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Rx For The Defense

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Committee Leadership

In This Issue

Chairs' Corner

Sara Gourley, Outgoing Chair

With this report, I have reached the end of my term as the chair of the Drug and Medical Device Committee. I am so proud of all that our committee has accomplished, the camaraderie we have enjoyed, and the efforts we have made to move the law forward in a responsible way for the benefit of our clients. Our steering committee recently met in Chicago, and I was thrilled with the enthusiasm and new ideas generated! Stay tuned! I am leaving my role in exceptionally good hands, with Gail Rodgers as the committee chair and Shelia Boston as vice chair. I look forward to continuing to work with all of you in the years to come.

Gail Rodgers, Incoming Chair

Happy Holidays! It is hard to believe that Annual Meeting has come and gone and we are into the holidays already. As we celebrate this festive season, I find myself reflecting on the many things I have to be thankful for. High on that list are the many, many colleagues and friends I know through the Drug and Device Committee of DRI. I am grateful and enthusiastic to be taking over the reins from the inimitable Sara Gourley, who has led our strong committee to a great place. I look forward to serving as your new leader as we begin a new decade of defending our drug and medical device clients. If you are interested in becoming more involved in the committee, just drop me a line (gail.rodgers@dlapiper.com) and we will put you to work!

Sara Gourley is a partner in the Chicago office of Sidley Austin and a practice leader for the Firm's Product Liability and Mass Tort practice. She focuses on the national and regional defense of drug and medical device litigation. She is the outgoing Chair of the Drug & Medical Device Committee of DRI.

Gail Rodgers is a partner in the New York office of DLA Piper. She focuses her practice on the national and regional defense of drug and medical device litigation and investigations and compliance. She is the new Chair of the Drug & Medical Device Committee of DRI.

From the Editor

By Heather Howard

Happy Holidays! If you are interested in writing an article for publication in *Rx for the Defense*, please contact Heather Howard at hhoward@kslaw.com to find out more information about the publication guidelines and the selection process.

Heather Howard is Counsel in the Atlanta office of King & Spalding LLP, where she is a member of the firm's Trial & Global Disputes practice. Ms. Howard focuses her practice on the defense of pharmaceutical and medical device manufacturers in product liability suits at the trial level and on appeal. Heather serves as the newsletter editor for the DRI Drug and Medical Device Committee.

Feature Articles

FTC Letters Highlight Potential Risks in Deceptive Plaintiff Lawsuit Advertising

By Sean P. Fahey and Rebecca J. Reed


Turn on the television, and chances are you will eventually be asked whether you or a loved one has suffered from cancer, heart attack, infection, or any other number of injuries "caused" by a medication—and offered the option of calling a plaintiffs' law firm to assess your case. Such advertisements, which reach directly to consumers, distort the actual risks of a medication or device by conflating association with causation. Sensationalist claims may twist the warnings provided in the label of a drug or device into a misleading pronouncement that the product causes a serious injury. But as a recent announcement by the Federal Trade Commission makes clear, law firms and lead generators are not excused from the fundamental principle that advertisements regarding drugs and devices must not be misleading.

When plaintiff legal ads go beyond the product labeling to exaggerate the potential risks of a product, patients may react without consulting their health care provider, with serious, and even deadly, consequences. For example, in 2015, an analysis of Xarelto MedWatch reports revealed at least 30 serious adverse events in patients who had stopped taking the blood thinner, including two patient deaths. *See* Paul Burton & W. Frank Peacock, *A MedWatch Review of Reported Events in Patients Who Discontinued Rivaroxaban (XARELTO) Therapy in Response to Legal Advertising*, Heart Rhythm Case Reports, v. 2, issue 3, 248–49 (May 2016). Four years on, the problem has not abated.

In a February 2019 letter, at the request of Congressman Andy Harris in the U.S. House of Representatives, the FDA analyzed the FDA Adverse Event Reporting System (FAERS) for reports of adverse events involving legal advertisements. The FDA identified 213 MedWatch reports of patients who viewed a legal advertisement and then discontinued their anticoagulant, antidiabetic, or antidepressant medication. Approximately 27 percent of those reports described an adverse event after the patient discontinued the medication. Letter from Maren McBride, Legislative Director for Appropriations, U.S. Food & Drug. Admin, to Hon. Andy Harris, M.D., U.S. House of Rep. (Feb. 6, 2019), *available at* https://www.agingresearch.org/app/uploads/2019/05/2019-0206-Harris-Letter.pdf.

