurity Breaches in Medical Devices (Part 2 of 3)

January 11, 2017 | Suzanne Billam and Megan Sterchi Lammert

The Inherent Risks, Impacts of Security Decisions, and Practical Approaches – Cybersecurity and Attacks on Medical Devices

Continuing from our prior post in this three-part series on effectively addressing cybersecurity breaches in medical devices, this second post will focus on specific examples of cybersecurity attacks on medical devices.

Cybersecurity and attacks on medical devices

If you have tuned on the television, read the news, or listened to the radio recently, you have heard that cybersecurity threats are something we all have to be concerned about. We hear about data breaches affecting the disclosure of personal financial information or breaches into the nation’s military weapons system. But in the context of medical devices, cybersecurity is the process of preventing a breach or unauthorized user from gaining access, modifying, misusing, or denying use to information that is stored, accessed, or transferred from a medical device to an external recipient.

Unlike breaches into military systems, where we trust the government is initiating measures to safeguard the general public from threats and direct attacks, the threat to cybersecurity attacks in healthcare is very real, wide-spread, and right in our backyards. There have been numerous real and fictional examples of medical devices falling victim to a cybersecurity attack. A recent study revealed that ninety-four (94) percent of healthcare institutions reported being victims of cyber-attacks.

Below are some real-life examples of actual medical devices falling victim to a cybersecurity attack:

- **August 12, 2011:** Hacking into an insulin pump. While the hacking was done as a presentation at a security conference, the presenter showed how to hack into his own insulin pump, albeit it required security expert knowledge and fairly close proximity to the pump. However, the presentation, even back in 2011, brought back to the limelight whether manufacturers of medical devices were taking the necessary security measures to protect its consumers/patients and the devices from an attack.

- **April 25, 2014:** Article explores and/or exposes the vulnerabilities of hospital equipment and their high susceptibility to being hacked, including, but not limited to insulin pumps, defibrillators, and hardcoded passwords in medical devices, used at a large chain of Midwest health care facilities.

- **February 2015:** Anthem, Inc. attacked by hackers who obtained data that may have exposed 80 million customers’ personal information. A lawsuit is pending in the Northern District of California, the consolidated complaint alleging that the hackers stole income tax refunds and placed false charges on their credit cards.

- **June 1, 2015:** Court dismisses claim arising out of a data security breach by Amazon.com (Zappos.com), because the victims lacked standing to sue when they could not identify any specific harm that they had sustained as a result of the data breach that occurred 3.5 years prior.

- **July 31, 2015:** FDA issues alert for healthcare facilities to discontinue the use of Hospira Symbiq Infusion System due to cybersecurity vulnerabilities. In other words, as the FDA’s statement set forth, the Hospira system could be accessed remotely through a hospital’s network, giving an unauthorized user access and control to the device and change the dosage of general infusion therapy the pump delivers.

- **June 2016:** Hacker gains access to 397,000 patient records from the internal network of a large database in Georgia, 210,000 patient records from a database somewhere in the Midwest (retrieved from a ‘severely misconfigured network’), and 48,000 records located in Farmington, Missouri. The hacker then put the information up for sale at around $485K. This is just one of many recent “ransomware” stories, which is a category of malicious software (“malware”) that encrypts a user’s disk drives and demands some form of compensation in return for critical data held hostage, which have occurred recently.

For best practices on how to prepare, mitigate, and otherwise manage vulnerabilities and potential cybersecurity attacks, stay tuned for part three of this series coming soon. Read part one of this series on navigating the medical device field and vulnerabilities of medical devices here.

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[vi] Id.

[vii] Id.

A vulnerability in a medical device is a weakness within that device, which may be exploited in the device's information system, system security procedures, and internal devices. While the definition may appear almost too all-encompassing to the unfamiliar or untrained eye, the definition is inclusive of the ten to fifteen million (and growing) medical devices within United States hospitals. It includes, for example, an infusion pump attached to a hospital bed, yet excludes health and wellness applications that run on mobile devices.

So, what exactly is a "medical device?" Just as the technology available in our networked and mobile world progresses, so does the fluid definition of "medical device." As these medical devices become increasingly interconnected with other clinical systems, they become more vulnerable to both intentional and unintentional misuse, as well as cybersecurity attacks.

Introduction

In today's modern society, recent technological advances have resulted in transformations in health care delivery, which improve health care and increase the ability of health care providers to treat patients. For example, wireless medical devices such as pacemakers are being implanted in patients, accompanied by software which allows the health care provider to receive and transmit information directly to the device from a remote location. But these devices aren't without risk. As these medical devices become more and more connected, they become more vulnerable to both intentional and unintentional misuse, as well as cybersecurity attacks.

Navigating the medical device field

The safety, effectiveness, and security of medical devices is regulated by the Food and Drug Administration ("FDA"), among other regulatory bodies. These regulatory bodies have acknowledged the seriousness and enormity of the problem of medical device cybersecurity by publishing recommendations for managing cybersecurity risks and protecting patient health information, to assist manufacturers in their submissions for FDA approval of medical devices. But who has an equal, if not greater responsibility for maintaining device functionality, integrity and confidentiality of information, patient privacy, and device and information availability, to prevent adverse effect on patient safety? Such a responsibility is shared equally by manufacturers, health care providers, and patients.

So, what exactly is a "medical device?" Just as the technology available in our networked and mobile world progresses, so does the fluid definition of "medical device." The FDA (comprehensively) defines a medical device as:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

(1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.[iii]

While the definition may appear almost too all-encompassing to the unfamiliar or untrained eye, the definition is inclusive of the ten to fifteen million (and growing) medical devices within United States hospitals. It includes, for example, an infusion pump attached to a hospital bed, yet excludes health and wellness applications that run on mobile devices.

Vulnerabilities of medical devices

A vulnerability in a medical device is a weakness within that device, which may be exploited in the device's information system, system security procedures, and internal systems.
controls, or may be exploited through implementation. A threat is the potential for a vulnerability to be exploited, the existence of which is determined by taking the likelihood of the threat actually occurring, juxtaposed with the severity of any potential adverse impact.[iv] The term “exploited” means that a vulnerability or vulnerabilities have been exercised or exposed either accidentally or intentionally, potentially impacting the essential clinical performance of a medical device or the system to which that medical device is connected or networked.[v] However, a vulnerability is not the same as a breach, inasmuch as a breach is the actual disclosure of financial or protected health information (“PHI”) to a third-party unauthorized user.

The increased use of wireless network connectivity and connection of devices to the Internet, coupled with the desire to make use of the information collected on a medical device in other health systems, has made medical devices more open, and subsequently more vulnerable, to cybersecurity threats. The FDA has become aware and warned of potential cybersecurity vulnerabilities and incidents that may have a direct impact on medical devices through hospital network operations, which include: networked medical devices being infected and/or disabled by malware; the use of wireless technology (i.e., cell phones, tablets, hospital computers, etc.) to access patient data, monitoring systems and implanted patient devices; uncontrolled distribution of passwords for privileged device access; failure to provide timely security software updates and patches to address vulnerabilities in older medical devices and networks; and security vulnerabilities in off-the-shelf-software that are not preventing unauthorized device or network access (i.e., use of plain text code, lack of authentication, hard-coded passwords, poor coding, etc).[vi]

Medical devices are vulnerable to attacks for a myriad of reasons. One reason is that unauthorized third parties or hackers are provided information that may allow them to compromise a medical device via public information provided by certification agencies, device manuals and patent databases. A second reason is that not all operating systems are compatible with one another, which leads to misconfiguration and vulnerabilities through gaps in security. Attacks may also involve medical devices that are already compromised, which can be used to attack other health care organization networks. Having less encryption on the medical devices, while beneficial for emergency access, also presents opportunities for attacks. Other reasons include late or lack of software updates and/or basic security features to prevent tampering, as well as there being a lack of knowledge, awareness, and education on cybersecurity issues and best practices.[vii]

For more on cybersecurity and attacks on medical devices, and best practices to prepare, mitigate, and otherwise manage vulnerabilities and potential cybersecurity attacks) stay tuned for parts two and three of this series, coming soon.

References


Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach and Product Liability

Attorneys: Suzanne Billam and Megan Sterchi Lammert

FDA Launches Webpage Allowing Anonymous Reports of Regulatory Misconduct Regarding Medical Devices

October 25, 2016

On October 24, 2016, the FDA announced the launch of a new webpage at fda.gov titled “Reporting Allegations of Regulatory Misconduct.” The new webpage allows anyone to “file a complaint reporting an allegation of regulatory misconduct” by medical device manufacturers or individuals marketing medical devices. Although the FDA encourages people making the reports of alleged regulatory misconduct to provide contact information, the new webpage permits anonymous reporting. Thus, reports can be made without ever knowing the source or the agenda of the person making the report. According to the announcement for the new webpage, this new reporting process “can help make the FDA aware of regulatory concerns it may not learn of otherwise.” The new webpage includes a table of examples of allegations. The table includes claims that manufacturers or individuals are promoting devices for off-label uses; failure of manufacturers to submit required medical device safety reports (MDRs); failure to meet design or manufacturing responsibilities; marketing a device with 510(k) clearance or PMA approval; and several violations concerning importation or registration of devices. Of course, the list also includes the catch-all of a manufacturer knowingly deceiving the FDA by hiding information or falsifying documents.

The new webpage makes it easy to submit a report by simply clicking on the “Allegations of Regulatory Misconduct Form” link under the question “How do I submit an allegation about a medical device manufacturer to the FDA?” which is located in the middle of the page. The form itself is also quite simple and merely asks the reporter to
The district court in Kleiner first determined that Germany was an adequate alternative forum because defendant was subject to German jurisdiction and the alternative forum was made based on forum shopping reasons, as opposed to some other rational basis. Kleiner v. Spinal Kinetics, Inc. at 241.

While plaintiff's chosen forum is generally accorded deference in any forum exists, and that the balance of private and public interest factors favors dismissal. Aimed at preserving judicial efficiency. In order to have a plaintiff's case dismissed based on forum non conveniens, a defendant first must prove that an adequate alternative forum exists, and that the balance of private and public interest factors favors dismissal. Alternatively, plaintiffs in personal injury or torts actions often have a choice of multiple courts in which to file, that all may potentially have concurrent jurisdiction. Yet, as the U.S. District Court for the Northern District of California recently enunciated in Kleiner v. Spinal Kinetics, Inc., No 5:15-cv-02179, 2016 WL 1565544 (N.D. Cal. Apr. 19, 2016), just because a plaintiff can obtain jurisdiction over a defendant in a particular forum does not mean it is the best suited forum to hear the case. This notion is particularly evident when a foreign plaintiff files suit against a U.S. company in the company's home forum.

Device manufacturers and their employees should be aware of the new webpage and be prepared to respond to FDA investigations concerning reports made on the new webpage.

Related Services: Pharmaceutical & Medical Device, Product Liability

Forum Non Conveniens - When Home Isn't Always Convenient

July 5, 2016 | Suzanne Billam

In civil litigation, the practice of “forum shopping” refers to the deliberate examination of multiple courts or jurisdictions in order to file or transfer the case to one that is most likely to treat that party’s claims most favorably. Often, this forum shopping is blatant — where plaintiffs deliberately attempt to establish their claims in a forum they view as favorable, without any real connection or nexus to the chosen forum. Alternatively, plaintiffs in personal injury or torts actions often have a choice of multiple courts in which to file, that all may potentially have concurrent jurisdiction. Yet, as the U.S. District Court for the Northern District of California recently enunciated in Kleiner v. Spinal Kinetics, Inc., No 5:15-cv-02179, 2016 WL 1565544 (N.D. Cal. Apr. 19, 2016), just because a plaintiff can obtain jurisdiction over a defendant in a particular forum does not mean it is the best suited forum to hear the case. This notion is particularly evident when a foreign plaintiff files suit against a U.S. company in the company’s home forum.

In Kleiner, a purported class action, plaintiffs Sebastian Kleiner and Silvana Kraftschik, both German citizens, alleged to have suffered injuries they attributed to spinal implants designed and manufactured by defendant in Sunnyvale, California. The devices implanted into plaintiffs were sold by defendant’s wholly-owned German subsidiary, and the plaintiffs underwent their respective implantation operations, suffered their alleged injuries, and were treated for these alleged injuries in all Germany by German doctors. Although the majority of witnesses, including plaintiffs, their family members, co-workers, the implanting surgeons, and the treating physicians, are all located in Germany, plaintiffs filed suit in defendant’s home forum, California. Why? Presumably because their counsel determined the potential recovery of punitive damages under California law (which are unavailable under German law) made California a more favorable forum for plaintiffs’ claims. The defendant moved to dismiss the case on the basis of forum non conveniens, arguing there was an alternate adequate forum that was more appropriate for adjudication of the plaintiffs’ claims. While at first blush it might strike as strange that the defendant would assert that its home forum is an inconvenient forum, but the forum non conveniens determination is dependent upon the individual facts of each case, and strong precedent supports such a motion. See Piper Aircraft Co. v. Reyno, 454 U.S. 235 (1981).

