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LAY OF THE (MDL) LAND:

A Bird's-Eye View of Pharmaceutical Litigation.

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Have you ever wondered how pharmaceutical Multi-District Litigation stacked up against other litigation in the MDL? In "Lay of the (MDL) Land: A Bird's-Eye View of Pharmaceutical Litigation," we analyze how much of the MDL is pharmaceutical litigation and offer some interesting statistics about the cases filed there.

Off-label promotion is too often an allegation against pharmaceutical companies in both civil and criminal actions. "Off-Label Promotion: Is it Free Speech?" discusses this timely issue.

Everyone is talking about social media – even the FDA. "Like it or not? The FDA is Following Social Media," discusses how two recent FDA guidances may help your company navigate social media without violating rules and regulations. It also highlights areas where you are still on your own as to what a pharmaceutical or medical device company can post on social media.

It is not often that corporations are handed a new weapon for their defense arsenal by the United States Supreme Court. The Court, however, did just that in the recent *Daimler AG v. Baumer* case. You will want to read "It's Personal: The Supreme Court Equips Corporate Defendants With a Potent Defense From an Almost Forgotten Friend," to see how this case will affect your company and how it has already resulted in dismissals of actions against corporations.

We think this issue is one that will be useful to your business. We hope you agree.

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LAY OF THE (MDL) LAND:

A BIRD'S-EYE VIEW OF PHARMACEUTICAL LITIGATION

In the world of pharmaceutical litigation, the acronym "MDL" – Multidistrict Litigation – is an all-too-common part of litigators' and clients' daily vocabulary. This article touches briefly on what an MDL is and how one is created, then turns to its main purpose: offering a bird's-eye view of the current (yet constantly evolving) universe of pharmaceutical MDLs.

BASIC ROADMAP OF MDL PRACTICE

An MDL is a creature of federal statute. Authorized by 28 U.S.C. §1407, any party – defendant or plaintiff – may request an MDL in any federal district court in the country. Not to be confused with a class action, the practical effect of a new MDL means that a single federal district court is vested with the authority to manage any number of individual cases that have been deemed similar enough to be handled on a collective basis, at least through the discovery process.

The statute itself contains only two threshold criteria: first, that there are civil actions pending in different districts, and second, that the cases involve "one or more common questions of fact."[1] The mechanics of requesting an MDL begin with filing a Motion to Transfer with the governing authority, the Judicial Panel on Multidistrict Litigation ("JPML" or "the Panel").[2] Based in Washington, D.C., with its own Clerk and staff, the JPML consists of seven federal judges, no two of whom may be from the same circuit.[3] Members are appointed to serve on the JPML by the Chief Justice of the United States Supreme Court.[4] The Panel is chaired today by Judge Sarah S.

For those in the trenches of pharmaceutical litigation, it may be initially surprising to learn that pharmaceutical MDLs do not dominate other types of MDLs – at least in terms of the overall number of MDLs nationwide.

JPML – PANEL JUDGES

CHAIR:

Judge Sarah S. Vance (Eastern District of Louisiana)

MEMBERS:

Judge Marjorie Rendell (Third Circuit Court of Appeals)
Judge Charles Breyer (Northern District of California)
Judge Ellen Segal Huvelle (District of District of Columbia)
Judge Lewis Kaplan (Southern District of New York)
Judge Catherine D. Perry (Eastern District of Missouri)
Judge R. David Proctor (Northern District of Alabama)

Vance (U.S. District Court, Eastern District of Louisiana), who assumed this role in August 2014 following the long tenure of Judge John Heyburn II. Three current members – Judges Ellen Segal Huvelle, Catherine Perry and R. David Proctor – are new additions to the Panel as of 2013-2014.[5]

The Panel meets roughly every two months in different locations. At these scheduled sessions, the JPML hears argument on Motions to Transfer (i.e., to create an MDL) and also rules on (usually without oral argument) other MDL-specific filings.[6] As pertinent here, if the Panel (a) concludes that the civil actions in question present one or more common questions of fact, and (b) further determines that transfer to a single district court for pretrial proceedings "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions," the motion will be granted.[7]