Although plaintiff law firms (unlike drug and device manufacturers) are not bound by FDA regulations regarding prescription drug and medical device advertising, they must nonetheless abide by regulations set forth by the Federal Trade Commission (FTC), which has broad authority over advertising in connection with drug or device sales. *See* Section 5 of the Federal Trade Commission Act, 15 U.S.C. §45(a)(2) (providing the FTC with authority to prohibit "unfair or deceptive acts or practices"); Section 12(a)(2) of the FTC Act, 15 U.S.C. §52(a)(2) (prohibiting false advertisements that affect the sales of drugs or devices); *see also* Deception Policy Statement, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984), cited with approval in *Kraft, Inc. v. FTC*, 970 F.2d 314 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993). The FTC defines deceptive advertising as "a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment." *Id.* In implementing this standard, the FTC analyzes the overall net impression of the ad through a three-part inquiry: (1) the claims conveyed in the ad; (2) whether those claims are false and misleading; and (3) whether those claims are material to prospective consumers. *Kraft*, 970 F.2d at 314.

On September 24, 2019, the FTC announced it had sent warning letters to seven unidentified law firms and lead generators regarding ads that may be deceptive and thus in violation of FTC regulations. Federal Trade Commission Press Release, *FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits*, *available at* https://www.ftc.gov/news-events/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits (Sept. 24, 2019). Although the FTC declined to identify specific firms or advertisements, the overarching principles articulated in the press release provide guidance as to how the FTC analyzes whether plaintiff advertising is potentially deceptive.

First, plaintiff advertisements must have "competent and reliable scientific evidence to substantiate their claims about the purported risks" of a product. *Id.* A constant

refrain in drug and device manufacturer defense is that association does not equal causation. But well before these cases ever see a courtroom, plaintiff advertising that equates association with causation exaggerates a medication's potential risks. When plaintiffs veer from the FDA-approved language of a product's label to generate leads, the ad may become increasingly deceptive to patients.

Second, plaintiff advertisements must clearly be, well, *advertisements*. "[L]awsuit ads that open with sensational warnings or alerts [] may initially mislead consumers into thinking they are watching a government-sanctioned medical alert or public service announcement." *Id.* Cloaking claims about what a medication "causes" in the veneer of an official pronouncement is another factor in deception. Plaintiff advertisements do not provide medical advice; these ads promote services and "should be identifiable as advertising from the beginning." *Id.*

And third, the FTC is well aware of FAERS reports of adverse events in patients who view plaintiff advertising and discontinue their medications, with potentially dangerous consequences. This is important because it goes to the third prong of the FTC analysis—whether the claims are material to customers. As the press release's reference to the FAERS reports makes clear, when plaintiffs make claims that reach beyond the label, scared patients may react to their detriment. The claims in these advertisements, therefore, are indeed material to patients.

The FTC press release indicates a clear next step: "[t]o prevent consumer injury . . . lawsuit ads may need to include clear and prominent audio and visual disclosures stating that consumers should not stop taking their medications without first consulting their doctors." *Id.* Disclosure is supported by other stakeholders as well. The American Medical Association ("AMA") takes a similar position, advocating for a requirement that such ads include "warnings that patients should not discontinue medications without seeking the advice of their physician." AMA, Attorney Ads on Drug Side Effects H-105.985, *available at* https://policysearch.ama-assn.org/policyfinder/detail/Attorney%20Ads%20?uri=%2FAMADoc%2FHOD-105.985.xml (last accessed Nov. 7, 2019). The AARP has previously advised seniors to speak with their healthcare providers before discontinuing a medication based on a lawyer advertisement. AARP Online Community, *Don't Let Lawsuit Ads Put You at Risk*, *available at* https://community.aarp.org/t5/Scams-Fraud/Don-t-let-Lawsuit-Ads-Put-You-at-Risk/m-p/1984308 (last accessed Nov. 7, 2019). And the states of Texas and Tennessee both enacted statutes in 2019 which require, among other measures, that legal advertisements clearly identify themselves (Tenn. Code Ann. §47-18-5602(a); Tex. Gov't Code §81.153(a)) and include language advising consumers to speak with their health care provider before discontinuing medication (Tenn. Code Ann. §47-18-5602(c)(1); Tex. Gov't Code §81.153(b)). Tenn. Pub. Chap. 2019-116 (H.B. 352) (to be codified at Tenn. Code §§47-18-5601 *et seq.*); S.B. 1189, 86th Leg. (Tex. 2019) (to be codified at Tex. Gov't Code §§81.151 *et seq.*).