The common-law doctrine of forum non conveniens is a discretionary power that permits a federal district court to decline to accept jurisdiction over an action over which it has jurisdiction and venue, and to dismiss the case where another court, or forum, is better suited to hear the case. See, e.g., Sinochem Int’l Co. Ltd. v. Malaysia Int’l. Shipping Corp., 549 U.S. 422, 429 (2007); Ford v. Brown, 319 F.3d 1302, 1306-07 (11th Cir. 2003). Thus, even a plaintiff who establishes proper venue in a U.S. District Court nonetheless may have his case dismissed on grounds of forum non conveniens. See American Dredging Co. v. Miller, 510 U.S. 443, 448 (1994); Piper Aircraft Co. v. Reyno. Forum non conveniens not only is an important tool for a defendant being sued by a foreign plaintiff (or by a domestic plaintiff for conduct abroad), it is also a critical doctrine aimed at preserving judicial efficiency. In order to have a plaintiff’s case dismissed based on forum non conveniens, a defendant first must prove that an adequate alternative forum exists, and that the balance of private and public interest factors favors dismissal. Piper Aircraft Co. v. Reyno; Gulf Oil Corp. v. Gilbert, 330 U.S. 501 (1947). Underlying its analysis of the private interest factors, a federal court must take into account the degree of deference that must be given to a Plaintiff’s choice of forum. See Piper, 454 U.S. at 241. While plaintiff’s chosen forum is generally accorded deference in any forum non conveniens analysis, this deference carries less weight when the plaintiff is foreign. See Kleiner v. Spinal Kinetics, Inc. (citing Lueck v. Sundstrand Corp., 236 F.3d 1137, 1449 (9th Cir. 2001)). This is particularly true where it appears that the plaintiff’s choice of forum was made based on forum shopping reasons, as opposed to some other rational basis. See Iragorri v. United Techs. Corp., 274 F.3d 65, 71 (2d Cir. 2001) (“The more it appears that the plaintiff’s choice of a U.S. forum was motivated by forum-shopping, . . . the less deference the plaintiff’s choice commands.”).
The district court in Kleiner first determined that Germany was an adequate alternative forum because defendant was subject to German jurisdiction and the alternative forum provided at least some remedy for the harm allegedly suffered by the plaintiffs. Defendant's product, the M6-C, was marketed and sold to customers in Germany, defendant expressly consented to submit itself to German jurisdiction for the purposes of litigating this case, and defendant's subsidiary, Spinal Kinetics GmbH, was incorporated in and subject to the jurisdiction of the German courts. Further, the court determined that under German law, plaintiffs could bring their product liability suit and possible recover damages for their injuries. While plaintiffs argued that German law did not provide a satisfactory remedy for plaintiffs' injuries, defendant only needed to establish that the forum's laws did not "completely deprive" plaintiffs of a remedy. Tuazon v. R.J. Reynolds Tobacco Co., 433 F.3d 1163, 1178 (9th Cir. 2006).

Next, the district court weighed a number of private interest factors in conducting its forum non conveniens analysis. In Gulf Oil Corp. v. Gilbert, the U.S. Supreme Court first provided federal courts with a non-exclusive list of private factors to consider in determining whether the forum non conveniens doctrine should be applied. 330 U.S. 501, 508 (1947). The Gilbert Court explained that relevant considerations are:

1. The relative ease of access to sources of proof;
2. Availability of compulsory process for attendance of unwilling, and the cost of obtaining attendance of willing, witnesses;
3. Possibility of view of premises; and
4. All other practical problems that make trial of a case easy, expeditious and inexpensive.

These factors have been rephrased and applied countless times by federal courts. The Gilbert factors are non-exclusive and are to be applied flexibly; in fact, the United States Supreme Court repeatedly has "refused to identify specific circumstances which will justify or require either a grant or denial of [the forum non conveniens] remedy." Piper Aircraft Co. v. Reyno at 249-50 (each case must turn on its specific facts, and "[c]entral emphasis were placed on any one factor, the forum non conveniens doctrine would lose much of the very flexibility that makes it so valuable."). Nevertheless, even if courts apply the Gilbert factors flexibly, with no one factor being dispositive, one factor that often provides substantial support to a defendant is access to evidence. "Perhaps the most important private interest is access to evidence." Ford v. Brown, 319 F.3d at 1308.

The Kleiner court focused on the location of relevant witnesses and other evidence in Germany, and "the materiality and importance of the anticipated witnesses' testimony." (citing Gates Learjet Corp. v. Jensen, 743 F.2d 1325, 1335-36 (9th Cir. 1984). The court noted, "the key inquiry … requires assessing the materiality and importance of these witnesses' testimony and determining whether some of these witnesses are "critical" and beyond the jurisdiction of domestic courts. The surgeons, by virtue of their role in implanting and subsequently removing Defendant's products from Plaintiffs, possess substantial material information regarding the cause and extent of the Plaintiffs' injuries. Likewise the treating physicians possess material information regarding the extent of Plaintiffs' injuries and the effect of their treatment."

The Kleiner court noted the private interest factors at issue weighed in favor of a German forum, and further determined the public interest factors did as well. As with the private interest factors, the pivotal case setting forth the public interest factors is Gulf Oil Corp. v. Gilbert. The Gilbert court reasoned that, among other things, "[j}ury duty is a burden that ought not to be imposed upon the people of a community which has no relation to the litigation." Id. at 508-09. Further, "in cases which touch the affairs of many persons [in an alternate forum], there is reason for holding the trial in their view and reach rather than in remote parts of the country where they can learn of it by report only." Id. at 509.

Germany was determined to have a significant local interest in the suit, as plaintiffs "are residents of Germany, underwent their respective implantation operations in Germany, and suffered similar injuries there[,]" which outweighed California's interest because the product was designed in and entered the stream of commerce from California. Further, the Kleiner court found that Germany's interest in applying its laws far outweighed the interest of California because both of the plaintiffs, German citizens, were allegedly injured by defendant's product, which was sold to its customers in Germany by defendant's wholly owned German subsidiary.

As noted above, the district court focused significantly on the case specific evidence – i.e., the location of plaintiffs' respective surgeries, injuries, and subsequent treatment, and importantly, the location of material witnesses, which are beyond the jurisdiction and subpoena powers of domestic courts. While plaintiffs feebly argued the existence of evidence in California relating to the design and manufacture of the subject product, and certainly defendant was subject to jurisdiction in California, the private and public interest analysis ultimately weighed in favor of a German forum.

Various federal district courts apply the Gilbert private and public factors flexibly in conducting the forum non conveniens analysis, yet nonetheless, it is clear that great emphasis is afforded to the residence of parties, witnesses, and other evidence, including the materiality and importance of key witnesses located outside the domestic courts' jurisdiction, the local interest of the respective available forums in the lawsuit, and the domestic court's familiarity with the governing law. We urge our clients to consider these factors if faced with similar disputes.

Related Services: Pharmaceutical & Medical Device, Personal Injury Defense and Product Liability

Attorneys: Suzanne Billam

Third Circuit Affirms Dismissal Opining No Physical Injury Equals No Ascertainable Loss

March 15, 2016 | Suzanne Billam
On February 12, 2016, a panel of the U.S. Court of Appeals for the Third Circuit affirmed dismissal of a lawsuit accusing GlaxoSmithKline ("GSK") of violating the Missouri Merchandising Practices Act ("MMPA") by failing to adequately warn of the risks associated with the use of a prescription drug, Avandia. In Re: Avandia Marketing, Sales Practices and Products Liability Litigation, No. 15-2145, 3rd Cir.; 2016 U.S. App. LEXIS 2463. The Court affirmed a lower court decision granting GSK’s motion for judgment after finding that the patient/Plaintiff failed to show that she suffered an “ascertainable loss” as required by the Act.

Appellant Staci Laurino is a former user of GSK’s Avandia, a prescription drug approved by the Food and Drug Administration to aid in the lowering of blood glucose in patients with type 2 diabetes. Laurino did not sue on the grounds that she had been physically injured as a result of taking Avandia, rather Laurino alleged GSK “engaged in misrepresentations, and failed to adequately advise consumers and medical providers of the risks of Avandia, including but not limited to the increased risk of heart attacks and deaths[,]” in violation of the MMPA, and sought damages equal to the difference between the drug’s actual value and the value of the drug had it been as represented by GSK.

The case, originally filed in the U.S. District Court for the Eastern District of Missouri, was transferred to the pending In re Avandia Multi-District Litigation in the Eastern District of Pennsylvania. Laurino then filed an Amended Complaint, and GSK moved to dismiss for lack of standing pursuant to Federal Rule of Civil Procedure 12(b)(1) and for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). The District Court found Laurino had standing, but held that she received all of the benefits of taking Avandia without suffering any harm, thereby sustaining no ascertainable loss as required under the MMPA. For failure to state a claim under the MMPA, and because the District Court further believed Laurino would be unable to correct the fundamental deficiency of “ascertainable loss” if given the opportunity, the District Court dismissed Laurino’s Amended Complaint with prejudice. Laurino appealed.

The purpose of the MMPA is to “preserve fundamental honesty, fair play and right dealings in public transactions.” Zmuda v. Chesterfield Valley Power Sports, Inc., 267 S.W.3d 712, 716 (Mo. Ct. App. 2008). Under the MMPA, “[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce . . . , in or from the state of Missouri, is declared to be an unlawful practice.” Mo. Stat. Ann. § 407.020.1. “Any person who purchases or leases merchandise primarily for personal, family or household purposes and thereby suffers an ascertainable loss of money or property, real or personal, as a result of an unlawful practice may bring a civil action. Mo. Stat. Ann. § 407.025.1.

In her appeal, Laurino argued the District Court erred in relying on the lack of physical injury and misapplied Missouri law that allows an ascertainable loss through the benefit-of-the-bargain rule.[1] Laurino sought support in the Missouri Court of Appeals’ holding in Plubell v. Merck & Co., Inc., 289 S.W.3d 707, 715 (Mo.App. W.D. 2009) that because the plaintiffs alleged the drug was worth less than the product as represented, “they stated an objectively ascertainable loss under the MMPA using the benefit-of-the-bargain rule.” However, upon thorough consideration, the District Court explained the statement was made in the context of class certification under Missouri state procedural law, and did not “inquire whether the plaintiffs will prevail on the merits or even whether the plaintiffs have stated a cause of action.” Laurino v. SmithKline Beecham Corp. (In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.), 100 F. Supp. 3d 441, 446 (E.D. Pa. 2015) (quoting Plubell, 289 S.W.3d at 715).

The District Court then, persuaded by federal court opinions interpreting Missouri law[2], opined Laurino’s:

“proposed liability theory, which requires no demonstrable loss of any benefit, would lead to absurd results…

The absurdity is inherent in the nature of Plaintiff’s claimed loss, which is based only on the idea that Avandia is inherently worth some unspecified amount less than whatever Plaintiff might have paid for it. The logical extension of this argument in the prescription-drug context is that there is some price point at which a patient would agree to take a drug, despite the risk of side effects and despite the existence of other, equally effective drugs that do not carry such risk. The Court cannot imagine what that price point might be. Plaintiff received all the benefits of taking Avandia without any harm, and therefore suffered no loss.”

Laurino, at 446-47.

In In re Bisphenol-A (BPA) Polycarbonate Plastic Products Liab. Litig. (“In re BPA”), three classes of Missouri consumers moved for class certification on claims for violation of the Missouri Merchandising Practices Act, breach of the implied warranty of merchantability, and unjust enrichment as to sales of baby bottles and sippy cups. In denying class certification, the U.S. District Court for the Western District of Missouri found that the proposed class could not be certified because (1) it included individuals who had not suffered an injury in fact: consumers who knew about the Bisphenol-A polycarbonate plastic and purchased the products anyway suffered no injury, and (2) consumers who fully used Defendants’ baby bottles and other products without physical harm before learning about BPA suffered no injury and could not assert a claim under consumer protection statutes.

Likewise, in Mikhlin v. Johnson & Johnson, plaintiffs did not claim physical harm or the recovery of personal injury damages, but claimed to not received the benefit of their bargain based upon studies indicating an increased risk of ovarian cancer associated with genital use of Johnson’s® Baby Powder. The U.S. District Court for the Eastern District of Missouri held that “[a]lthough Plaintiffs contend that they would not have purchased Johnson’s® Baby Powder if they had known the “true facts,” they obtained the “full value” of the product before learning the truth so they have not suffered any economic damage from their purchase. Id. at *10

In affirming the District Court’s Order dismissing Laurino’s Amended Complaint with prejudice, the U.S. Court of Appeals for the Third Circuit panel held “Laurino received the drug she was prescribed; the drug did the job it was meant to do (i.e., controlled her blood sugar levels), and it caused no apparent physical injuries.” In re Avandia, 2016 U.S. App. LEXIS 2463, at *7. She received all the desired benefits and was unaffected by any alleged concealment. Id. (quoting Laurino, 100 F. Supp. 3d at 446.). “Under such circumstances, there could be no ascertainable loss.” Id. “[I]n short, Laurino received the benefit of the bargain and accordingly sustained no ascertainable damages under the MMPA.” Id. at *7-8.

While the panel’s opinion was not an opinion of the full Court and does not constitute binding precedent upon courts in the Third Circuit, the current holding among federal courts in Missouri is clear:
Missouri consumers who purchase products, and completely use (and benefit from) such products – in the absence of other physical injury, obtain the full benefit of their bargains and suffer no loss.

See [here](#) for more on pending Missouri legislation affecting the Missouri Merchandising Practices Act.

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[1] The benefit of the bargain rule compares the actual value of the item to the value of the item if it had been as represented at the time of the transaction. *Plubell v. Merck & Co.*, 289 S.W.3d 707, 715 (Mo. Ct. App. 2009).


Related Services: Pharmaceutical & Medical Device

Attorneys: Suzanne Billam

**FDA Issues Draft Guidance Document for Postmarket Management of Cybersecurity in Medical Devices (Part 4 of 4)**

February 26, 2016 | Paul Penticuff

**The Proper Elements of an Effective Postmarketing Cybersecurity Program**

The most practical portion of the FDA’s proposed guidelines is found in the Appendix. In this Section, the agency attempts to bring together all of the concepts from their recommendations into a cohesive summary of the necessary components of a proper cybersecurity program. The section discusses five broad concepts drawn from the NIST Framework: (1) Identify; (2) Protect; (3) Detect; (4) Respond and (5) Recover. All of these concepts are essential to a company’s cybersecurity program.

The first issue is how to properly identify threats. As a medical device manufacturer, this process is rooted in having a solid definition of “essential clinical performance.” As you will recall from Part One, “essential clinical performance” is the “performance that is necessary to achieve freedom from unacceptable clinical risk.” The manufacturer determines the potential severity outcomes if the device is compromised and also the risk acceptance criteria. This allows the manufacturer to properly “triage” potential vulnerabilities for remediation. The concept of essential clinical performance is the main criteria in determining whether or not particular cybersecurity vulnerability requires immediate mitigation or some lesser level of response. It is not enough that the manufacturer simply respond to cybersecurity threats in the field. Manufacturers need to actively engage in identifying cybersecurity signals and handle such vulnerability information in a way that reduces risk.