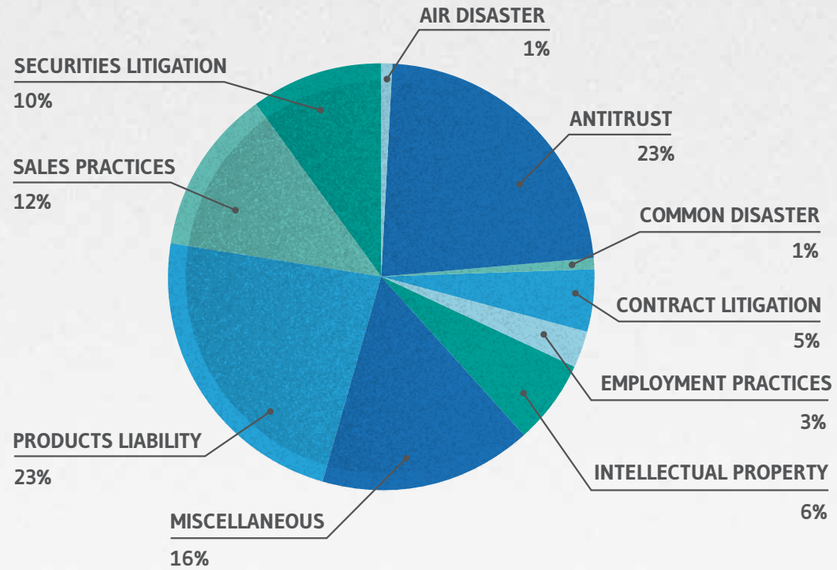
The logistics of transferring cases from various districts to the newly minted MDL court (i.e., the "transferee court") is beyond the scope of this article, as is the process for remanding and/or trying cases in the MDL. Instead, this article provides a snapshot of how pharmaceutical MDLs stack up in the grand scheme of MDLs nationwide, and further provides detail on current pharmaceutical MDLs in terms of who (courts, judges), what (products, numbers of actions and plaintiffs) and where (locations of MDL courts).

THE LANDSCAPE OF NATIONWIDE MDLS

An MDL can be created for almost any imaginable civil action. Common MDL subject matter includes antitrust, intellectual property, securities, products liability, contract litigation, sales practices and employment, as well as a catchall "miscellaneous" category that runs the gamut of topics. For those in the trenches of pharmaceutical litigation, it may be initially surprising to learn that pharmaceutical MDLs do not dominate other types of MDLs – at least in terms of the overall number of MDLs nationwide. Those same folks in the trenches, however, will not be surprised to hear that pharmaceutical MDLs overwhelmingly lead in terms of the number of active cases per MDL category.

OVERALL MDL NUMBERS

Statistics compiled for this article, obtained from the JPML's October 15, 2014 official reports, identify a nationwide total of 281 MDLs considered "open" or current. The JPML categorizes pending MDLs via 10 categories of actions or "docket types," currently identified as follows:

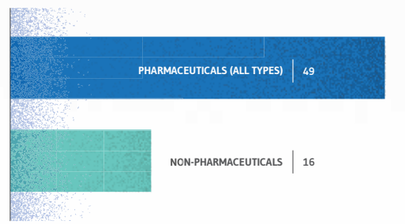


MDLs BY DOCKET TYPE

As the chart above shows, Products Liability and Antitrust are roughly equal in terms of the total number of active MDLs (65 and 64, respectively). Pharmaceutical MDLs, however, far outpace Antitrust MDLs in terms of active member actions (cases) – with pharma at nearly 116,000 cases and antitrust at approximately 1,600.

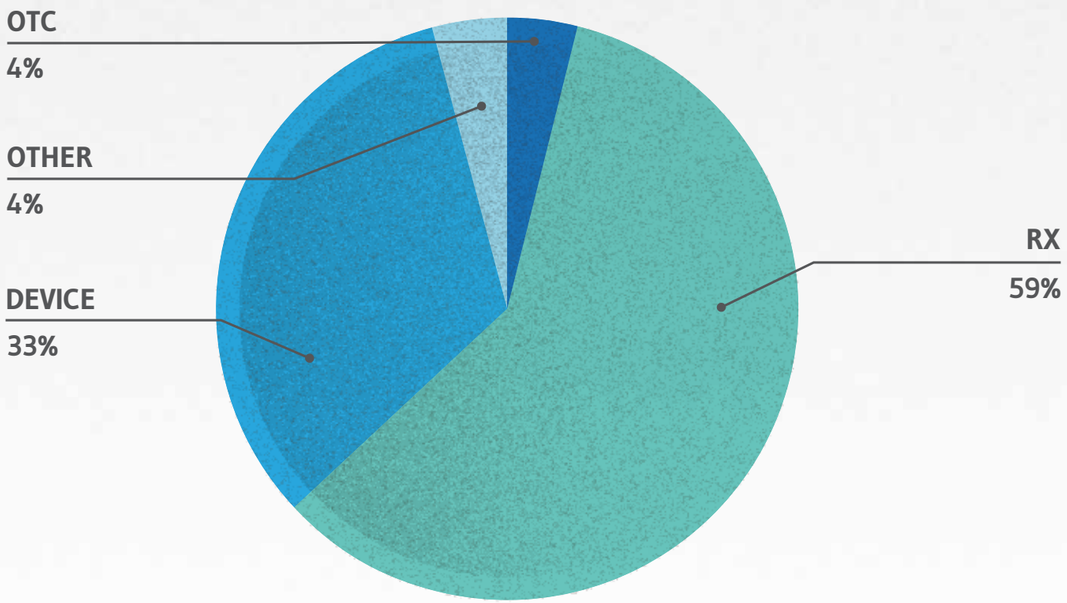
PHARMACEUTICAL VS. NON-PHARMA PRODUCTS LIABILITY MDLS

Further analysis of the 65 current MDLs making up the Products Liability category reveals that 49 MDLs involve some type of pharmaceutical product:



Of the 49 pharmaceutical MDLs, more than one-half (59%) involve prescription drug products. Another 33% involve medical devices, and a small fraction (4%) involve over-the-counter products:

PHARMACEUTICAL PRODUCTS LIABILITY MDLS BY PRODUCT



PHARMACEUTICAL MDLS: WHO, WHAT, WHEN, WHERE, HOW LONG

According to JPML reporting, currently active pharmaceutical MDLs include the following 49 matters, with case captions substantially and intentionally abbreviated here. Note that several of these MDLs are, for practical purposes, closed – or are close to it – yet for consistency and writing purposes, statistics were obtained and compiled from JPML reporting as of October 15, 2014.