Where does this leave drug and device manufacturers? There are a few broad points to bear in mind here. If you are not closely tracking TV and website advertisements that attack your client and its products, start. When you see misstatements and overstatements—and you will—communicate your concerns to the advertising law firm promptly and create a record. Make sure you modify your standard notice letters to include the importance of complying with the recent FTC guidance. In our experience, most law firms will modify their advertising, and these recent developments should give even the most aggressive advertisers pause. After all, most of their advertising is based on language from warning letters. If your concerns are not addressed, consider escalating the issue through traditional litigation or reporting these concerns to the people in Washington that have shown they care about these issues. The more real-world examples they have, the better.

Sean P. Fahey *is a partner and chair of the Mass Tort and Complex Litigation Practices of the Health Sciences Department at Pepper Hamilton LLP. He has served as national counsel for the world's largest pharmaceutical, medical device, life science and other companies and as trial counsel and settlement counsel for many of these companies in some of the most challenging jurisdictions in the country. Sean is a member of Pepper's Executive Committee and Diversity Committee, and was the firm's representative with Diversity Lab, an incubator for innovative ideas and solutions that boost diversity and inclusion in law.*

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3D Printed Medical Devices and Organs: The Canadian Legal Framework

By Glenn Zakaib, Lydia Wakulowsky, and Edona Vila



Although 3D printing has been around since the 1980s, economies of scale and cost considerations have led to a proliferation of the technology in recent years. The industry is currently worth an estimated 15 billion dollars and is expected to grow to 35 billion by 2022. *See* https://bit.ly/2moYYTc. In a state of greater infancy, 4D printing technology is also positioned to have an impact in the very near future. The fourth dimension that 4D printers add to their end-product is the ability to react when subjected to a stimulus (*e.g.*, exposure to heat, ultraviolet light, or others). *See* https://bit.ly/2kIErZo. At this stage, academic institutions, non-profit organizations, and for-profit corporations are racing to improve clinical outcomes through the use of 3D and 4D printed medical devices and organs. For these two technologies, Canada's regulator, Health Canada, has issued some guidance to manufacturers and distributors of 3D printed medical devices and organs. In this article, we explore these regulatory developments, along with emerging liability concerns for 3D printing manufacturers and distributors.

What Are 3D Printed Medical Devices and Organs?

3D printers are considered an additive manufacturing device because successive layers of raw material are printed and piled until a solid 3D object is formed. *See* https://bit.ly/2Nn0rGN at 3 ("CADTH report"). This process can produce nearly limitless iterations. For this reason, early use of the technology in the medical context has been geared to creating customized medical devices.

3D printed organs are made using the same underlying technology and process of layering. Unlike medical devices, the "ink" used to produce 3D printed organs is made of human tissue. This printing method is referred to as "bio-printing." An example is the 3D printed heart, which was developed in Tel Aviv earlier this year and engineered from cells, blood vessels, ventricles, and chambers. *See* https://bit.ly/2KB7DNU.

While essentially the same technology is responsible for the creation of both types of products, it is important to keep in mind that their distinct features impact the way in which each of these products is regulated.

Regulatory Aspects of 3D Printed Medical Devices and Organs

The Canadian regulator has had its eyes on 3D printing technology for years, culminating with an initial guidance document to the industry in April 2019. The history of the regulator's focus on 3D printing has its origins in the work of the Canadian Senate. Particularly, beginning in 2016, the Canadian Senate focused its attention on 3D printed medical devices by adopting an Order of Reference authorizing the Standing Committee on Social Affairs, Science and Technology to examine and report on innovative technologies in healthcare (including artificial intelligence and 3D printing). From February to May of 2017, the Senate Committee met with several expert witnesses in the field to hear their opinions. *See* https://bit.ly/2yjsT49. As part of this process, and perhaps most importantly, the Senate Committee engaged Canada's regulator in this space, Health Canada.