The second issue is protecting against potential and known threats. This requires a manufacturer to conduct a proper vulnerability characterization and assessment. When measuring the potential exploitability of a known vulnerability, the company should look at “remote exploitability, attack complexity, threat privileges, actions required by the user, exploiting code maturity and report confidence.” Using a scorings system, such as CVSS (“Common Vulnerability Scoring System”) gives additional guidance as to how to quantify the risk and protect against the threat. This is used in risk analysis and threat modeling. “Threat modeling” is an important concept, in that it is a procedure that identifies vulnerabilities and then designs countermeasures to mitigate or eliminate the risk, prior to any actual threat taking place.

The third issue is detecting potential threats in the “real” world. Depending on the sophistication of the device, there may be very little internal ability to detect cybersecurity threats in real time. Networked devices are largely reliant (and dependent) on the security features of the parent network. Non-networked devices face different threats and are often even more vulnerable to threats that evade detection. Manufacturers are encouraged to incorporate design features that “establish or enhance” a device’s ability to detect and capture evidence of a cyberattack. In addition, the company should also have a procedure in place to assess the impact of a cyberattack across the entire device lineup.

The fourth issue is responding to threats. In order to reduce the risk to essential clinical performance, compensating controls must be implemented and provided to users to prevent harm. These remediations include everything from official and permanent fixes to temporary fixes and work-arounds. The company must respond appropriately to threats, while endeavoring to keep important medical devices functional and safe.

The final issue, which is the device manufacturer’s ability to recover following a cyberattack, is really an outgrowth of following the above guidelines. If the company has properly assessed the risk of a particular vulnerability, then the company should develop a response that is appropriate based on the risk to essential clinical performance. If the risk is mitigated, then the device continues to benefit the public, protected from cyberthreats.

In the end, the proposed FDA guidelines are fairly common sense adoptions of accepted cybersecurity principles. Most of the guidelines are industry-led, and the agency leaves manufacturers significant leeway in developing their own cybersecurity policies within the framework of known and accepted industry standards. We will continue to track changes to these recommendations as they are further revised by the agency, with input from both industry and citizen groups.

Read “Part 1 - Background and Overview of Essential Concepts” [here](#); “Part 2 - Risk Assessment and Management in a Dangerous World” [here](#); and “Part 3 - Remediating and Reporting Cybersecurity Vulnerabilities” [here](#).

Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach

Attorneys: Paul Penticuff
FDA Issues Draft Guidance Document for Postmarket Management of Cybersecurity in Medical Devices (Part 3 of 4)

February 22, 2016 | Paul Penticuff

Remediating and Reporting Cybersecurity Vulnerabilities

Manufacturers are required to determine if the residual risk of a cybersecurity vulnerability is “controlled” (acceptable) or “uncontrolled” (unacceptable). Following this initial determination of the seriousness of the risk to “essential clinical performance”, the FDA has recommended a variety of both remediation and reporting requirements. These requirements are logical and pragmatic, in that controlled risk obviously requires a different (lesser) level of response than an uncontrolled risk.

The level of response required is similar to that I experienced with a certain cantankerous 1980 Oldsmobile in my youth. For minor issues, such as random stalling at stop signs, all I needed was a quick hit of carb cleaner and a long shanked screwdriver to loosen the butterfly valve and be on my way. For major problems, I was going to need a tow truck or a fire extinguisher. Trust me, once the fire extinguisher made an appearance, there were definitely “reporting requirements” (at least as to my parents).

The FDA set forth general guidelines for manufacturers before diving into the proper responses to controlled and uncontrolled risks. An initial reminder pointed out that cybersecurity risk management is an ongoing task, and thus, “for cybersecurity routine updates and patches”, the FDA will not require premarket approval, nor will the FDA need to approve software changes. The guidelines went on to list 6 different procedures which manufacturers should adopt as part of their normal course of cybersecurity risk management. Among the guidelines were practicing “good cyber hygiene”, which essentially would ask manufacturers to constantly innovate within the product life cycle to lessen even controlled risks. In addition, manufacturers were encouraged to reduce all vulnerabilities, even those that may not immediately impact essential clinical performance. Software validation was also stressed, as were a variety of communications with users, which would enable them to understand the reasoning behind certain controls and instructions, and thus mitigate their own risks.

The FDA’s guidelines go to recommend procedures to address controlled and uncontrolled risks to essential clinical performance.

In dealing with a “controlled” risk to a device’s essential clinical performance, the manufacturer is obviously dealing with a relatively minor issue. However, this does not relieve the manufacturer from certain overall recommendations, such as the overarching requirement that the company promote good cyber hygiene and constantly work to reduce risk, even controlled risk. As such, the company will have some work to do, even when the risk is controlled. As previously mentioned, when a company enhances the security of a device via a patch or software update, such changes need not be reported to the FDA. The exception to this rule is a PMA device with periodic reporting requirements. In these situations, a manufacturer may need to discuss the specific cybersecurity vulnerabilities in its periodic (annual) report. Examples are provided to assist the manufacturer in determining whether or not the annual report is required. See Section I.A. Assuming the company is pursuing the general goal of having a robust cybersecurity system in place, there is no need for immediate reporting or remediation if the risk is “controlled”.

In sharp contrast, an “uncontrolled” risk to a device’s essential clinical performance is a much more serious threat to the user of the device, and thus, the manufacturer has been given more extensive guidance and stricter requirements for both remediation and reporting. In Section IV. B., the FDA begins by requiring remediation of the vulnerabilities which will lower the risk to essential clinical performance “to an acceptable level”. First and foremost, the manufacturer is tasked with fixing the vulnerability. The FDA recognizes that an immediate fix may not be available, so the manufacturer should implement work-arounds and temporary fixes to mitigate risk in the short term. These immediate fixes should be communicated to users so they can take appropriate steps to mitigate their own personal risk.

As to reporting uncontrolled risk, there are a variety of decision trees at work here, depending on the type of device. Initially, manufacturers must report vulnerabilities to the FDA, depending on a variety of conditions, set forth in the 3rd bullet point of Section IV. B. Following an assessment of the need for immediate reporting, the FDA noted that Class III devices must include a report on the remediation in the annual report. For all PMA devices, the information regarding the cybersecurity vulnerability, the device changes and any compensating controls should be reported in the periodic (annual) report. (See Section VIII. for the list of suggested topics in the PMA Periodic Report.) In addition, a manufacturer should take a close look at any device changes during remediation to determine whether or not there is a need to submit a premarket submission, such as a supplement to the PMA or 510k.

The FDA noted that remediation was critical when the uncontrolled risk to clinical performance “may be considered to have a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death.” In such cases, the agency stated that the product could be held to be in violation of the Food, Drug and Cosmetic Act and subject to enforcement. If this situation arises, it would be similar to any other known risk and the strictures of the act could require the company to take swift action to protect the public.

Stay tuned for the final part of this four part series “Proper Elements of an Effective Postmarketing Cybersecurity Program” coming soon. Read “Part 1 - Background and Overview of Essential Concepts” here and “Part 2 - Risk Assessment and Management in a Dangerous World” here.

Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach

Attorneys: Paul Penticuff
Risk Assessment and Management in a Dangerous World

Manufacturers of medical devices are faced with ever-increasing cyberattacks that could impact patient safety and the efficacy of useful devices. One insurance group identified cyberthreats to medical devices as "open and growing," describing a difficult "real world" scenario involving implantable defibrillators. The article noted that a variety of critically helpful medical devices could have been impacted by hackers seeking to extort money, or, in a darker scenario, cause harm to patients. Clearly, an individual willing to cause harm to people by gaining control of a medical device could not only hurt individual patients, but also create panic in patient groups who are in need of medical devices to maintain good health. If patients come to distrust medical devices, their rejection could severely impact the medical community's ability to effectively treat certain diseases and acute medical issues. As such, it is critical that manufacturers engage in appropriate risk management, which protects consumers from losing viable health care options, as well as preventing serious attacks on the safety of individual patients.

The FDA’s draft guidelines would require manufacturers to include “risk analysis, risk evaluation (and) risk control” as a part of the lifecycle management of a medical device. The process must focus on “assessing the risk to the device’s essential clinical performance.” (emphasis in original) In looking at the risk, the manufacturer must consider “(1) the exploitability of the cybersecurity vulnerability, and (2) the severity of the health impact to patients if the vulnerability were to be exploited”. The FDA clearly is looking at a risk/benefit analysis that focuses on the likelihood the risk can be exploited and the relative severity of the health impact to patients in the event the of such exploitation. In assessing the vulnerability of a medical device, the FDA recommends using a vulnerability scoring system which provides a ranking that ultimately is translated into low, medium and high degree of vulnerability to exploitation. While there are several such scoring systems, the agency quotes from the “Common Vulnerability Scoring System, Version 3.0” as a useful tool. This tool looks at a myriad of factors, including: attack vector, attack complexity, privileges required, user interaction, scope, confidentiality impact, integrity impact, availability impact, exploit code maturity, remediation level and report confidence. In utilizing these concepts, the scoring system ultimately allows the manufacturer to plot the vulnerability of its product as low, medium or high.

The other side of the ledger is assessing the severity of the impact to the patient's health, if the vulnerability were exploited. Again, the agency does not require a specific system, but it does quote from "ANSI/AAMI/ISO 14971: 2007/(R)2010: Medical Devices—Application of Risk Management to Medical Devices. This assessment tool rates the health impact in five categories: Negligible; Minor; Serious; Critical; and Catastrophic. Obviously, the severity of health impact increases up the continuum.

When a manufacturer assesses both the Exploitability of the vulnerability and the Severity of Impact the Health (if Exploited), it can plot the points graphically and gain additional understanding regarding the severity of the risk. Obviously, even a low level of Exploitability must be monitored and readied for remediation if the severity of impact to health is catastrophic. Likewise, a potentially high Exploitability number may not be problematic when compared to a negligible or minor risk. The scale is not rigid. The current draft recommends that "manufacturers make a binary determination that the vulnerability is either controlled or uncontrolled using an established process that is tailored to the product, its essential clinical performance and the situation."

The graph below demonstrates an example of how a company could plot these numbers and utilize the matrix to assist in developing a plan from remediation.


Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach

Attorneys: Paul Penticuff

FDA Issues Draft Guidance Document for Postmarket Management of Cybersecurity in Medical Devices (Part 1 of 4)

February 15, 2016 | Paul Penticuff

Background and Overview of Essential Concepts
As part of the increase in cybersecurity issues in an increasingly networked society, the FDA has decided to provide medical device manufacturers with structure and specificity in its quest to counter threats to patient safety. Although most of the recommendations offer industry a chance to self-police relatively minor security issues, the agency has proposed that a small subset of vulnerabilities “may compromise the essential clinical performance of a device and present a reasonable probability of serious adverse health consequences or death” and would thus require that manufacturers notify the FDA of imminent threats to the public health.

The genesis of this highlighted commitment to cybersecurity is rooted in Executive Order 13636 – Improving Critical Infrastructure Cybersecurity (Feb. 19 2013), in which cyberthreats to the nation’s welfare were highlighted, specifically including public health and safety as an area of concern. As a part of this mandate, Presidential Policy Directive 21—Critical Infrastructure Security and Resilience (Feb. 12, 2013) tasks all government entities and private stakeholders to accept responsibility for strengthening the nation’s infrastructure, including the security of medical devices. In response, industry has created a general framework of best practices, standards and guidelines to address cybersecurity concerns. In order to foster cooperation within industry, Information Sharing Analysis Organizations (ISAOs) will serve as both focal points for discussion as well as storehouses for the collective wisdom of private sector collaboration.

Following this overview, we will focus three major areas of concern for the FDA, (1) risk assessment (2) remediating and reporting vulnerabilities and (3) the elements of an effective postmarketing cybersecurity program.

In order to understand the more practical aspects of the FDA’s focus, we must first become familiar with several important concepts. Chief among these concepts is the idea of protecting “essential clinical performance”. Essential clinical performance is “performance that is necessary to achieve freedom from unacceptable clinical risk, as defined by the manufacturer.” It is up to the manufacturer to set proper guidelines for acceptable performance, the potential severity of outcomes if performance is compromised and risk acceptance criteria. The essential clinical performance of the device often determines the relative risk of potential vulnerabilities. The FDA stated that a cyberthreat to a thermometer is far less that the potential threat caused by a threat to an insulin infusion pump because of the clear difference in the impact of a degradation of the essential clinical performance of the respective devices. Whereas a near total failure of a thermometer would be unlikely to impact patient safety, any variation in the amount of insulin delivered by an infusion pump would have an immediate impact on the patient’s blood glucose level.

Once a manufacturer determines the essential clinical performance of a device, the manufacturer must not only be on the lookout for potential threats to the device, but also the vulnerabilities within the device. Threats are broadly defined as “any circumstance or event with the potential to adversely impact the essential clinical performance of the device...” Threats also include things that would impact organizational operations, organizational assets, individuals or other organizations. Such threats could be impact an information system “via unauthorized access, destruction, disclosure, modification of information, and/or denial of service.” Threats exploit “vulnerabilities”, which are defined as “weakness(es) within the information system, system security procedures, internal controls or implementations”. Essentially, the remainder of the guidelines focus on creating a practical roadmap for manufacturers in both dealing with cyberthreats and meeting new FDA reporting requirements. The ultimate goal is to keep safe and effective products on the market, knowing that some may have various levels of vulnerability to cyberattack. With proper risk assessment, threat modeling, remediation and postmarketing surveillance, a medical device company should be able to promote patient safety and continue to make medical devices safer in a dangerous world.

Stay tuned for “Part Two of Four – Risk Assessment” coming soon.

Related Services: Pharmaceutical & Medical Device, Cyber Liability, Privacy & Data Breach

Attorneys: Paul Penticuff

Forget the Pitchers - The H.E.A.T. Team Brought the Real Heat in October

November 10, 2015

October is a magnificent month. The leaves change, bringing forth gorgeous colors seen only in Autumn. And then as temperatures drop, the ghosts and goblins come out to play. And of course we have post-season baseball. During the World Series this year, Mets pitcher Noah Syndergaard garnered a lot of attention by throwing the first pitch of Game 3 high and tight past Alcides Escobar. Mr. Syndergaard later explained that he intended the pitch to send a message. Although they may not admit it, the message might have worked because it was the only game the Royals lost in the World Series.