The list is organized by year of creation of the MDL; it shows that a handful of old MDLs are still on the books, and without question, new requests for MDLs continue to be granted – with more than a dozen pharmaceutical MDLs having been created over the past two years and still active. These statistics further reveal that pharmaceutical MDLs currently account for 116,000 active member actions (cases) today:

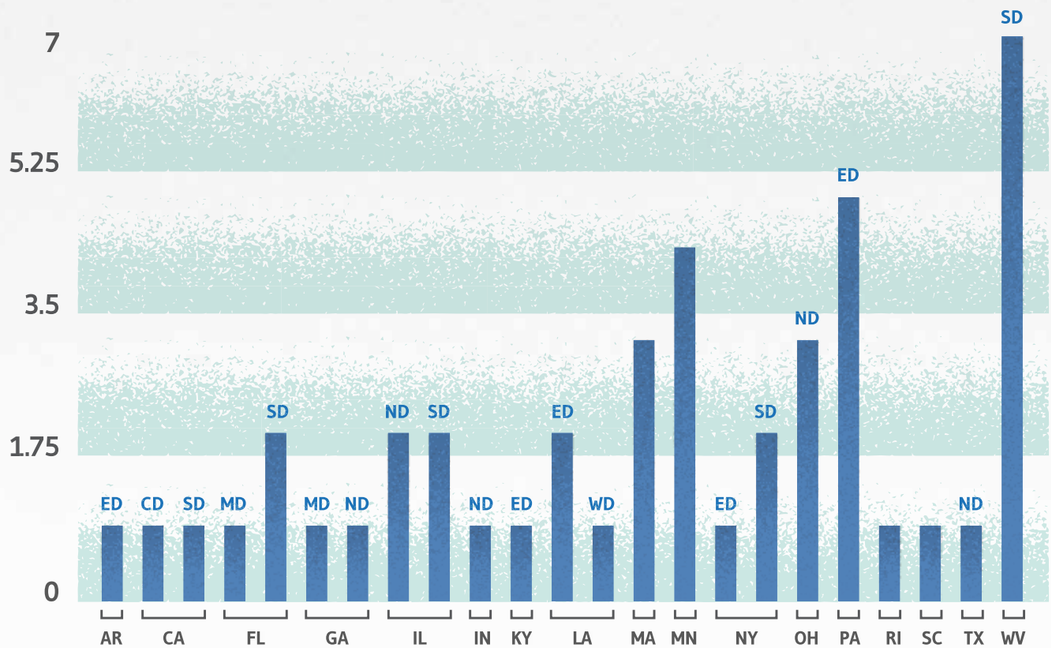
Product	Began	Number of Actions (as of 10-15-2014)	MDL Court	Judge Presiding
Diet Drugs	1997	20	Pennsylvania (E.D.)	Hon. Harvey Bartle, III
Baycol	2001	1	Minnesota	Hon. Michael James Davis
Prempro	2003	61	Arkansas (E.D.)	Hon. Billy Roy Wilson
Accutane	2004	3	Florida (M.D.)	Hon. James S. Moody, Jr.
Neurontin	2004	2	Massachusetts	Hon. Patti B. Saris
Vioxx	2005	403	Louisiana (E.D.)	Hon. Eldon E. Fallon
Fosamax (I)	2006	902	New York (S.D.)	Hon. John F. Keenan
Ortho Evra	2006	4	Ohio (N.D.)	Hon. David A. Katz
Avandia	2007	2,570	Pennsylvania (E.D.)	Hon. Cynthia M. Rufe
Kugel Hernia Mesh	2007	665	Rhode Island	Hon. Mary M. Lisi
Mirapex	2007	3	Minnesota	Hon. Michael James Davis
Heparin	2008	10	Ohio (N.D.)	Hon. James G. Carr
Levaquin	2008	259	Minnesota	Hon. John R. Tunheim
Mentor ObTape	2008	452	Georgia (M.D.)	Hon. Clay D. Land
NuvaRing	2008	1,763	Missouri (E.D.)	Hon. Rodney W. Sippel
Trasylol	2008	3	Florida (S.D.)	Hon. Donald M. Middlebrooks
Denture Cream	2009	82	Florida (S.D.)	Hon. Cecilia M. Altonaga
Yasmin	2009	6,951	Illinois (S.D.)	Hon. David R. Herndon
CR Bard Pelvic Repair	2010	9,863	West Virginia (N.D.)	Hon. Joseph R. Goodwin
DePuy ASR Hip	2010	8,509	Ohio (N.D.)	Hon. David A. Katz
Zimmer Durom Hip	2010	309	New Jersey	Hon. Susan D. Wigenton