The Senate Committee asked Health Canada several questions about how 3D printed products would fit into the existing regulatory regime. *See* https://bit.ly/2kIFp7Y, (hereinafter, "Health Canada Response"). As part of its response, Health Canada announced that it was actively monitoring the introduction of innovative technologies such as 3D printing in the medical context. On this same note, it was suggested that printed medical devices would likely be considered a Class III device (out of the four existing classes of the risk-based framework of categorising medical devices). (*Note:* The system of classification is based on the risk level associated with each medical device class. For example, implantable devices like prosthetics are considered to be class IV versus thermometers, which are classified as class I.)

Medical devices produced using 3D printing are subject to the *Medical Device Regulations*, which the regulator views as sufficiently flexible and adaptive to accommodate for innovative technologies. In October 2018, the regulator released a draft guidance document for manufacturers wishing to obtain licenses for implantable 3D printed medical devices. Following feedback by relevant stake-

holders, in April of 2019, the regulator issued a final draft of its guidance document entitled *Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing*. Guidance documents are an administrative tool by which the regulator provides assistance to the industry on complying with the governing medical device laws. Health Canada had made it clear that this document represents "the first phase" in the evolving 3D printing technology policy in Canada.

This initial guidance document is helpful for manufacturers and distributors of 3D printed medical devices (including hospitals) seeking to obtain a license to produce implantable 3D class III and IV medical devices. The guidance document also makes it clear that healthcare facilities that manufacture 3D printed implantable medical devices under their own name and distribute them outside their organization would be considered a manufacturer and must therefore abide by all regulatory requirements under the regulations. The document, however, does not provide guidance for standalone software, custom-made devices, and anatomical models incorporating viable living cells. Perhaps most notable are the sections of the document relating to the additional information that manufacturers will need to provide for the purpose of obtaining a license to sell and/or distribute 3D printed class III and IV implantable medical devices in Canada.

To provide some context, a manufacturer must obtain a licence to sell or import products that fall within the *Medical Device Regulations*. To do so, an application must be made to the federal Minister of Health to demonstrate the safety and effectiveness of the product such as evidence of safety and effectiveness, biocompatibility testing, and software validation. In addition to all of the information that would be required under an ordinary Class III or IV licencing application for non-3D printed devices, Health Canada stated in its guidance document, *see* https://bit.ly/2lZ4Xhc, that applications pertaining to 3D medical devices must also provide detail with respect to the following aspects:

- Device description (including reference to starting material and any additives) and the description of the 3D printing method (*e.g.*, laser sintering, metal laser sintering and power bed fusion) and any post-processing steps;
- A description of the "design philosophy" which "may" include an explanation of the choice to use 3D printing as a manufacturing process;
- Justification for why modifications may exist from a previously approved device produced using other methods (for example, changes in material, post-processing steps, material-printer combination, software-related changes affecting the finished device);
- A description of the marketing history of the 3D printed device or relevant previously approved comparable device or components;
- A declaration of conformity with design and manufacturing standards, but the regulator has made it clear that the "use of standards" is not compulsory as the manufacturer may demonstrate safety and effectiveness independent of any standard;
- Pre-clinical performance testing summary for all pre-clinical testing performed, but specific test requirements vary depending on the device type and other indicia such as whether the device is patient-matched or manufactured to pre-determined sizes;
- For devices with a novel design, material, or intended use, the regulator may require clinical studies and animal studies to support safety and effectiveness; and
- Considerations on the specific labeling of patient matched devices, along with a warning that the patient should be assessed for potential anatomical changes prior to any procedure involving the custom-made device.

While 3D printed medical devices are subject to the *Medical Device Regulations*, the regulatory umbrella for 3D printed organs is less clear. When asked about how 3D printed organs should be regulated, Health Canada's response was more nuanced than it was for 3D printed medical devices. First, Health Canada affirmed that because this process involves the use of human tissue and cells, it would generally be regulated under the *Food and Drug Regulations*, and not the *Medical Device Regulations* (as is the case for 3D printed medical devices). Second, the regulator stated that in a situation where a combination of biologic and inert materials is used, the entire product maybe regulated under either the *Food and Drug Regulations* and/or the *Medical Device Regulations*. *See* Health Canada Response at Question 3. This suggests that a re-evaluation of the current regulatory framework may be required to address the appropriate regulatory pillars for evaluating the safe use and effectiveness of 3D printed organs.