But this October, none of the fastballs thrown by the post-season pitchers compare to the heat brought by the Department of Justice’s Health Care Fraud Prevention and Enforcement Action Team initiative (the DOJ ignores the “C” in “Care,” the “F” in “Fraud” and the “P” in “Prevention” and simply calls it the “HEAT initiative”). In October 2015, the HEAT team sent messages louder than a high and tight fastball to the health care industry.

In October, the first month of the 2016 fiscal year, the DOJ announced HEAT initiative settlements totaling $719,750,000. The settlements ranged from $3 million by a hospice group up to $256 million against a urine drug and genetic testing laboratory. Mixed in were two other nine figure settlements. First, there was a $125 million global settlement with Warner Chilcott U.S. Sales LLC for alleged Anti-Kickback and False Claims Act violations. Second, on the last business day of the month, the DOJ announced that 457 hospitals would pay over $250 million to resolve False Claims Act allegations concerning the implantation of cardioverter defibrillators.

Not only do the settlements range widely in amounts, they also cover a broad scope of alleged improper conduct. For instance, the
FDA's New Draft Guidance Concerning Animal Studies for Medical Devices Makes "Strong" Recommendations

October 22, 2015

Results of animal studies are frequently used by both plaintiffs and defendants in medical device litigation. Each side uses studies to support certain themes or to refute the strength or validity of the opposing side’s studies. Because animal studies can provide key evidence of the safety and efficacy of the devices at issue, adherence to regulatory and industry standards and recommendations can be beneficial.

On October 14, 2015, the FDA issued a draft guidance document titled “General Considerations for Animal Studies for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff.” If the guidance document becomes final, it will supersede the July 29, 2010, guidance titled “Guidance for Industry and FDA Staff: General Considerations for Animal Studies for Cardiovascular Devices.”

In the draft guidance, the FDA expands the scope beyond prior guidance documents and makes a couple of “strong” recommendations to the device industry about animal testing. Because the FDA must think simple “recommendations” might be ignored, twice in the draft guidance the FDA “strongly recommends” certain actions. First, the FDA “strongly recommends” that members of industry “work with a pathology expert such as a veterinarian boarded by the American College of Veterinary Pathology to develop the study protocol.” Later, the FDA “strongly recommends” that submitting parties “conduct definitive animal studies on the market ready device except as required to scale, if needed, to implant in the animal model.”

This second “strong recommendation” is part of a theme repeated in the draft document. In the draft document, the FDA emphasizes that submitting parties should use the “market ready device” (mentioned twice) or the “final clinical design” (used twice in the same paragraph) or the “final design” (used in bold type in Appendix B: Sample Decision Tree for Medical Device Animal Studies question 2). So, not only has the Agency made it a “strong recommendation,” it has also emphasized the strength of the
recommended shortly after she started taking metoclopramide in 2004. Attempting to circumvent governing Iowa law. As for the generic manufacturer, Pliva, both the Iowa trial court and the appellate court agreed that each of Huck's claims were preempted under number of product liability theories against both sets of defendants, including claims for breach of warranty, negligence, fraud, and misrepresentation. The branded manufacturer has failed to timely update a label with new FDA-approved safety information.

The new draft guidance document is not limited to cardiovascular devices. Rather, FDA intends the new guidance to apply to all "medical devices intended for use in humans, as defined in section 201(h) of the Federal Food, Drug and Cosmetics Act (FD&C Act)." The new guidance will "apply to animal studies submitted in support of an IDE application, premarket approval (PMA) application, premarket notification (510(k)), humanitarian device exemption (HDE) application, or a request for de novo classification." Thus, this new guidance will apply to far more devices than the existing guidance.

Because the new draft guidance applies to more categories of devices, the draft guidance has deleted language from the existing guidance which applied only to cardiovascular devices. Additionally, the draft guidance contains numerous format and stylistic changes including moving certain statements from one section to another or one paragraph to another.

But the new draft guidance also makes a number of substantive changes as well. For instance, in the "Overview" section, FDA expressly states that for animal studies being submitted to Agency to support the safety of a device, Good Laboratory Practice (GLP) 21 C.F.R. Part 58 applies.

In the existing guidance for cardiovascular devices, FDA merely stated that submitting parties "should follow Good Laboratory Practice (GLP) for all animal studies involving cardiovascular devices that are to be submitted to the Agency." In FDA parlance, "should" means that "something is suggested or recommended, but not required."

The new draft guidance repeatedly emphasizes that compliance with GLP and Part 58 is required. In the new "Study Assurances" section, the FDA states bluntly that "animal studies that are intended to support the safety of a medical device must comply with the GLP requirements detailed in 21 CFR Part 58." Unlike the existing guidance which does not use the word "must" at all, the draft guidance uses the word "must" three more times in the first paragraph of the "Study Assurances" section alone. In short, the FDA makes a clear shift to requiring compliance with specific subsections of Part 58.

Another new theme throughout the draft guidance is that the FDA repeatedly encourages industry participants to use the Pre-Submission Program before undertaking the animal studies. See the FDA guidance issued on February 18, 2014 titled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff." The existing guidance document mentioned the former Pre-IDE program only once and that was only if the submitting party "would like FDA feedback on your proposed animal study strategy."

For instance, in Appendix B, the Sample Decision Tree for Medical Device Animal Studies, the Agency has added a new question. The new question asks whether "the risk analysis suggest than an animal study is necessary to assess potential safety problems." If yes, then the party can move to the next question. If not, then the party should "consider submitting a Pre-Submission and request FDA feedback."

Interested parties have 90 days from the publication of the draft guidance in the Federal Register to submit comments or suggestions concerning the draft.

Related Services: Pharmaceutical & Medical Device, Product Liability

Kicking the Can Down the Road: The U.S. Supreme Court Denies Certiorari in "Failure to Update Labeling" Case Against Generic Drug Manufacturer

May 20, 2015 | Paul Penticuff

Sometimes, a Magic 8 Ball is just as good as the highest court in the land when it comes to providing answers to difficult questions. In the case of determining whether or not "failure to update labeling" claims are preempted, the United States Supreme Court picked “Better not tell you now”. After the United States Supreme Court denied generic drug manufacturer Pliva’s petition for certiorari in Pliva, Inc. v. Huck (Docket No. 14-544), manufacturers have no resolution on the issue of whether failure-to-update labeling claims against generic drug manufacturers are preempted under the Court’s earlier holding in Pliva, Inc. v. Mensing, 131 S. Ct. 2567 (2011). Further compounding the confusion, there is a jurisdictional split regarding the reach of Mensing and whether it operates to preempt state-law failure-to-warn claims based on the theory that a generic drug manufacturer has failed to timely update a label with new FDA-approved safety information.

In Huck, just as in Mensing, the plaintiff alleged that she developed tardive dyskinesia after ingesting Pliva’s metoclopramide, the generic form of the prescription drug Reglan. When she began taking the medicine in 2004, the labeling warned that the drug was not was approved for therapy longer than 12 weeks and that tardive dyskinesia, a severe neurological disorder, was a possible side effect of treatment. Approximately 5 months later, the FDA approved an update to the brand name label, which included a bolded warning advising that the medicine should not be used for more than 12 weeks. Ms. Huck continued taking generic metoclopramide for another two years. Pliva never updated its labeling to provide the bolded warning.

Following her use of metoclopramide, Ms. Huck developed tardive dyskinesia, prompting her to sue both the branded and generic manufacturers of Reglan. She raised a number of product liability theories against both sets of defendants, including claims for breach of warranty, negligence, fraud, and misrepresentation. The branded manufacturers were dismissed early the proceedings, successfully arguing that, because Huck never took branded Reglan, she could not prove legal causation under governing Iowa law. As for the generic manufacturer, Pliva, both the Iowa trial court and the appellate court agreed that each of Huck’s claims were preempted under Mensing. Huck v. Trimark Physicians Group, No. 3-129, 12-0596, 2013 Iowa App. LEXIS 435 (Iowa Ct. App. Apr. 24, 2013). Importantly, both courts rejected plaintiff’s attempt to circumvent Mensing by arguing that Pliva’s liability should rest on its failure to update its labeling to include a boldface warning about duration of use, which FDA
Franzman v. Wyeth, Inc., et al.

October 16, 2014

In Franzman v. Wyeth, Inc., et al., case number ED100312, the Missouri Court of Appeals for the Eastern District recently reversed the trial court’s judgment in favor of the manufacturers of the generic form of Reglan (the “Generic Defendants”) on the portion of Franzman’s failure-to-warn claim relating to the Generic Defendants’ failure to update their warning labels to reflect the 2004 brand-name label revision. Importantly, the Missouri Court of Appeals held that this failure-to-warn claim was not pre-empted under the United States Supreme Court’s decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

In 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a labeling change to add a bold-face warning that: “Therapy should not exceed 12 weeks in duration.” After this change was made to the brand-name label, various generic manufacturers (including, Franzman alleges, the Generic Defendants) failed to update the warning label on their products to match the new FDA approved warning.

The Generic Defendants argued that all state law failure-to-warn suits against manufacturers of generic drugs may be summarily dismissed under Mensing. However, the Court determined that Mensing does not provide blanket immunity. Instead, the Court stated that the proper analysis was to consider whether a conflict exists between the relevant state law and federal law in order to determine if simultaneous compliance by the Generic Defendants was possible or impossible.

Under the relevant state law (Kentucky), drug manufacturers have a duty to adequately warn of the foreseeable risks associated with the use of their product. Kentucky courts have defined an adequate warning as one “sufficient to apprise the general practitioner as well as the ‘unusually sophisticated medical man’ of the dangerous propensities of the drug.” Larkin v. Pfizer, Inc., 153 S.W.3d 758, 764 (Ky. 2004). Franzman alleged that the Generic Defendants failed to adequately warn of the dangers of long-term use of metoclopramide (the generic form of Reglan) by failing to update their label to conform to the Reglan label revision approved by the FDA in 2004. Thus, the warning label on the generic drug ingested by Franzman did not include the same bold-face warning language. The Court reasoned that while the Generic Defendants were limited with respect to the warnings they could provide by their “federal duty of sameness”, as described in Mensing, federal law did not prohibit the Generic Defendants from updating their label to conform to the 2004 Reglan label revision. Put another way, the Court determined that it was not impossible for the Generic Defendants to comply with their duties under Kentucky state law and fulfill their duty under the FDCA by updating their label to conform to the 2004 revision. The Court concluded that Franzman’s state law failure-to-warn claim was not preempted by federal law to the extent her claim is limited to the Generic Defendants’ failure to adopt the additional wording language approved in 2004. The Court affirmed the trial court’s judgment in favor of the Generic Defendants in all other respects.

The take-away from this decision is that despite the preemption principles set forth in Mensing, one must analyze whether it is possible or impossible to comply with both state and federal law with regards to warning labels.

Also of interest, the Court of Appeals affirmed the trial court’s grant of summary judgment in favor of the Brand Defendants because under Kentucky product liability law, the Brand Defendants’ product was not the legal cause of Franzman’s injuries. Franzman admitted that she only ingested generic metoclopramide, and innovator liability is not the...
law in Kentucky.

Related Services: Healthcare, Pharmaceutical & Medical Device, Product Liability

**Weeks II: Alabama bucks the trend and accepts the Innovator-Liability Theory**

October 10, 2014

On August 15th, the Alabama Supreme Court endorsed the theory of “innovator liability” and held for the second time in *Wyeth, Inc. v. Weeks*, 2014 Ala. LEXIS 109 (Ala. Aug. 15, 2014), that a plaintiff who took only the generic version of the heartburn medication Reglan could still make a claim against the brand-name manufacturers. Plaintiff Danny Weeks brought suit against the generic and brand-name manufacturers, claiming he developed tardive dyskinesia, a movement disorder, after using generic Reglan.

The *Weeks* case was originally decided in January of 2013. In that opinion, the Alabama Supreme Court held that brand drug manufacturers could be liable for injuries caused by generic drugs because the warnings and labels relied on were those of the brand drug. The Alabama court agreed in June 2013 to reconsider its previous decision. In concluding once again that the brand-name manufacturers could be held liable under Alabama law, the court emphasized that, under these circumstances, liability is premised not on product defect, but on the alleged misrepresentations in the brand-name product's labeling, which FDA regulations require generic manufacturers to use.[1](#)

See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (state-law failure-to-warn claims against generic drug manufacturers are preempted by federal law because the generic manufacturers are required to utilize the same labeling as the equivalent branded drug).

Despite the fact that the court did, in practical terms, accept the “innovator liability” theory, the court stated that it was not creating a new tort of "innovator liability" or "turning products-liability law . . . on its head" because the ruling applies only to brand-name and generic drug manufacturers, which the court says have a "unique relationship" due to the distinctive federal statutory and regulatory framework in which they operate.

There were three dissenting opinions. Chief Justice Moore took the position that the court should not have addressed the issue because "critical facts" were not before the Court. Justice Parker stated that "nothing in federal legislation or regulations at issue here requires this Court to ignore, modify, or override our bedrock legal principles of duty and privity with regard to the originator of a pharmaceutical drug and a consumer who has not consumed a drug manufactured by the originator of the drug." He warned that the Court’s modification of these principles could have “grave and unforeseen effects in other areas.” Justice Murdock opined that plaintiffs’ inability to hold a generic drug-maker accountable after the U.S. Supreme Court decided *PLIVA, Inc. v. Mensing*, “is not a ‘wrong’ that this or any court should attempt to correct with a second ‘wrong.’”