Product	Began	Number of Actions (as of 10-15-2014)	MDL Court	Judge Presiding
Actos	2011	3,718	Louisiana (W.D.)	Hon. Rebecca F. Doherty
Darvocet	2011	3	Kentucky (E.D.)	Hon. Danny C. Reeves
DePuy Pinnacle Hip	2011	6,632	Texas (N.D.)	Hon. James Edgar Kinkeade
Fosamax (II)	2011	517	New Jersey	Hon. Joel A. Pisano
Zimmer NexGen Knee	2011	1,319	Illinois (N.D.)	Hon. Rebecca R. Pallmeyer
AMS Pelvic Repair	2012	18,866	West Virginia (N.D.)	Hon. Joseph R. Goodwin
Biomet Hip	2012	1,947	Indiana (N.D.)	Hon. Robert L. Miller, Jr.
Boston Scientific Pelvic Repair	2012	14,094	West Virginia (N.D.)	Hon. Joseph R. Goodwin
Coloplast Pelvic Support Sys	2012	1,730	West Virginia (N.D.)	Hon. Joseph R. Goodwin
Ethicon Pelvic Repair	2012	21,643	West Virginia (N.D.)	Hon. Joseph R. Goodwin
Nexium	2012	22	California (C.D.)	Hon. Dale S. Fischer
Pradaxa	2012	2,479	Illinois (S.D.)	Hon. David R. Herndon
Propecia	2012	743	New York (E.D.)	Hon. John Gleeson
Wright Med. Conserve Hip	2012	398	Georgia (N.D.)	Hon. William S. Duffey, Jr.
Zoloft	2012	526	Pennsylvania (E.D.)	Hon. Cynthia M. Rufe
Cook Medical Pelvic Repair	2013	259	West Virginia (N.D.)	Hon. Joseph R. Goodwin
Effexor	2013	68	Pennsylvania (E.D.)	Hon. Cynthia M. Rufe
Franck's Lab	2013	34	Louisiana (E.D.)	Hon. Kurt D. Engelhardt
Fresenius GranuFlo	2013	2,127	Massachusetts	Hon. Douglas P. Woodlock
Incretin	2013	546	California (S.D.)	Hon. Anthony J. Battaglia
Mirena IUD	2013	1,042	New York (S.D.)	Hon. Cathy Seibel
New England Compounding	2013	615	Massachusetts	Hon. Rya W. Zobel
Plavix	2013	31	New Jersey	Hon. Freda L. Wolfson
Stryker Hip	2013	1,908	Minnesota	Hon. Donovan W. Frank
Tylenol	2013	164	Pennsylvania (E.D.)	Hon. Lawrence Stengel
Lipitor (II)	2014	1,355	South Carolina	Hon. Richard M. Gergel
Neomedic Pelvic Repair	2014	67	West Virginia (N.D.)	Hon. Joseph R. Goodwin
Testosterone Replacement	2014	223	Illinois (N.D.)	Hon. Matthew F. Kennelly