Emerging Liability Concerns for 3D Printing Manufacturers

In addition to how regulators plan to govern the production, distribution, and use of these technologies, manufacturers will also be concerned about how these new technologies may fit into the existing product liability legal framework.

A fundamental aspect of Canadian law regarding product liability is the manufacturers' duty to warn consumers of the potential risks associated with their products. This does not exclude the duty of care that others in the supply chain may have vis-a-vis the end user. *See Hollis v. Dow Corning Corp.*, [1995] 4 SCR 634, 1995 CanLII 55 (SCC) (hereinafter, *"Hollis")*. An important exception to this rule that is often relevant in the medical context is the learned intermediary rule.

In a situation where a consumer would put primary reliance on the opinion of a medical professional (such as a physician) rather than the manufacturer, the manufacturer can satisfy its duty to warn by sufficiently educating a learned intermediary on the risks of its product. *See Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681. In Canada, this doctrine has been held to apply in the context of implanted medical devices. *See Hollis*. We would not expect any deviations on the manufacturer's ability to rely on this doctrine as a defence in product suits in the context of 3D printed medical products. That said, the liability pendulum may shift further to the learned intermediary if the healthcare professional and/or the healthcare facility is equipped with a 3D printer capable of producing 3D medical products on demand. In this context, a physician and/or hospital may well be considered a manufacturer of the final product and the manufacturer of the 3D printer itself may then be subject to somewhat limited liability.

Another doctrine that becomes increasingly relevant in the wake of 3D and 4D printing for manufacturers of the printers is the defence of lack of knowledge of danger. Generally, a manufacturer will not be liable for its failure to warn of a risk related to its product that it neither knew or ought to have known of. *See Rivtow Marine Ltd. v. Washington Iron Works*, [1974] SCR 1189, 1973 CanLII 6 (SCC). This is not an unlikely predicament in the case of 3D printers, which may well be used to produce a limitless array of finished products. In this context, proper labeling and marketing materials may assist manufacturers to defend against such future claims.

Concluding Remarks

There truly is a great deal to be excited about with 3D printing technologies and their applications in health care. However, manufacturers and distributors should carefully monitor the evolving statutory and regulatory regime to mitigate against regulatory and litigation risks down the road. Most importantly for manufacturers looking to sell their products across jurisdictional borders, care should be taken to review jurisdictional differences in the regulation of 3D printed medical devices and organs so as to inform internal processes and procedures. For some manufacturers, the calculus of this method often results in abiding by the highest regulatory standard across the different applicable jurisdictions.

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Edona Vila *is a Senior Associate at Borden Ladner Gervais LLP. She specializes in complex product liability commercial disputes and risk advisory services. She represents national and multi-national manufacturers, distributors, and suppliers in relation to cross border and domestic product liability, commercial, and insurance disputes across many different industries, including pharmaceuticals and medical devices. Much of her practice is focussed on advising on the liability associated with autonomous systems, connected devices, Internet of Things, and additive manufacturing products.*

Multi-Plaintiff Consolidated Trials: Plaintiffs Push for Quantity Over Quality

By Meera U. Sossamon and Carlos A. Benach


In recent years, multi-plaintiff consolidated product liability trials have not only generated some eye-opening verdicts, but have also raised questions about the validity of consolidating multiple claims for purposes of trial. *See Ingham v. Johnson & Johnson*, in the Circuit Court of the City of St. Louis, Missouri; Cause No. 1522-CC10417-01. Plaintiffs' counsel across the country have been using multi-plaintiff trials to push claims to large verdicts through quantity, despite a lack of quality. It is inevitable that a juror when presented with multiple, unrelated plaintiffs in a single trial against a manufacturer defendant will think "Well, where there is this much smoke there must be a fire."