The Alabama Supreme Court’s position remains the minority view at this time. The vast majority of courts to address this issue have rejected the innovator-liability theory. To date, Alabama (*Weeks*), California (*Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008)), Vermont (*Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010)) and Illinois (*Dolin v. SmithKline Beecham Corp.*, No. 12 C 6403, 2014 WL 804458 (N.D. Ill. Feb. 28, 2014)) are the only states with opinions to the contrary. The Sixth Circuit Court of Appeals rejected *Dolin*, however, holding that the Illinois Supreme Court would not hold brand-name manufacturers liable for injuries caused by generic drugs. See *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 2014 WL 2959271 at *22-24 (6th Cir. June 27, 2014). There are cases from the following jurisdictions (primarily decisions in which federal courts are predicting state law) rejecting the innovator-liability theory:

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What is clear from these differing opinions is that while the innovator-liability theory has gained traction in some state courts, federal courts are continuing to reject it. We can expect this theory to remain hotly debated for the foreseeable future, but it is already apparent that this theory is not likely to be successful in most federal courts.

Related Services: Healthcare, Pharmaceutical & Medical Device, Product Liability

**FDA proposes a new layer of regulation for laboratory developed tests**
The Food and Drug Administration (FDA) announced its intention to expand the regulation of laboratory developed tests (LDTs). LDTs identify patients’ individual reactions to pharmaceutical treatments, so medical providers can prescribe the best treatment for the particular patient. Unlike medical devices from traditional manufacturers, LDTs are designed, manufactured, and used within a single laboratory. On July 31, 2014, the FDA notified Congress of the agency’s potential framework for regulating LDTs. Review the FDA’s description of the framework’s anticipated details to Congress here.

The FDA heralded the expanded regulatory framework as a commitment to personalized medicine. The FDA’s hope is that laboratories will identify the need for LDTs early in the drug development process. Early evaluation allows the drug and its companion test to be developed at the same time.

The FDA proposes to regulate LDTs based on the existing medical device classification system. High-risk LDTs will be subject to registration and listing (or notification), adverse event reporting six months after the guidance is finalized, and premarket review requirements twelve months after the guidance is finalized. Moderate-risk LDTs will be subject to registration and listing (or notification), and premarket review requirements five years after the guidance is finalized. LDTs that are traditional, low-risk, for rare diseases, or for unmet needs will be subject to registration and listing (or notification) and adverse event reporting.

One major issue with the FDA’s expanded role is that LDTs are already subject to other regulation. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires clinical laboratories to conduct laboratory tests and report them to the Centers for Medicare & Medicaid Services. Critics of the FDA’s expanded regulatory role argue that imposing two levels of regulation will stifle innovation, thereby limiting patient access to effective treatment. If the FDA’s framework is finalized, laboratories will have to send different reports to the FDA and the Centers for Medicare & Medicaid Services. Expanding CLIA instead could have improved the safety of personalized medicine without creating multiple layers of regulation.

Proponents of the FDA’s expanded role in LDTs argue that high-risk diagnostic tests should be regulated the same, regardless of whether created by traditional manufacturers or single laboratories. The new framework imposes regulatory requirements on LDTs like the requirements for medical devices from traditional manufacturers. The FDA’s stance is that the current regulatory framework fails to properly address the safety and effectiveness of LDTs.

The FDA plans for an upcoming 90-day public comment period after it releases its draft guidance. The FDA will host a public meeting during the comment period. The agency will publish notices for both the comment period and the meeting in the Federal Register.

After the FDA releases its draft guidance, we will post a link to both the draft guidance and the comment form on this blog.

**Related Services: Pharmaceutical & Medical Device**

**FDA Proposes Social Media Guidelines for Pharmaceutical and Medical Device Companies**

**July 3, 2014**

On June 17, the FDA released a draft guidance proposing guidelines for how manufacturers, packers, and distributors should present prescriptions and medical devices on internet/social media platforms with character space limitations, and guidelines regarding how a company may correct misinformation created or disseminated by independent third parties on FDA-approved or cleared products.

**Guidance for Industry: Internet/ Social Media Platforms with Character Space Limitations- Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices**

In its guidance, the FDA notes that promotional labeling for drugs and devices and advertisement for prescription drugs and restricted devices can misbrand the product if representations about the use of the product are made without disclosing certain information about the product’s risk. The draft guidance sets out provisions companies should consider to create a balanced presentation. Risk information should be comparable in content and prominence to benefit claims to achieve a balanced presentation. The FDA acknowledges the difficulty companies may face in presenting necessary information on products with complex indications or extensive serious risks, especially on Internet/social media platforms with character space limitations. Therefore, the FDA advises if an accurate and balanced presentation of risks and benefits of a product are not possible within the character limits, the company should reconsider using that platform.

The guidelines set out three sections for consideration in presenting risk and benefit information on Internet/social media platforms with character space limitations. The sections include: general factors that companies should consider in the communication of benefit information, factors that the FDA considers in disclosure of risk information, and additional recommendations for the inclusion of other product information.

**General Factors:** Benefit information should be accurate and non-misleading and reveal material facts within each individual character-space-limited communication. Benefit information should be accompanied by risk information. If a company finds that adequate benefit and risk information, and other required information, cannot be communicated within the character space limitations, the company should consider a different platform.

**Factors Considered in Disclosure of Risk Information:** Risk information should be presented together with benefit information in a posting. The FDA encourages, at a minimum, a company should include the most serious risks associated with the product. A concise disclosure of specific risk information should be presented together with benefit information. The FDA acknowledges that a company may face constraints because of character space limitations, therefore, they suggest a mechanism, such as a hyperlink, be provided to allow direct access to a more complete discussion of risk information. Risk information should be comparable to the benefit information, including formatting.

**Additional Recommendations for the Inclusion of Other Product Information:** The FDA recommends the established name accompany the trade or brand name of the product. Additionally, the name of at least one specific dosage form and the quantitative ingredient information should be provided. The FDA suggests that companies include the generic name of the product directly to the right of, or directly below, the brand name and at least display at least one dosage form and quantitative ingredient information.
on the land page associated with the hyperlink. The FDA notes that common abbreviations, punctuation marks, and other symbols may be used to address character space limitations.

It should be noted that the FDA states in the draft guidance that these suggested regulations do not address promotion via product websites, webpages on social media, and online web banners, as they do not impose the same character space constraints, such as twitter.

**Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices**

The second draft guidance released by the FDA responds to stakeholder’s requests for guidance regarding a company’s voluntary correction of misinformation created or disseminated by independent third parties. The FDA acknowledges that it may benefit the public health for companies to correct misinformation about their products. The FDA notes that the draft guidelines do not apply to communication owned, controlled, created, or influenced, or affirmatively adopted or enforced, by, or on behalf of, the company. The draft guidance sets out suggestions for companies to correct misinformation in a truthful and non-misleading way.

**Appropriate Corrective Information:** The FDA suggests that a company’s corrective information should be relevant and responsive to the misinformation, limited and tailored to the misinformation, non-promotional in nature, tone, and presentation, accurate, consistent with FDA- required labeling, supported by sufficient evidence, and discloses the person providing the corrective information’s affiliation with the company. In the alternative, the FDA suggests a company can provide a reputable source from which to obtain the correct information.

**Correcting a Clearly Defined Portion of a Forum:** Because a firm may not be able to correct all misinformation about its product in a single forum, a company should identify the misinformation it is choosing to correct in the forum, define the portion of the forum it is correcting, and describe the location or the nature of the misinformation that was corrected and should provide a date the correct is made to be sure that parties do not assume the company responded to the whole forum.

**Approaches to Correcting Misinformation:** A company may choose to correct misinformation directly on the forum, provide the corrective information to the independent author, or request that the site administrator remove the misinformation or allow comments to be posted. The FDA acknowledges that they will not hold a company accountable for an independent third party’s subsequent actions or lack thereof.

The FDA does not expect a company to continue to monitor the third-party website or communication once they have undertaken to correct the misinformation. Additionally, as long as the correction of misinformation is truthful and non-misleading pursuant to the recommendations by the FDA in the draft guidance the FDA does not intend to object to the voluntary corrections even if they do not satisfy otherwise applicable regulatory requirements. The FDA does provide a warning that “If a firm chooses to provide information outside the scope of this draft guidance, the firm should ensure the information it provides complies with any applicable requirements related to labeling or advertising.” Lastly, the FDA does not expect companies to submit corrections; however they do recommend that companies keep records to assist in responding to questions that may come from the FDA.

*Related Services: Pharmaceutical & Medical Device*

**Drager v. PLIVA USA, Inc.: Fourth Circuit Explicitly Rejects “Stop Selling” Attempt to Avoid Generic Preemption**

February 19, 2014 | Angela Higgins

The Fourth Circuit has recently weighed in on a generic drug maker’s duties in a post-Bartlett and PLIVA v. Mensing world. In *Drager v. PLIVA USA, Inc.*, 2014 U.S. App. LEXIS 1696, 2014 WL 292700 (4th Cir. Jan. 28, 2014), plaintiff conceded that his failure to warn claims against the generic manufacturer of metoclopramide (generic for Reglan®) were preempted, but argued that other claims remained viable.

First, plaintiff alleged that his claims of “negligent testing, inspection, and post-market surveillance” escaped preemption. The Fourth Circuit found that any duties to test, inspect, or conduct post-market surveillance were only actionable to the extent that there was an eventual sale to the consumer. To the extent that state law might impose a duty to avoid the negligent marketing and sale of a product,

\[\text{[It] is clear that a generic drug manufacturer whose product is unreasonably dangerous as sold could not satisfy that duty without changing its warnings, changing its formulation, exiting the market [the “stop selling” theory], or accepting tort liability.}\]


The *Drager* court noted that the U.S. Supreme Court has rejected the “change warnings” argument (*PLIVA v. Mensing*) and the “change formulation” argument (*Bartlett*). This leaves either “stop selling” or accept liability. The Fourth Circuit found that the negligence claims were preempted by the FDCA, because there was no possible way for PLIVA to comply with state and federal law and continue to sell its product.

The Fourth Circuit rejected the strict liability claim for the same reasons. PLIVA was authorized to market metoclopramide with the labeling and formulation approved by the FDA, and was not permitted to change the labeling or the formulation. This leaves only “stop selling” as an option to avoid the imposition of strict liability. The Fourth Circuit expressly held that “the stop selling rationale is an impermissible means of avoiding preemption under *Bartlett.*” *Drager*, 2014 U.S. App. LEXIS 1696 at *14.

Regardless of whether a risk-utility or consumer-expectations approach to liability is used, if the drug is FDA-approved but “unreasonably unsafe,” there is no change that the generic manufacturer can take under FDA regulations to comply with state law, and the manufacturer “cannot be required to stop selling its product.” *Id.* at *15. The court rejected plaintiff’s breach of express warranty, misrepresentation, and fraudulent concealment claims for the same reason – if the manufacturer’s only option to avoid liability is to leave the market, the claim is preempted. *Id.*

*Drager* is a well-reasoned opinion on preemption issues. The opinion also presents a clearly-articulated analysis of the implications of plaintiffs’ claims against generic
manufacturers, correctly noting that the essence of these claims is that the manufacturer should exit the market, an argument that the court emphatically rejected.

Related Services: Pharmaceutical & Medical Device

Attorneys: Angela Higgins

**Thompson v. Allergan: Further Eroding "Alternative Feasible Design" in Drug Cases?**

February 12, 2014 | Angela Higgins

As we previously wrote, the Supreme Court’s recent decision in *Mutual Pharmaceutical Co. Inc. v. Bartlett* raised the intriguing possibility that federal courts might be receptive to arguments by name brand pharmaceutical manufacturers that “feasible safer alternative design” arguments are preempted in product liability cases, due to the comprehensive nature of the FDA’s oversight of prescription medications.

*Bartlett* is expressly limited to the generic drug context, but in that opinion the Court found two reasons that redesign of the generic drug was not possible. The first was that the generic must be equivalent to the branded drug. The second, and far more interesting analysis, noted that any alteration to the chemical composition of the drug (the alternate design that is proposed to be “feasible” and “safer”) results in an entirely different drug that would require new FDA approval.

The U.S. District Court for the Eastern District of Missouri has recently issued an opinion, relying on *Bartlett*, that arguably takes us a step closer to this result for branded drugs. The case is *Thompson v. Allergan USA, Inc.*, 2014 U.S. Dist. LEXIS 10081, 2014 WL 308794 (E.D. Mo. Jan. 28, 2014).

*Thompson* was a putative class action brought by consumers who challenged the dosage regimen of the eye drop Restasis®. Plaintiff contended that the single-use vials of Restasis® contain more than the prescribed dosage of a single drop of the medication per eye, but that prescribing information required them to discard the excess medication after administering a single dose. Plaintiff claimed that she and other Missouri consumers suffered economic damages as a result of the waste created by the packaging of Restasis®, which she argued resulted in an unnecessarily high price for the medication. Plaintiff brought claims on behalf of herself and a purported class of Missouri consumers for violations of the Missouri Merchandising Practices Act (“MMPA”), unjust enrichment, and money had and received.

*Thompson* is not a product liability case, and plaintiff did not advance a theory of a “feasible safer alternative design.” Plaintiff did, however, argue that Allergan should have made use of an alternative design for its product that eliminated the waste occasioned by the dosing regimen and the requirement that the vials be discarded after a single use. Plaintiff argued that each single-use vial should have contained less medication.

Allergan argued (1) that plaintiff failed to state a claim, and (2) that federal law preempted plaintiff’s claims because Allergan was unable to reduce the amount of medicine in each vial without prior FDA approval. The court’s disposition of the failure to state a claim argument is consistent with the existing body of law with respect to “unfair practices” acts like the MMPA, finding that the plaintiff received the “benefit of the bargain” and that Allergan did not misrepresent what it was selling.

The district court explicitly relied upon *Bartlett* for its analysis of the preemption argument. The *Thompson* court found that plaintiff’s claim was preempted because Allergan was not permitted, under FDA regulations, to lower the volume in each vial of Restasis® on its own initiative without FDA approval. 2014 U.S. Dist. LEXIS 10081, *15–16*. The court also, notably, rejected plaintiff’s argument that Allergan bore the burden of proving that the FDA would have denied a request to make the volume change, another pet theory that plaintiffs advance in “feasible alternative design” product liability cases, and did so by relying upon *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011) (a generic labeling case).