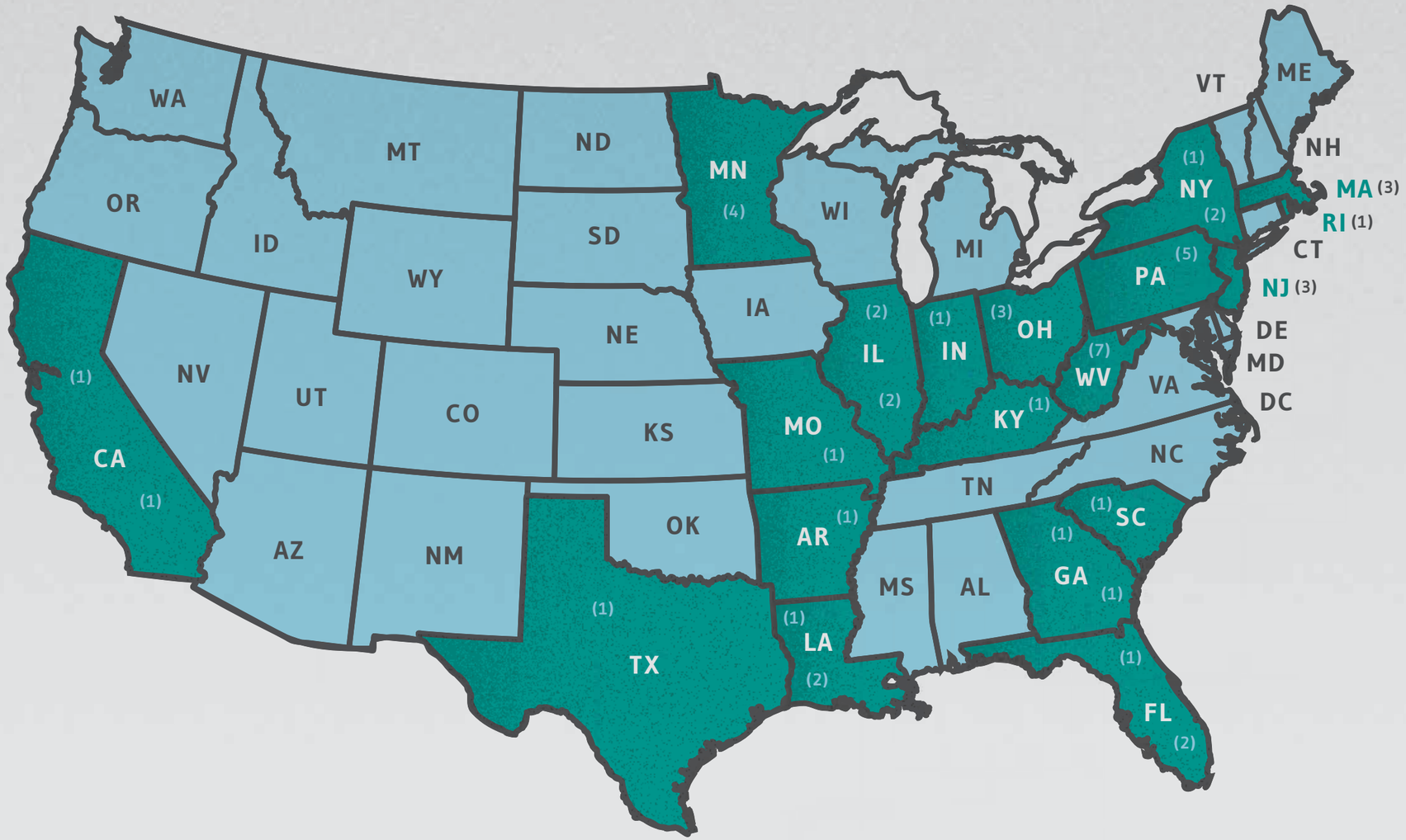
PHARMACEUTICAL MDLS: WHERE

Pharmaceutical MDLs are housed across the country, with the vast majority – all except three – found in courts in the eastern half of the U.S., as reflected in the chart below and graphic on the following page. Note, however, that reporting the locations of pharmaceutical MDLs must be taken with the proverbial grain of salt: consider that Judge Joseph R. Goodwin (Northern District of West Virginia) is alone presiding over seven MDLs involving pelvic mesh products by different manufacturers. The pelvic mesh MDLs, collectively, are reported to total more than 66,500 member actions – thus representing 57% of all pharmaceutical MDL plaintiffs nationwide.