And despite a court's instruction to a jury that "[y]ou may not even consider the fact that there's more than one case being brought," the reality is that multi-plaintiff trials burden the defense with trying to overcome this prejudice and figure out how to most efficiently and effectively defend multiple case issues at the same time. *See Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1315 (11th Cir. 2017). This article will review the legal standard and underlying rationale for case consolidation, review each side's arguments for and against consolidation, and provide some observations and insights related to consolidation motion practice.

Foundations for Multi-Plaintiff Consolidated Trials: FRCP Rule 42(a)

Per the Federal Rules of Civil Procedure, a party can move to consolidate lawsuits for trial "[i]f [the] actions before the court involve common questions of law or fact…" *See* Fed. R. Civ. P. 42(a). The essence of Rule 42 is simple: efficiency and economy. *See Hall v. Hall,* 138 S.Ct. 1118 (2018) (discussing the origins of Rule 42(a)). Most specifically, Rule 42(a) motions are used to create multi-plaintiff trial settings in which each consolidated case preserves its distinct identity and the rights of the parties in them. *Id.* at 1125.

The purpose of Rule 42(a) is to give a court the ability to decide how cases on its docket are to be developed and tried "so that the business of the court may be dispatched with expedition and economy while providing justice to all parties." §2381 History and Purpose of Rule 42, 9A Fed. Prac. & Proc. Civ. §2381 (3d ed.). However, just because there is a common question of law or fact does not mean that consolidation *must* be ordered, rather, consolidation is a matter left to the court's discretion. *See Enter. Bank v. Saettele,* 21 F.3d 233, 235 (8th Cir. 1994); *A.O.A. v. Doe Run Res. Corp.*, No. 4:11 CV 44 CDP, 2016 WL 1182631, at *2 (E.D. Mo. Mar. 28, 2016) (explaining "The threshold issue is whether the proceedings involve a common party and common issues of fact or law…The mere existence of common issues, however, does not mandate that the cases be joined."). Courts will consider various factors including the factual and legal similarities between the cases, whether consolidation would promote judicial economy and convenience, and whether consolidation will prejudice a party or confuse the jury. Fed. R. Civ. P. 42(a); *see also Eghnayem*, 873 F.3d at 1313; *Arnold v. E. Air Lines, Inc.,* 681 F.2d 186, 193 (4th Cir. 1982); *Dupont v. S. Pac. Co.,* 366 F.2d 193, 196 (5th Cir. 1966); *see also* Manual for Complex Litig. (4th ed. 2007), §§10.13, 11.631.

Rule 42's purpose provides the foundation for all arguments raised by parties with respect to consolidation. In the context of product liability litigation, plaintiffs typically focus their arguments on "expedience and economy," while defendants concentrate on ensuring "justice to all parties" -- namely avoiding the prejudice to the defense when they must defend against several unrelated plaintiffs in a single trial. Nevertheless, the specific factual and legal issues in each case, and context of the litigation play critical roles in creating persuasive arguments to defeat a motion to consolidate. Moreover, it is often critical to defeat consolidation at the trial court level, as on appellate review, the decision to consolidate is subject to the stringent "clear abuse of discretion" standard. *Eghnayem*, 873 F.3d at 1313 (*quoting Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1495 (11th Cir. 1985)).

Motions to Consolidate: Counteracting the Plaintiffs' Arguments

In the context of product liability, Plaintiffs' counsel's arguments in support of multi-plaintiff consolidated trials typically focus on the similar factual and legal issues between the proposed plaintiffs and the economy and judicial efficiency achieved in trying multiple cases together.

Often the proposed grouping of plaintiffs may be from the same state, and have the same resultant injury, with the idea being that it is efficient to apply the same state's law to the facts.

But plaintiff arguments on these points are often superficial and cursory.

For example, as to the factual issues in pharmaceutical drug and medical device litigation, Plaintiffs' counsel will argue that similar indications for use, concomitant drug use, and injury are exemplary of common facts that would warrant consolidation under Rule 42(a). *See In re: Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.,* 2010 WL 797273 (M.D. Ga. 2010); *In re Stand N' Seal Prods. Liab. Litig.*, 2009 WL 2224185 at *2 (N.D. Ga. 2009); *In re: Welding Fume Prods. Liab. Litig.*, 2006 WL 2869548 (N.D. Ohio 2006). The goal of this type of argument is to suggest that the operative facts related to each plaintiff are so similar that there should be no concern for jury confusion, nor should there be concern that a jury would award damages to compensate for an individual plaintiff's complicated injury/facts to the benefit of the consolidated group. *See Lillebo v. Zimmer, Inc.*, No. 03-2919 (JRT/FLN), 2005 WL 388598, at *10 (D. Minn. Feb. 16, 2005); *see also In re: C.R. Bard, Inc. Pelvic Repair Sys. Prod. Liab. Litig.* Plaintiff's Motion for Consolidation for Trial (No. 2:10-cv-1224) (S.D. W. Va. Mar. 3, 2013), ECF No. 111.