*Thompson*, while not a product liability case, is notable both for its holding that “alternative design” arguments with respect to FDA-approved medications were preempted, and for drawing upon *Bartlett* and *PLIVA* in a “brand name” drug case. We have long argued that drug design defect claims, whether they are directed at generic or branded drugs, should be barred as a matter of law, because any “alternative design” of a drug is an entirely different drug from the one approved by the FDA. Any finding that a drug is “defectively designed” is simply an opinion that the FDA should never have approved the drug, which is preempted. We think the district court reached the correct result, and will monitor this case for any appellate developments.

Related Services: Pharmaceutical & Medical Device

**A Winning Strategy: Using Publicly Available FDA Documents in a 12(b)(6) Motion to Dismiss is Advantageous**

February 10, 2014

In *Poll v. Stryker Sustainability Solutions, Inc., et al.*, the U.S. District Court for the District of Arizona notably held that courts may take judicial notice of documents on the FDA’s website when considering a motion to dismiss, 2014 U.S. Dist. LEXIS 6309 (D. Az. Jan. 17, 2014). Plaintiff Jeffrey Poll brought strict liability, breach of express warranty, implied warranty, negligent failure to warn, products liability failure to warn, and products liability defective design claims against Defendant[4] alleging injuries and damages arising out of the use of a hip resurfacing device consisting of the Cormet Cup and Cormet Head (the “Cormet System”), a Class III medical device under the FDCA.

In his Complaint, Plaintiff did not cite to the FDA documents -- the Cormet System approval letter, the Summary of Safety and Effectiveness, the labeling and instructions for use, and the Cormet System supplemental PMA approvals -- even though they were available to the public. However, when Defendants filed their Motion to Dismiss, they attached these documents. Plaintiff argued that Defendants’ Motion to Dismiss was converted into a Motion for Summary Judgment because it contained cites to, and relied on, materials and facts outside of the Complaint and not yet adduced in discovery.

A court may take judicial notice of matters of public record and consider them without converting a Rule 12 motion into one for summary judgment. In its analysis, the court cited to a significant number of cases holding that where the authenticity of a website or the accuracy of the information displayed on the website is not disputed, it is
appropriate for courts to take judicial notice of information displayed publicly on government websites. The court went on to find it appropriate to take judicial notice of the FDA documents and, therefore, Defendants’ Motion to Dismiss was not deemed converted into a summary judgment motion.

Plaintiff argued that he should be allowed to engage in discovery in an effort to find information to respond to the FDA documents. In his Motion for Rule 56(d) Relief he argued that the Supreme Court has interpreted FRCP 56(d) to require discovery where the nonmoving party has not had the opportunity to discover information that is essential to its opposition. However, the court reiterated that because judicial notice is appropriate, the Motion to Dismiss was not converted to a Motion for Summary Judgment, and therefore R. 56(d) was not relevant to the pending motion. On this basis, the court denied Plaintiff’s motion for relief.

In addition to the noteworthy discussion of the use of publicly available documents, Poll provides a succinct discussion of preemption principles and pleading requirements:

Plaintiff’s strict liability, breach of warranty and defective design claims were preempted under Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). Plaintiff’s strict liability and defective design claims would constitute the imposition of requirements in addition to those mandated by the FDA. Plaintiff’s warranty claims were not based on statements made to the FDA, but rather on alleged warranties/statements made to Plaintiff and medical personnel. The alleged warranties did not go beyond the conclusions made by the FDA and were therefore preempted.

Plaintiff’s failure to warn claims survived the preemption argument. Plaintiff claimed there were European studies that revealed problems with the Comet System and that Defendants knew but did not report these problems to the FDA. Relying on Twombly and Iqbal, the court held that these claims were not adequately pled. The Complaint did not specify what studies or what problems were at issue. Since the claims sounded in fraud, Plaintiff should have pled them with some level of specificity. In sum, Plaintiff’s allegations were conclusory, and the non-conclusory “factual content” did not plausibly suggest a claim entitling Plaintiff to relief. The court dismissed Plaintiff’s claims with leave to amend as to his failure to warn and breach of warranty claims.

[1] Defendants were: Stryker Sustainability Solutions, Inc., Stryker Sales Corporation, Stryker Corporation and Howmedica Osteonics Corporation.

Related Services: Pharmaceutical & Medical Device

Mississippi v. Au Optronics: Will There be an Increase in Parens Patriae Suits?

January 22, 2014

On January 14th, the Supreme Court issued its decision in Mississippi ex rel. Jim Hood, Attorney General v. Au Optronics Corp., et al., No. 12-1036, 2014 U.S. LEXIS 645, and made clear that in order to sustain a “mass action” in federal court pursuant to the Class Action Fairness Act of 2005 (“CAFA”), plaintiffs must be named parties before the court.

In Mississippi v. Au Optronics, the State of Mississippi (the sole named plaintiff) filed a parens patriae suit against liquid-crystal display (“LCD”) manufacturers in state court, alleging price-fixing and seeking restitution for LCD purchases made by itself and its citizens. The doctrine of parens patriae permits a state to bring an action on behalf of its citizens to protect the state’s sovereign or quasi-sovereign interests. The LCD manufacturers sought to remove the case to federal court. The District Court held that the suit qualified as a mass action, but remanded the suit to state court on the ground that it fell within CAFA’s “general public” exception,[1] The Fifth Circuit reversed, agreeing with the District Court that the suit was a mass action but finding that the general public exception did not apply.

The question before the Supreme Court was whether a suit filed by a State as the sole plaintiff constitutes a “mass action” under CAFA where it includes a claim for restitution based on injuries suffered by the State’s citizens. For the following reasons, the Court held that it did not constitute a mass action, and remanded the case to state court.

a) CAFA provides: “The term mass action means any civil action (except a class action) in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs’ claims involve common questions of law or fact...” 28 U.S.C. § 1332(d)(11)(B)(i). The parties did not dispute that this provision encompasses suits that are brought jointly by 100 or more named plaintiffs who propose to try their claims together. The issue was whether this provision includes suits brought by fewer than 100 named plaintiffs on the theory that there may be 100 or more unnamed persons who are real parties in interest as beneficiaries to any of the plaintiffs’ claims. The LCD manufacturers argued that “plaintiff” could be read to refer to the underlying claimants on whose behalf relief was sought. However, Justice Sotomayor, writing for a unanimous Court, thought that reading “would stretch the meaning of ‘plaintiff’ beyond recognition.”

b) The Court pointed out practical problems that would arise if “100 or more persons” and the proposed “plaintiffs” were not interpreted as one and the same. For example, since plaintiffs in mass actions must meet the $75,000 amount in controversy requirement, district courts would have to remand to state court the claims of all individuals whose claims were valued at less than $75,000 (who could not be readily identified if such persons were unnamed and plaintiffs were not seeking class certification) while allowing other claims exceeding $75,000 to proceed in federal court, resulting in parallel actions. In addition, CAFA provides that once removal occurs, a case shall not be transferred to another court “unless a majority of the plaintiffs in the action request transfer.” If “plaintiffs” included unnamed parties, it would be exceptionally difficult for a court to poll the enormous number of real parties in interest to decide whether an action may be transferred.

c) As the final prong of its analysis, the Court noted that the Fifth Circuit found it necessary to perform an inquiry regarding the real party in interest on the basis that “federal courts look to the substance of the action and not only at the labels that the parties may attach.” This was error according to the Supreme Court, as Congress did not intend this background inquiry to apply to the mass action provision. Rather, the Fifth Circuit should have relied on the text of CAFA.

In sum, the Supreme Court’s decision establishes that parens patriae actions are not removable “mass actions” under CAFA. It is not unusual for private plaintiffs’ attorneys to represent the states in parens patriae actions on a contingency fee basis. As such, Plaintiffs’ attorneys seeking to avoid federal court could solicit such actions on behalf of the states. Consequently, as a result of this decision we could see an increase in parens patriae actions.
technology until 2010, when it issued letters to several testing companies, warning that their products must be approved as safe and effective. The FDA stated that it has had

23andMe company executives previously stated that they first contacted the FDA in 2007, before launching their product. However, the agency did not take an interest in the

23andMe must now submit proof of the accuracy of the tests and information on the rate of false positives and false negatives. The FDA's warning letter provided the

negative could result in a failure to recognize an actual risk that may exist.”

is intended is the detection of mutations in BRCA genes that can signal increased risk for breast cancer. The FDA warns that the 23andME test could produce a false positive

The FDA also cautions that false-positive results could cause consumers to undergo unnecessary health procedures. For instance, the agency notes that a use for which PGC

for such mutations, which “could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false

injury, or death to the patient due to thrombosis or bleeding events that occur from treatment with a drug at a dose that does not provide the appropriately calibrated

According to the FDA, the test kits are designed to diagnose, mitigate or prevent disease, making them a “medical device” and requiring regulatory clearance under Section H

of the Federal Food, drug, and Cosmetic Act. The FDA warns that customers may “self-manage their treatments through dose changes or even abandon certain therapies

in a warning letter issued to the Silicon Valley company on November 22, 2013, Alberto Gutierrez, director of the FDA’s Center for Devices and Radiological Health, stated that

FDA ordered Google-backed home genetic test maker 23andMe to “immediately discontinue” its Personal Genome Service (PGS) after failing to undergo proper agency approval for its marketing claims.

On December 9, 2013, the Food and Drug Administration (FDA) released a draft guidance recommending that the size, shape, and physical attributes of generic drugs be of a

similar size to the corresponding Reference Listed Drugs (RLD). Citing concerns over “patient compliance and acceptability of medication regimens,” the FDA has sought to

limit variations in the size and shape of generic tablets and capsules.

In its guidance, the FDA noted that it is estimated that over 16 million people in the United States have some difficulty swallowing (a.k.a. dysphagia). One of the primary

reasons for standardizing certain physical characteristics of generic tablets and capsules is to combat problems with ingestion such as pain, gagging, choking, aspiration, and
disintegration of the product during esophageal transit. As justification, the FDA cited various studies indicating both that tablets greater than 8mm in diameter provoke

increased swallowing-related complaints from patients and that oval tablets may be easier to swallow and have faster esophageal transit times than flat or round tablets of

similar weights.

Other reasons to standardize size and shape include patient adherence to medicinal regimens. Unsurprisingly, patients are more likely to stray from their prescribed regimens

as complications with swallowing increase. The FDA also acknowledged that characteristics beyond size and shape should be considered (such as tablet coating, weight, surface area, etc.), but declined to address them in its draft guidance. Hopefully, standardizing sizes and shapes to ease swallowing will encourage greater adherence to

prescribed regimens.

Of particular concern to generic manufacturers going forward are potential trade dress issues given the FDA’s push for standardization. Trade dress strategies such as the

licensing of trade dress take on increased importance as manufacturers of RLDs seek methods to retain market share following the expiration of their market exclusivity. As

dtrade dress considerations are not addressed during the Abbreviated New Drug Application (ANDA) process, generic manufacturers must be mindful that their adherence to

FDA guidance does not expose them to future trade dress claims from RLD manufacturers.

FDA Orders Google-Backed Home Genetic Test Service 23andMe to Halt Marketing

The U.S. Food and Drug Administration (FDA) ordered Google-backed home genetic test maker 23andMe to “immediately discontinue” its Personal Genome Service (PGS)
after failing to undergo proper agency approval for its marketing claims.

In a warning letter issued to the Silicon Valley company on November 22, 2013, Alberto Gutierrez, director of the FDA’s Center for Devices and Radiological Health, stated that

23andMe had failed to show the tests were safe or effective. Consequently, the agency ordered 23andMe to stop marketing its tests immediately, warning that erroneous

results could cause customers to seek unnecessary or ineffective medical care.

23andMe launched its $99 saliva-based DNA test kit in 2007. The company promotes the tests as diagnostic for genetic diseases and asserts that the tests provide an

indication of risk for complex conditions such as diabetes, coronary heart disease, and breast cancer. Additionally, the company suggests that the tests can provide warnings of

potential interactions between genes and drugs, such as cholesterol-lowering statins and blood thinners.

The FDA also cautions that false-positive results could cause consumers to undergo unnecessary health procedures. For instance, the agency notes that a use for which PGC

is intended is the detection of mutations in BRCA genes that can signal increased risk for breast cancer. The FDA warns that the 23andME test could produce a false positive

for such mutations, which “could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false

negative could result in a failure to recognize an actual risk that may exist.”

23andMe must now submit proof of the accuracy of the tests and information on the rate of false positives and false negatives. The FDA’s warning letter provided the

company fifteen (15) business days to respond with an outline of actions the company is taking to address the FDA’s concerns. Warning letters are not legally binding, however, the government can take companies to court if they are ignored.

23andMe company executives previously stated that they first contacted the FDA in 2007, before launching their product. However, the agency did not take an interest in the

technology until 2010, when it issued letters to several testing companies, warning that their products must be approved as safe and effective. The FDA stated that it has had
more than "14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications" with 23andMe to discuss compliance. "However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses . . . ."

Company founder and Chief Executive Anne Wojcicki stated on November 26, 2013 that 23andMe had corresponded with the FDA and had submitted its first application for clearance in July 2012 followed by another submission in September. However, she acknowledged the firm had received feedback on the submissions and was behind schedule in its replies to the FDA.

23andMe Inc. issued a brief statement in direct response to the regulatory warning letter, asserting that the company's relationship with the FDA is "extremely important to us and we are committed to fully engaging with them to address their concerns." Subsequently, a 23andMe Inc. spokeswoman stated that the company will stop all television, radio and online marketing in response to the FDA's directive.

The complete FDA regulatory warning letter ordering 23andMe to discontinue marketing its Personal Genome Service may be found here.

Related Services: Pharmaceutical & Medical Device

The Eighth Circuit Paves the Way for More Removals under CAFA's "Mass Action" Provision

December 4, 2013

The Eighth Circuit’s recent opinion in Atwell v. Boston Scientific Corporation is bound to have an impact on mass action litigation nationwide. Atwell involves the interpretation of the Class Action Fairness Act of 2005 ("CAFA"), which provides for the removal from state to federal court of certain actions, including mass actions. Atwell, Nos. 13-8031, 13-8032, 13-8033, 2013 WL 6050762 at *1 (8th Cir. Nov. 18, 2013) (citing 28 U.S.C. §§ 1332(d), 1453(a)-(b)). The term ‘mass action’ means "any civil action . . . in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs’ claims involve common questions of law or fact, but does not include an action in which the claims have been consolidated or coordinated solely for pretrial proceedings." Id. (citing 28 U.S.C. § 1332(d)(11)(B)(i)-(ii)). Put another way, state court plaintiffs with common claims against a common defendant may bring separate cases with fewer than 100 plaintiffs each to avoid federal jurisdiction under CAFA -- unless their claims are “proposed to be tried jointly.”