PHARMACEUTICAL MDLS BY LOCATION



PHARMACEUTICAL MDLS ACROSS THE COUNTRY

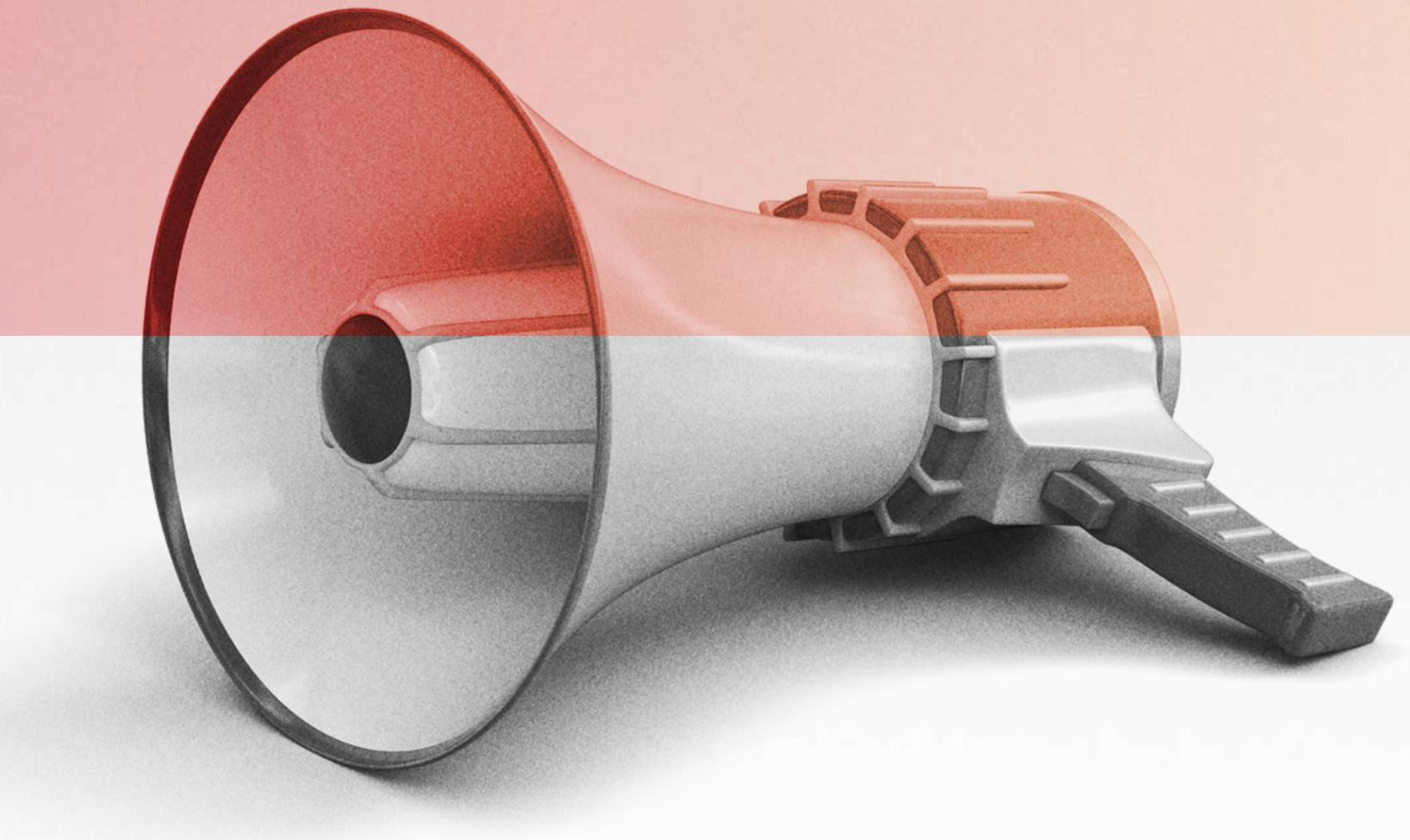


CONCLUSION

Given the vagaries of overall civil litigation at any point in time, an across-the-board comparison of nationwide MDLs is not feasible nor readable outside a treatise on the topic. What is evident, however, is that pharmaceutical MDLs play a significant role in the nationwide MDL scene, in terms of types, numbers, lengths of time and locations of the MDL courts overseeing them. ■

1. 28 U.S.C. § 1407(a).
2. 28 U.S.C. § 1407(a).
3. 28 U.S.C. 1407(d).
4. 28 U.S.C. § 1407(d).
5. Roster of Current and Former Judges of the United States Judicial Panel on Multidistrict Litigation, http://www.jpml.uscourts.gov/sites/jpml/files/Panel%20Judges%20Roster-10-16-2014_0.pdf (last accessed Oct. 17, 2014).
6. A list of upcoming hearings may be found at http://www.jpml.uscourts.gov/hearing-information (last accessed Oct. 17, 2014).
7. 28 U.S.C. § 1407(a)-(c).

By Richelle Kidder



OFF-LABEL **PROMOTION:** IS IT FREE SPEECH?

Case law decided in 2011 and 2012 created an illusion of security that pharmaceutical manufacturers' communications regarding medications approved by the Food and Drug Administration (FDA) are protected by the First Amendment. *See Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011); *United States v. Caronia*, 703 F. 3d 149 (2d Cir. 2012). Specifically, these cases stand for the proposition that the Food, Drug and Cosmetic Act (FDCA) could not be interpreted to prohibit truthful, off-label promotion because that type of off-label promotion is commercial speech protected by the First Amendment. The pronouncement in these cases, particularly *Caronia*, seems clear, but they are in marked contrast to the plain language of the Food and Drug Cosmetic Act (FDCA) as well as FDA guidance documents as to what the companies can and cannot do with respect to off-label promotion. Moreover, *Caronia* left open the door for the government to use off-label promotion as evidence of a crime of fraud or misbranding. And we have yet to see any decrease in the Justice Department's off-label investigations or pending settlements for alleged off-label marketing of drugs for uses not yet approved by the Food and Drug Administration (FDA).

1. RECENT CASE LAW ESTABLISHES THAT OFF-LABEL PROMOTION IS FREE SPEECH PROTECTED BY FIRST AMENDMENT

In *Sorrell*, the United States Supreme Court decided that a Vermont statute that prohibited pharmaceutical companies from using prescriber-identifying information for marketing purposes violated the First Amendment.

Sorrell was used as a stepping stone in the seminal case that has garnered significant attention on the application of the First Amendment to off-label promotion *Caronia*. In *Caronia*, the Defendant sales representative was charged with conspiracy to misbrand a medication because he was promoting the medicine for unapproved uses. The jury instruction provided by the district court stated: "A misbranded drug may be shown by a promotion of a drug by a distributor for an intended use different from the use for which the drug was approved by the FDA." [1]*Caronia*, 703 F.3d at 158. The Defendant was convicted in the Eastern District of New York for misbranding, specifically promoting an off-label use of an approved prescription drug. The United States Court of Appeals for the Second Circuit vacated and remanded the decision finding that the application of the FDCA's misbranding provisions to his off-label promotional statements unconstitutionally restricted his right to free speech under the First Amendment. In making its decision, the Court reasoned that the FDCA does not make it a crime or expressly prohibit off-label promotion. Id. at 159; see 21 C.F.R. § 201.128. However, it held that the "The promotion of off-label uses plays an evidentiary role in determining whether a drug is misbranded under 21 C.F.R. § 352(f)(1)." Relying on the *Sorrell* decision, the Court found that "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by the *Free Speech Clause of the First Amendment.*" *Id.* at 161 (citing *Sorrell*, 131 S. Ct. at 2659 [emphasis in original]). The government did not appeal the Second Circuit's decision, so we do not know how the Supreme Court would have ruled on this precise issue.