But the defense response to these arguments focuses on a more meaningful review. Plaintiff arguments that the injury complained of and medicine taken are the same ignore the myriad other factual differences between plaintiffs that are often critical to the determination of causation and liability—including pre- and post-injury treatment, comorbidities, physician testimony, and medical specific causation evidence. *See e.g. Guenther v. Novartis Pharm. Corp.*, No. 6:08-cv-456-Orl-31DAB, 2012 U.S. Dist. LEXIS 154748, at *5–7 (M.D. Fla. Oct. 12, 2012) *confirmed and adopted*, No. 6:08-cv-456-Orl-31DAB, 2012 U.S. Dist. LEXIS 154747 (M.D. Fla. Oct. 29, 2012); *Michael v. Wyeth, LLC,* Nos. 2:04-0435, *et al.*, 2011 U.S. Dist. LEXIS 42917, at *11–12 (S.D. W. Va. Apr. 20, 2011); *Johnson v. Advanced Bionics, LLC,* 2011 WL 1323883 (W.D. Tenn. Apr. 4, 2011).

Moreover, these factual differences between plaintiffs' cases are often exploited to the benefit of plaintiffs and the prejudice of defendants—or example, photographs of one plaintiff's gruesome injury that would otherwise be inadmissible and irrelevant in a trial of three other plaintiffs is now presented to the jury hearing all the cases at once. *See Eghnayem*, 873 F.3d at 1316; *Sidari v. Orleans County*, 174 F.R.D. 275, 282 (W.D.N.Y. 1996) (explaining "consolidation of the two cases would likely be overly prejudicial to the defendants" because "lumping" the claims together "amount to guilt by association"). A limiting instruction from the judge is cold comfort to un-ring these prejudicial bells.

Plaintiffs similarly paint the alleged commonality of legal issues with a broad brush when arguing for consolidation. For example, Plaintiffs in *In re Levaquin* argued that seven common legal questions existed amongst three claimants who were proposed for a consolidated trial setting. *In re: Levaquin Prods. Liab. Litig.*, Plaintiff's Memorandum in Support of Motion for Selection and Consolidation of Bellwether Cases for Trial (No. 8-md-1943) (D. Minn Oct. 23, 2009), ECF No. 580. Plaintiffs also argued that the similar generic liability experts for each party, documentary evidence of defendant's liability, and identical testimony of defense fact witnesses supported their position on the common legal issues in the case. *Id.*

But this too is a red herring. Particularly in product liability cases involving drugs and medical devices, the applicable law and affirmative defenses available in individual cases can vary greatly and often significantly impact the outcome and exposure—*e.g.*, statute of limitations, the learned intermediary doctrine, medical causation, superseding and intervening causes, and contributory/comparative fault, or even the law in effect at the time the particular plaintiff actually used the product. As one federal judge explained in denying a Rule 42(a) motion about an intrauterine contraceptive device, "no single proximate cause applies equally to each potential class member and each defendant" and thus "[n]o one set of operative facts establishes liability." *Hasman v. G.D. Searle & Co.*, 106 F.R.D. 459, 461 (E.D. Mich. 1985); *see also In re: Consol. Parlodel Litig.*, 182 F.R.D. 441, 447 (D.N.J. 1998) (explaining that "a consolidated trial....would compress critical evidence of specific causation and marketing to a level which would deprive [the defendant] of a fair opportunity to defend itself"); *Janssen Phamaceutica, Inc. v. Grant*, 873 So. 2d 100, 102 (Miss. 2004) (denying the aggregation of four cases for trial and noting the distinct litigable events underlying each plaintiff's case, including the warnings received and injuries sustained by each plaintiff).