In Atwell, groups of plaintiffs filed product liability actions in the Circuit Court for the City of St. Louis against manufacturers of transvaginal mesh medical devices. Three groups included claims against Boston Scientific for alleged defects in its devices. These groups are referred to by the names of the first named plaintiffs: (1) Atwell, (2) Evans, and (3) Taylor. Each group consisted of less than 100 plaintiffs.

In St. Louis City, cases are initially docketed for trial in Division I, where the presiding judge sits, and assigned to a motion division judge who prepares the case for trial. As the trial approaches, the presiding judge assigns the case to a general division judge for final disposition. However the local rules allow the presiding judge to assign extraordinary cases requiring individual and continuing attention to general divisions for trial setting, pretrial motions and trial. The local rules also provide that when there are three or more actions pending in the Circuit for the City of St. Louis, involving claims of personal injury by multiple plaintiffs against the same defendants, arising out of exposure to a product, the presiding judge may reassign such cases to a single general division if the presiding judge determines that the administration of justice would be served by the reassignment.

Under these local rules, the Atwell group moved to have its case assigned “to a single Judge for purposes of discovery and trial.” The motion did not request a common assignment with the other transvaginal mesh plaintiffs. Counsel for the Atwell group said the motion was intended “to have it assigned to the judge that’s going to try the case because of the complexity that’s going to occur all the way through . . . [there’s going to be a process in which to select a bellwether case to try.]” The Evans and Taylor groups also moved for assignment to a single judge for pretrial and trial matters, but each group noted it was not seeking to consolidate with the other cases. Plaintiffs’ counsel argued that while the cases should not be consolidated, assignment was needed for “consistency of rulings, judicial economy, [and] administration of justice.” Following the hearing on these motions, Boston Scientific removed the cases to the Eastern District of Missouri, based on the assertion that the federal court had jurisdiction under CAFA because plaintiffs had proposed to join their cases in a mass action with more than 100 plaintiffs. However, the cases were remanded to state court on the grounds that no case included more than 100 plaintiffs and plaintiffs had not proposed that the actions be “tried jointly.”

On appeal, the crux of the issue before the Eighth Circuit was whether the groups of plaintiffs had proposed to try their cases jointly, which would make the cases removable, or had simply asked for their respective cases to be consolidated or coordinated for pretrial proceedings, in which case removal would not be permitted. In its analysis, the Eighth Circuit looked to a Seventh Circuit case, Koral v. Boeing Co., 628 F.2d 945 (7th Cir. 2011), in which Judge Posner stated that in determining whether plaintiffs have “proposed” that their claims be tried jointly, “the proposal can be implicit.” Koral, 628 F.2d at 947.

The Eighth Circuit also considered, and ultimately followed, the Seventh Circuit’s approach in In re Abbott Laboratories, Inc., 698 F.3d 568 (7th Cir. 2012). Abbott Labs involved ten personal injury actions which included several hundred plaintiffs who had moved for consolidated proceedings “through trial” and “not solely for pretrial proceedings.” The Seventh Circuit reversed the district court’s remand order, pointing to plaintiffs’ request for consolidation “through trial”. Importantly, the Seventh Circuit stated: “it is difficult to see how a trial court could consolidate the cases as requested by plaintiffs and not hold a joint trial or an exemplar trial with the legal issues applied to the remaining cases. In either situation, plaintiffs’ claims would be tried jointly.”

By contrast, the Eighth Circuit was not persuaded by the Ninth Circuit’s decision in Romo v. Teva Pharmaceuticals USA, Inc., 731 F.3d 918 (9th Cir. 2013). In Romo, the appellate court affirmed the district court’s order remanding 40 product liability actions where the plaintiffs had requested coordination (not consolidation) “for all purposes” in
state court. The Eighth Circuit agreed with the dissenter in Romo, who stated: “a natural and probable consequence” of coordination was that the actions would be tried together or with bellwether trials, “which amounts to the same thing.”

In Atwell, the Eighth Circuit noted that the statements made by plaintiffs’ counsel revealed the purpose of their motions – “a joint assignment in which the inevitable result will be that their cases are tried jointly.” The Eighth Circuit held that the motions for assignment to a single judge filed by the three plaintiff groups to the same circuit court, combined with plaintiffs’ candid explanation of their objectives, required denial of the motions to remand.

Atwell widens the split between the Circuits regarding the interpretation of CAFA’s “tried jointly” language. In the Seventh and Eighth Circuits, even if plaintiffs argue that they want to consolidate or coordinate their cases solely for pretrial proceedings, defendants have a winning argument that the inevitable result will be to try the cases jointly, and that therefore, the cases constitute a removable mass action under CAFA. In the Ninth Circuit, at least for the time being, plaintiffs can seek coordination without risking removal to federal court.

**Proposed FDA Rule Effectively Abrogates Pliva v. Mensing and Mutual Pharmaceutical v. Bartlett and Opens Up Liability for Generic Drug Manufacturers**

November 15, 2013

On November 13, 2013, the U.S. Food and Drug Administration proposed a new rule allowing generic drug manufacturers to independently change their product’s labeling to reflect newly discovered safety information. The FDA’s proposed rule allows generic manufacturers the ability to unilaterally change the labeling through a “changes being effected - 0” (hereafter “CBE”) supplement. The underlying reason generic manufacturers have previously been shielded from liability is due to their inability to unilaterally or independently change their label to differ from the brand-name product’s label. The Supreme Court’s decision in *Pliva, Inc. v. Mensing*, shielding generic manufacturers from failure to warn claims, hinged on the fact that generic manufacturers did not have the ability to submit a labeling change under the CBE process. 131 S.Ct. 2567 (2011). Because the generic manufacturer did not have the ability under the FDA’s regulatory scheme to deviate their labeling from that of the brand-name drug manufacturer’s label, the failure to warn claims were held to be pre-empted due to what is commonly referred to as impossibility pre-emption.

Under current regulations, a generic drug manufacturer’s product labeling must be exactly the same as that of the brand name manufacturer’s label. This “sameness” requirement has protected generic manufacturers from liability. For example, in *Mensing* the Supreme Court held that because FDA regulations prohibit generic drug manufacturers from “independently” or “unilaterally” changing their products’ labeling, state-law-failure-to-warn claims are pre-empted. *Pliva Inc. v. Mensing*, 131 S.Ct. 2567, 2579 (2011). Conversely, because brand name manufacturers have the opportunity to submit a CBE, state-law-failure-to-warn claims are not pre-empted. In *Mutual Pharmaceutical v. Bartlett*, the Supreme Court again shielded the generic drug manufacturer from liability based upon the FDA requirements that the generic be substantially equivalent in design to the brand-name version of the drug and that it contain the same labeling as approved for the brand-name manufacturer. 133 S.Ct. 2466 (2013). Because generic drug companies were unable to change their design or labeling under the Hatch-Waxman Act and the FDAs regulatory scheme, state law failure to warn and design defect claims were held to be pre-empted by the U.S. Constitution’s Supremacy Clause.

Due to the increased risk of potential liability from product liability lawsuits that this proposed new rule would create, generic drug manufacturer’s obligations would also increase. Generic manufacturers would need to have systems in place to determine whether new literature and adverse event information, among other things, met an appropriate level to require a label change strengthening a warning or updating safety information. Most generic drug manufacturers are not set up to for this extensive analysis. This type of change could escalate the cost of generic drugs. Furthermore, another downside to the rule is that generic manufacturers, who are not as experienced and do not have the resources for pharmacovigilance departments, will end up diluting the label with unnecessary warnings. In short, the new rule could water down the effect of real warnings in product labels.

Proponents of the new proposed rule argue that it will ensure the most up to date safety information and create parity between generic makers and their brand-name counterparts.

The proposed rule will undoubtedly be challenged. The biggest challenge will be to whether or not the FDA has authority to implement such a rule. The proposed FDA regulation would allow temporary differences in the labels of brand name drugs and the corresponding generic products, which some argue violates the Hatch-Waxman Act, which mandates sameness in labeling, i.e., that the generic and brand labeling must always be the same. Opponents of the proposed new rule argue that the FDA is usurping the authority of Congress by venturing in their territory.

The FDA’s position of course is that there is no conflict with Hatch-Waxman and they have authority to promulgate this rule. Even under current regulations, if the brand name manufacturer strengthens its labeling through a CBE supplement, there is a brief period of time where the warnings do not match. Now, the FDA proposed rule would allow the flip side. The generic manufacturer could unilaterally strengthen its warnings, just as the brand-name manufacturer can do now. Upon FDA approval of the CBE supplement by the generic manufacturer, the brand-name manufacturer would then be required to make the same labeling update as the generic. If the FDA disapproves, the generic drug manufacturer must revert back to the previous label. As such, the discrepancy between the labels is only for a short period of time.

The proposed rule was published in the Federal Register on Nov. 13, 2013 and interested parties have 60 days to comment. The proposed rule can be found here.

**Mutual Pharmaceutical v. Bartlett: Hope for an End to "Alternative Feasible Design" in Drug Cases?**

July 24, 2013 | Angela Higgins
The U.S. Supreme Court recently issued its opinion in Mutual Pharmaceutical Co. Inc. v. Bartlett. Bartlett involved a claim by a woman who contracted Stevens-Johnson syndrome, a bizarre and rare reaction to an alleged wide variety of drugs (including over-the-counter drugs) that causes necrosis of the skin, following consumption of a generic anti-inflammatory drug. The primary holding of Bartlett continues the Supreme Court’s recent trend of immunizing generic drug manufacturers from liability based upon FDA requirements that the generic be substantially equivalent in design to the “innovator” or branded version of the drug, and that it contain the same labeling as approved for the branded version.

While Bartlett is expressly limited to the generic drug context, it presents a tantalizing glimpse of the Court’s potential receptiveness to similar arguments regarding supposed feasible safer alternative design in the context of branded pharmaceuticals. The Court noted that redesign of the generic drug was not possible for two reasons, the first being requirements that the generic be equivalent to the branded drug, but the second, and more interesting to branded manufacturers, being that an alteration to the chemical composition of the drug results in an entirely different drug that would require new FDA approval. Slip Op. at 10-11.

We have long argued that any drug design defect claim should be barred as a matter of law, because any “alternative design” of a drug is an entirely different drug from the one approved by the FDA. Any opinion that a drug is “defectively designed” is simply an opinion that the FDA should never have approved the drug.

Modification of a drug’s chemical formulation results in a different drug, not an “alternatively designed” drug, with potentially different pharmacological effects, and which would be subject to an individualized FDA approval process and clinical testing. Any argument that this is the better “alternative design” presupposes that the FDA would have approved such a formulation, which is almost always pure conjecture if the alternative drug is not presently marketed. No expert can honestly opine that approval would have been granted without engaging in pure, unfounded speculation. The FDA is solely vested with authority to approve or disapprove the drug application. Drug approval is a years-long give-and-take process between the manufacturer and the FDA, based upon the subjective analysis of the FDA, which cannot be replicated by plaintiffs’ experts in a courtroom. Indeed, the truckloads of data (including the phases of clinical testing) necessary to be developed for drug approval could never be replicated by plaintiffs’ experts and have never been developed by them.

Drug designs are different from other product designs. The Restatement (Third) of Torts: Products Liability § 6(c) recognizes the logical disconnect in applying the common law rule regarding a “safer alternative design” in the drug product case. Under the Restatement (Third) § 6(c), plaintiffs may establish defectiveness by showing that safer alternative drugs were available on the market, which reasonable health care providers would have prescribed in place of a defendant’s drug for all classes of patients. But proposing a different drug formulation is proposing a different drug, not proposing an “alternative design” for an existing drug, and there are pharmacological as well as regulatory reasons why plaintiffs should not have the same unfettered ability to propose “alternative designs” for drug products as they would for other types of product. In jurisdictions that require plaintiffs to prove a “feasibly safer alternative design,” the feasibility of a proposed alternative design must require plaintiffs to prove that such a formulation could be marketed and sold in the U.S. (i.e., that it would receive FDA approval). To take such matters outside of the realm of pure speculation, this means, practically, that only already-marketed alternatives should be considered in assessing whether the drug at issue is defectively designed, e.g., Williams v. Ciba-Geigy Corp., 686 F. Supp. 573, 578 (W.D. La. 1988), aff’d 864 F.2d 789 (5th Cir. 1988); Ortho Pharm. Corp. v. Heath, 722 P.2d 410, 416 (Colo. 1986).

Still, this leaves the question of second-guessing the FDA’s approval of the drug in question. While the Supreme Court has not yet been receptive to the preemption of claims against innovator pharmaceutical defendants in the same manner in which it has barred claims against pre-market approved medical devices, any “design defect” claim in the context of an extensively regulated, thoroughly-reviewed product like a prescription drug necessarily comes down to an argument that the FDA erred in approving the drug in question, which should be a preempted claim. See Sanofi Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir 1990) (the courts are not empowered to “usurp” the power of the FDA); see also Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341, 349 n.4 (2001).

We look forward to seeing whether any defendants seize upon the Bartlett opinion’s recognition that an “alternative design” of a branded drug results in a different drug entirely. If you have made such arguments, please feel free to contact us (especially if you can brag about your results).

Related Services: Pharmaceutical & Medical Device

Attorneys: Angela Higgins

The Effect of Recall on PMA Medical Device Preemption

July 2, 2013 | Angela Higgins

Recalls (and manufacturers’ unwillingness to issue them) are frequently in the news these days. We are often asked to analyze the effect of a product recall upon claims and liability. It is apparent that a recall (or, perhaps, a refusal to conduct one) tends to lead to increased litigation. But does a recall result in increased liability? In the context of pre-market approved (“PMA”) medical devices, there is abundant authority that this is not and should not be the case.