2. CONFLICT WITH FDA REGULATIONS AND GUIDANCES

In the aftermath of *Caronia*, pharmaceutical companies are left with uncertainty as to best practices to use that are in line with the *Caronia* holding as well as the FDA rules and regulations. Regulations provide that pharmaceutical manufacturers may lawfully provide off-label use information in accordance with the following: as part of scientific exchange, in response to unsolicited requests, in the context of continuing medical education (CME) and other scientific and educational activities, and in medical journal articles and scientific or medical reference publications disseminated to prescribers and healthcare entities. *See* 21 C.F.R. §312.7(a); 59 Fed. Reg. 59.820, 59.823; 62 Fed. Reg. 64,074; 74 Fed. Reg. 1,694.

GUIDANCE DOCUMENTS PROVIDE THE FOLLOWING RECOMMENDATIONS:

Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (December 2011)

This draft guidance provides the FDA's recommendations to companies wishing to respond to unsolicited requests for off-label information about their products, including both requests made directly and privately to companies and requests made in public forums, including through emerging electronic media. The draft guidance discusses the difference between unsolicited and solicited requests and presents a number of examples of both types of requests. The guidance states that if a company responds to unsolicited requests for off-label information in the manner described in the draft guidance, the FDA does not intend to use such responses as evidence of the firm's intent that its product be used for an unapproved or uncleared use. Such responses also would not be expected to comply with the disclosure requirements related to promotional labeling and advertising. The FDA advised that companies which choose to respond to unsolicited requests for information about off-label uses of their approved or cleared products in a manner other than that recommended in the draft guidance would not be violating the law per se, but such responses could potentially be introduced as evidence of a new intended use.

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See "Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices," December 2011. *Available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf. *Last accessed* October 22, 2014.

Revised Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices (February 2014)

On March 3, 2014, the FDA issued a new draft guidance allowing manufacturers to distribute journal articles, textbooks and clinical practice guidelines containing information about off-label uses of approved/cleared drugs and medical devices. The draft updates the FDA's 2009 reprints guidance and represents the first time the FDA has ever acknowledged in a guidance or regulation that it is permissible for a manufacturer to distribute such guidelines, and represents the FDA's continued effort to respond to the issues raised by the Medical Information Working Group (MIWG) and its member companies in two citizen petitions filed with the FDA in 2011 and 2013.[2] On June 6, 2014, the FDA granted these Citizen Petitions submitted by the MIWG that requested clarification of the agency's position on

drug and device manufacturer communications concerning investigational products and unapproved uses of approved products. MIWG specifically asked the agency to review its regulations and policies in light of recent First Amendment case law, including the Sorrell and Caronia cases. In its response to the petitions, the agency stated that it has already addressed many of the specific issues raised by MIWG in recent guidance on unsolicited requests (2011); social media (2013); and reprints, reference texts, and clinical practice guidelines (2014). The agency also issued a call for comment on the scope of "scientific exchange" in December 2011. In addition to these initiatives, the FDA reported that it plans to issue two new guidance documents before the end of 2014 – one addressing unsolicited requests, distributing scientific and medical information about unapproved new uses, and manufacturer discussions concerning scientific information more generally, and another on healthcare economic information.

See "FDA Revised Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices," February 2014. *Available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf. *Last accessed October* 22, 2014.

3. CRIMINAL PROSECUTIONS

To further muddy the issue, pharmaceutical companies have been faced with repeated prosecutions from the government, resulting in massive dollar value settlements, where the focus of the conduct has been off-label promotion. *See e.g., United States v. GlaxoSmithKline, LLC,* 12-cr-10206, ECF Docket No. 13 (D. Mass. July 10, 2012).

Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that the FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label uses" – renders the product "misbranded." *Caronia*, 703 F.3d. at 154. It is under the theory that off-label use rises to misbranding that prosecutions against companies are resulting in significant charges and settlements. In these criminal matters, the government unlawfully alleges promotion of FDA-approved medications for unapproved indications. For example, the United States will typically allege that, among other things, a company participated in preparing, publishing and distributing misleading medical journal articles that misreported clinical trial information. The Government will then focus on sales activity directed at promoting the medication for unintended uses. Id. However, one could argue that there is a requirement of fraud or falsity required for the government to be successful in prosecuting these types of claims.

Until this issue is more settled, pharmaceutical manufacturers should remain aware of, and be wary of, the risks of off-label promotion.