Observations and Insights

So what can defendants do to combat the consolidation trend? At bottom, the plaintiff pitch is often deceptively simple and appealing to the court: multiple trials for the price and time of one. Further, particularly important to mass tort and multi-district litigation ("MDL"), consolidation

appeals to the notion that more cases can be resolved at once. The supposed selling point is that a consolidated trial will not only lead to the resolution of the proposed cases, but will also potentially serve as representative case for global settlement. *See In re: Mentor Corp.*, 2010 WL 797273, at *3; *In re Dow Corning Corp.*, 211 B.R. 545, 584 (Bankr. E.D. Mich. 1997); *In re Bendectin Litig.*, 857 F.2d 290, 317 (6th Cir. 1988). But as opposed to "common accident" litigation, product liability MDLs are more aptly characterized as "pattern litigation" and in these settings consolidation offers "little advantage over a few test trials that may produce more settlement than would lengthy and complicated cases." *In re N. Dist. Cal., Dalkon Shield IUD Litig.*, 693 F.2d 847, 854 (9th Cir. 1982).

The defense objective is to shift the judge's focus from the theoretical appeal of a consolidated trial to the practical realities and concerns of how it plays out and its very real prejudices to the defense, including jury confusion. *See Leeds v. Matrixx Initiatives, Inc.,* No. 2:10cv199DAK, 2012 U.S. Dist. LEXIS 47279, at *8 (D. Utah Apr. 2, 2012) (denying a motion to consolidate because of "significant case specific issues with respect to specific causation and damages" and the potential for prejudice to the Defendants and jury confusion"); *Cain v. Armstrong World Indus.,* 785 F. Supp. 1448, 1457 (S.D. Ala. 1992) (ordering a new trial, and observing that "[a]s the evidence unfolded ..., it became ... obvious ... that a process had been unleashed that left the jury the impossible task of being able to carefully sort out and distinguish the facts and law of thirteen plaintiffs' cases that varied greatly"); *In re Joint E. & S. Dists. Asbestos Litig.*, 125 F.R.D. 60, 63 (E. & S.D.N.Y. 1989). And emphasizing that the purported "efficiency" of this process is one-sided: Plaintiffs in a consolidated trial benefit from presenting cumulative sympathetic, graphic, and moving testimony and evidence from multiple injured plaintiffs, while defendants are limited to mounting one defense.

In almost every instance in which a court has denied a Rule 42(a) motion, the court has emphasized concerns with not providing the parties their fair opportunity to fully develop case specific facts and issues. Therefore, the more data the defense can present in its oppositions to motions to consolidate, the better. One effective way to demonstrate case specific distinctions is to use a chart to compare critical facts in each case. *See, e.g.*, *In re: Levaquin*, Defendant's Opposition to Plaintiff's Motion to Consolidate (No. 8-md-1943) (D. Minn. May 26, 2010), ECF No. 1385; *see also In re: Levaquin*, Order Denying Plaintiff's Motion to Consolidate Cases for Trial (No. 8-md-1943) (D. Minn. May 28, 2010), ECF No. 1389. A chart provides an easy way for the judge to quickly visualize confusion that a jury may stumble upon in analyzing and evaluating a case. This ability can perhaps be amplified by the current emerging trend to use technology in mass litigation or MDLs (like online repositories for plaintiff fact sheets and demographic tracking), to help defendants facing consolidation of multi-plaintiff trials demonstrate in measurable, quantifiable ways why such consolidation would only result in more confusion, and why plaintiffs' cases are more dissimilar than they are alike (*e.g.*, by pulling demographics on length of use of the product, when used, comorbidities, and so on, on a grand scale). For instance, the ability to pull out demographics and statistics on the disparity of length of use or severity of injury among a common state's plaintiffs quickly and in an easily digestible medium (graphs, charts, tables) may present a compelling visual rebuttal to plaintiffs' arguments and ultimately help defeat a Rule 42(a) motion to consolidate.

The goal is to use today's litigation technology and ability to assess plaintiff data to help the court break away from the plaintiffs' simplistic, 20,000-foot overview of why consolidation is appropriate. As is often the case, the prescription for the defense is to delve into the details, and hopefully show courts that the quality of plaintiffs' consolidation arguments is lacking.

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