Kansas follows the majority rule and does not impose any duty to recall or to retrofit products, including medical devices. The Kansas Supreme Court has clearly specified that “product recalls are properly the business of administrative agencies as suggested by the federal statutes that expressly delegate recall authority.” Patton v. Hutchinson Wil-Rich Mfg. Co., Inc., 253 Kan. 741, 763, 861 P.2d 1299, 1315 (1993). Accordingly, the Court must look to federal law in determining what effect, if any, a recall has upon the preemptive status of a medical device.

Recalls of medical devices are governed either by 21 C.F.R. §§ 7.40-7.59 (for voluntary field actions) or by 21 U.S.C. § 360(h)(e) and 21 C.F.R. §§ 810.10-810.18 (for recalls mandated by the FDA). Nothing in these regulations even remotely suggests that a recall under either set of regulations results in the withdrawal of a device’s PMA.

To the contrary, an entirely separate statutory and regulatory process governs withdrawal of approval. See 21 U.S.C. § 360(e)(e); 21 C.F.R. § 814.46. Moreover, and importantly, the standards for withdrawal of PMA are wholly distinct from those governing recalls. Cf. 21 U.S.C. § 360(e)(1) with 21 C.F.R. §§ 7.40(a), 7.41(a), and 7.46(a). Furthermore, the provisions governing withdrawals of PMA require the FDA to give manufacturers notice and the opportunity to be heard. See 21 U.S.C. § 360(e)(1)
(withdrawal may be ordered only “after due notice and an opportunity for informal hearing”); 21 C.F.R. § 814.64(c) (same).

Where there has been a recall, even an FDA-mandated recall, of a PMA device, but the PMA status has not been revoked, the preemptive effect of PMA approval should still bar state law claims. See In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d 1147, 1155-56 (D. Minn. 2009), affirmed 623 F.3d 1200 (8th Cir. Oct. 15, 2010); Talbott v. C.R. Bard, Inc., 63 F.3d 25, 28 (1st Cir. 1995) (preemption applies as long as the FDA has not revoked PMA).


In the Sprint Fidelis Leads litigation, the PMA-approved devices began to experience cracks in the outer sleeve of an electrical wire, subjecting some patients to inappropriate cardiac shocks. The manufacturer initiated a voluntary recall of the devices. In applying the law of Riegel to the facts of Sprint Fidelis, the court held the device’s PMA approval was not invalidated by the subsequent recall. 592 F. Supp. at 1155-56, 1162. No statutes or regulations support the notion that a recall, without more, is sufficient to void an approved PMA. Id. Further, the court emphasized that plaintiffs’ claims, if allowed to proceed, would interfere with the PMA process by “retroactively[ ] second-guessing” the FDA’s decision to approve the device in the first place. Id.

The proper focus in any products liability claim is on the date of manufacture and sale, not some later date. See Mays v. Ciba-Geigy Corp., 233 Kan. 38, 52, 661 P.2d 348 (1983). As noted in the Sprint Fidelis MDL, “Plaintiffs’ argument ignores that the PMA . . . was in place at the time the leads were implanted,” which “is what matters.” 592 F. Supp. 2d at 1156. Similarly, in Kemp v. Pfizer, Inc., the court noted that preemption applied despite a recall because, “when the [device] was implanted . . . it had received pre-market approval by the FDA.” 635 F. Supp. 1015, 1023 (E.D. Mich. 1993); accord, Blanco, 70 Cal. Rptr. 3d at 580-81.


Of those courts that would allow claims to proceed against the manufacturer of a PMA device based upon a recall, it is usually only where the FDA itself has found a violation of the conditions of approval for the PMA or a violation of the FDA’s good manufacturing practices. See Gelber v. Stryker Corp., 788 F. Supp. 2d 145 (S.D.N.Y. April 18, 2011) (relying upon FDA warning letter regarding manufacturing processes); Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 998 A.2d 543 (N.J. Super. A.D. July 23, 2010) (FDA warning letter); Phillips v. Stryker Corp., 2010 WL 2270683 (E.D. Tenn. June 3, 2010) (recall was FDA-mandated, not voluntary).

While there are exceptions, there is a good body of case law that supports the continued preemptive effect of PMA approval even if a device has been recalled (indeed, even if the FDA has mandated such approval) where the pre-market approval is not withdrawn from the device. As always, please contact a licensed attorney regarding the law in your jurisdiction to evaluate the viability of recall-related claims.

Related Services: Pharmaceutical & Medical Device

Attorneys: Angela Higgins

Buckman Preemption & State Safe-Harbor Presumptions of Non-Liability for Approved Warnings

December 27, 2012

In an attempt to insulate drug and device manufacturers from the flood of tort liability in the latter half of the twentieth century, many states adopted “safe-harbor” statutes. These safe-harbor provisions created the presumption that a drug or device manufacturer was not liable for injuries in tort if the FDA approved the drug or device as “safe and effective” and the drug or device and labeling complied with the FDA’s approval. Yet, some states allowed plaintiffs to rebut that presumption if the manufacturer “withheld information from or misrepresented information” to the FDA.

In 2001, the United States Supreme Court ruled that state law “fraud-on-the-FDA” claims were preempted as the state law claims “inevitably conflicted with the [FDA’s] responsibility to police fraud consistently with the Administration’s judgment and objectives.” Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 350 (2001).

At first, the Buckman decision seemed to indicate that such “withholding or misrepresentation” exceptions would also be preempted as the Sixth Circuit applied the Buckman analysis to reach that result. See Garcia v. Wyeth, 385 F.3d 961 (2004). However, a circuit split was soon created when the Second Circuit upheld such an exception as valid. Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2006).

The Second Circuit distinguished Buckman on three grounds. First, the Second Circuit concluded that the cornerstone of the Buckman decision—an absence of the presumption against preemption because states did not have an historical interest in policing fraud against federal agencies—did not apply because states had a traditional interest in protecting the health and safety of its citizenry through common law tort actions. Second, plaintiffs’ claims for recovery were founded in the common law duty of care rather than a new “fraud-on-the-FDA” claim. Finally, proof of “fraud-on-the-FDA” was not an element of the claim but an affirmative defense. Finding preemption where no element of the claim was at issue would stretch preemption far beyond its historical application.

An evenly-divided U.S. Supreme Court, with the Chief Justice abstaining, failed to reverse the Second Circuit in Warner-Lambert v. Kent, 128 S. Ct. 1168 (2008). In 2012, the
A recent district court opinion arising out of the Third Circuit continues that split as The Honorable Robert Kugler of the United States District Court for the District of New Jersey adopted the Second Circuit's reasoning. As the Third Circuit has not had the opportunity to rule on this split, appellate review of Tigert v. Ranbaxy Pharmaceuticals, Inc., No. 12-00154 (Dec. 18, 2012) will hold important ramifications for what defenses are available to Defendants in three states where mass tort litigation is at home.

**Related Services: Pharmaceutical & Medical Device**

**Soely Updating Package Insert is Insufficient to Warn Prescriber**

December 6, 2012

More plaintiffs' attorneys have adopted the recent trend of alleging that pharmaceutical companies must distribute "Dear Doctor" letters or otherwise affirmatively call attention to label changes to satisfy their duty to warn prescribers besides merely updating the package insert with new warnings. The Eighth Circuit recently gave Plaintiffs' argument support by upholding a Minnesota jury verdict finding that a drug manufacturer failed to warn a doctor despite the warning appearing in the package insert. Schedin v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., No. 11-317, 2012 WL 5971181 (Nov. 30, 2012).

In 2005, Dr. John Beecher prescribed John Schedin, who was 76 at the time, the drug Levaquin and a concomitant corticosteroid. The package insert warned that Levaquin could cause ruptures of the Achilles tendon and was amended in 2001 to also warn that the risk could be increased in patients receiving corticosteroids, especially in elderly patients. Schedin suffered an Achilles tendon rupture and sued Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJP), the company that marketed the drug.

The package insert and the Physician Desk Reference both included the warning regarding corticosteroids and the elderly. The risk of tendon rupture was listed in the Warnings section of the label but was not required to appear in a boxed warning until 2008, after Schedin’s injury. The sales representative testified that her common practice was to discuss labeling changes with prescribers but her notes from meetings with Dr. Beecher did not reference discussion of the warning and the sales aids she used at the time did not mention the risk of tendon rupture. Dr. Beecher testified that he was not aware of the risk associated with corticosteroids and the elderly and would not have prescribed Levaquin had he known of the risk.

Schedin argued that OMJP’s duty to warn obligated it to call prescriber’s attention to changes in the labeling through "Dear Doctor" letters or efforts by sales representatives. The jury returned a verdict for the Plaintiff despite the appearance of the warning in the package insert, the amendment of the PDR to reflect the warning, and the testimony regarding the sales representatives’ common practice to discuss labeling changes.

The Eighth Circuit acknowledged that many other jurisdictions held that pharmaceutical manufacturers satisfied their duty to warn as a matter of law if the warning appeared in the package insert and the PDR. However, as Minnesota courts had not addressed the issue, the Eighth Circuit held that there was sufficient evidence for a jury to find that OMJP had not adequately communicated the increased risk to prescribers.

The procedural posture limits the dangers this opinion poses to pharmaceutical companies. However, the Eighth Circuit highlighted that OMJP should have known that its warnings were inadequate due to the continued receipt of adverse events of tendon rupture in elderly patients prescribed concomitant corticosteroids after the label was amended in 2001. Further, the Court repeatedly described the warning as buried in a 15 page document of small type. These emphasized facts and the lack of weight given to the sales representative’s testimony confirm that pharmaceutical companies must carefully manage label changes, both in active litigation and to prevent future litigation.

**Related Services: Pharmaceutical & Medical Device**

**Free-speech Protections May Alter Off-Label Promotions**

December 4, 2012

The FDA has historically prohibited pharmaceutical companies from engaging in “off-label” promotion of its products. The Food, Drug, & Cosmetic Act also criminalizes misbranding by pharmaceutical companies. Misbranding occurs when a drug’s label does not provide instructions to allow for the safe use of intended indications. The FDA typically will not permit package inserts to provide information regarding off-label uses. Thus, the FDA interprets promotion of off-label uses as an intended indication and without these proper accompanying instructions, the action constitutes misbranding. Pharmaceutical manufacturers and their employees can be charged with misdemeanor and felony offenses and can be sanctioned with as much as three years’ imprisonment or a $10,000 fine.

While numerous pharmaceutical manufacturers have argued that this criminal prosecution violates their and their employees’ rights to free speech, the FDA has not altered its policy. Yet, the Second Circuit recently held that the FDA’s criminal prosecution of pharmaceutical manufacturers and their representatives for truthful, non-misleading speech promoting an FDA-approved pharmaceutical product unconstitutionally encroaches upon the First Amendment. U.S. v. Caronia, No. 09–5006–cr, 2012 WL 5992141 (2d Cir. Dec. 3, 2012).

The Second Circuit applied heightened scrutiny to the FDA’s prosecution and concluded first, that the government’s ban did not directly advance its interest and second, that the government’s prohibition was not narrowly tailored to achieve its interest. The FDA claimed that its interest in the regulation was to promote the integrity of the approval process and limit the public’s exposure to unsafe or ineffective products. However, the Second Circuit reasoned that because physicians are allowed to prescribe approved drugs for off-label uses, the FDA’s ban did not limit off-label use or protect the public. Further, by stifling the flow of truthful communication, the FDA prohibition denied prescribers and patients important information about that product, including safety information. Finally, the FDA’s actions also were not narrowly tailored as the FDA could prohibit off-label uses, cap off-label prescriptions, or launch educational campaigns to achieve its interests more narrowly.

The FDA is expected to appeal the decision by either petitioning for en banc review by the Second Circuit or for a grant of certiorari by the Supreme Court. Until appellate
options are exhausted, the FDA is unlikely to alter its regulations concerning off-label promotion. If the FDA is forced to change its regulatory scheme, pharmaceutical manufacturers will likely still need to be vigilant that communications could not be construed as "untruthful" or "misleading" to escape disciplinary action by the FDA.

Related Services: Pharmaceutical & Medical Device

**Supreme Court to Consider Preemption of Design Defect Claims**

December 3, 2012

Plaintiff Karen Bartlett was prescribed the generic drug, sulindac, to treat shoulder pain. In 2005, Ms. Bartlett developed a severe skin reaction known as Stevens Johnson Syndrome or Toxic Epidermal Necrolysis. She filed suit in New Hampshire against Mutual Pharmaceutical Co. (the generic drug manufacturer) alleging that sulindac was unreasonably dangerous because its risks outweighed its benefits. The jury awarded her a $21 million verdict in 2010.

The United States Supreme Court issued its decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), holding that failure-to-warn claims against generic manufacturers were preempted by the Food, Drug, & Cosmetic Act and FDA regulations because generic manufacturers could not change product labeling and therefore could not comply with the duties imposed by state law failure to warn claims. Mutual then appealed the jury verdict in the *Bartlett* matter.

Mutual Pharmaceutical argued that Ms. Bartlett’s theory of recovery was preempted because the Supreme Court’s *Mensing* decision imposed on generic manufacturers a “duty of sameness” that applied to product design as well as labeling. Ms. Bartlett responded with the popular theory among plaintiffs that Mutual could have satisfied its state law obligations and federal obligations by merely opting not to market the product. The First Circuit held that the *Mensing* decision was limited to labeling and did not preempt Ms. Bartlett’s design defect claim. Yet, the First Circuit acknowledged that it could not justify its distinction between these theories of recovery and encouraged the Supreme Court to review the issue.

Mutual then petitioned the United States Supreme Court for a writ of certiorari in the matter, noting the First Circuit’s concerns and claiming that a circuit split existed between the First and the Fifth, Sixth, and Eighth circuits on the issue. On November 30, 2012, the United States Supreme Court granted review. Given how heavily litigated this issue, more guidance from the Supreme Court regarding the scope of its preemption holding will be welcome. Parties interested in the proceedings can monitor the Supreme Court docket here.

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