4. RECENT DEVELOPMENTS

In April, at the Food and Drug Law Institute Annual Meeting, the FDA senior officials stated that the organization is taking the industry's concerns seriously that its existing off-label policies are not in line with the most recent First Amendment case law. See Coalition for Healthcare Communication, *"FDA Willing to 'Re-examine' Off-label Policies in Light of First Amendment Rulings,"* April 28, 2014. *Available at* http://www.cohealthcom.org/2014/04/28/fda-willing-to-%E2%80%9Cre-examine%E2%80%9D-off-label-policies-in-light-of-first-amendment-rulings/. *Last accessed* October 21, 2014. Additionally, in a recent California case alleging violation under the False Claims Act, PhRMA filed an amicus brief to support Defendants' motion to dismiss arguing that the conduct in question, dissemination of published articles, is protected by the First Amendment. *See United States ex rel. Solis v. Millennium Pharmaceuticals, Inc.,* 2014 WL 1270591 E.D. Cal,. Mar. 26, 2014. The thrust of the argument on behalf of the Defendants is that the First Amendment does not permit the criminalization of truthful, off-label promotion.

Until there are additional promulgations from the FDA in the form of guidances, or regulations or further responses to the Citizen Petitions and other requests from industry working groups, we continue to monitor cases and stakeholder positions that may implicate future action in this area. Until this issue is more settled, pharmaceutical manufacturers should remain aware of, and be wary of, the risks of off-label promotion. ■

1. Although the appeal challenged the use of the instruction, the Second Circuit did not reach a decision on that issue because of its ruling related to the restriction on the First Amendment.
2. *See* "Citizen Petition," September 3, 2013 *Available at*, found at http://www.cohealthcom.org/wp-content/uploads/2013/09/citizen-petition.pdf . Last accessed October 21, 2014.

By Alyson Jones

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LIKE IT OR NOT?

THE FDA IS FOLLOWING SOCIAL MEDIA

The FDA is watching to make sure pharmaceutical and drug device manufacturers aren't "liking" social media posts that promote the off-label use of their drug, or posting about the benefits of a drug without any mention of the risks. In keeping up with the times, many drug and device companies have taken advantage of the information superhighway to expand their advertising and promotional reach. As tempting as it is, some companies have been hesitant to swim in the murky waters of social media promotion due to uncertainties about how the FDA would react.

In 2009, the FDA requested input from the public about appropriate promotional use via the Internet and social media in an attempt to catch up with technology since the FDA's public meeting in 1996 to discuss issues related to promotion of FDA-regulated drugs and devices on the Internet. The update was driven by new technologies and tools, such as blogs, microblogs (Twitter), podcasts, social media (Facebook), video sharing (YouTube) and wiki pages (Wikipedia). In looking to redefine its social media guidance for industry, the FDA asked for input on the types of online communications manufacturers should be held accountable for, how industry would communicate both the benefits and risks, the parameters that should apply to posting of corrective information on websites controlled by third parties, when the use of links is appropriate and issues related to Internet adverse-event reporting.

In June of 2014, the FDA issued two draft guidance documents on social media to help ensure accurate and truthful promotion and communication of drugs and devices by manufacturers. The first guidance provides recommendations for balancing both benefit and risk information when using social media platforms with character limitations, such as Twitter and paid search results on Google. The second guidance provides the FDA's recommendations for companies to address the correction of misrepresentations or wrong information from third parties who post misinformation about their drug or medical device on the Internet. The director of FDA's Office of Prescription Drug Promotion in the Agency's Center for Drug Evaluation and Research (CDER) stated that the FDA is "committed to ensuring that the information about these products that their manufacturers and distributors direct at patients and healthcare providers is accurate and balanced." Although these two guidances provide some clarity, it is clear that the FDA is still doing its due diligence to collect public comments. On September 26, 2014, the FDA posted that it is "reopening the comment period for the two draft social media guidances," giving the public an additional 30 days to provide feedback.

In June of 2014 the FDA issued two draft guidance documents on social media to help ensure accurate and truthful promotion and communication of drugs and devices by manufacturers.

CHARACTER SPACE LIMITATIONS – PRESENTING RISK AND BENEFIT INFORMATION FOR PRESCRIPTION DRUGS AND MEDICAL DEVICES:

Companies and the FDA have wrestled with how to address fair balance when faced with a constraint text or character space limitations. The two most widely discussed platforms include Twitter, which limits "tweets" to 140 character spaces, and online paid searches such as Google advertisements which are supposed to attach risk information through sitelinks. Critics of the FDA's Social Media Guidance on Character Space Limitations have complained that companies could still be in violation of fair balance even if they follow the guidance because sitelinks containing risk information are not guaranteed to appear on Google Ads. Further complicating matters is that some descriptions of the sitelinks might not appear at all, and others might not appear on mobile sites due to character limitations, which could in essence cause the company to be advertising while not in compliance with fair balance if the FDA-required sitelinks fail to appear. Unfortunately, the FDA guidance failed to address various character and sitelink limitations imposed by the increasingly popular mobile platforms. While this guidance includes microblogs such as Twitter and online paid searches for Google-sponsored links, it does not provide guidance on product websites, webpages on social media platforms, online web banners or responsive web design (mobile device and tablet formats).

An overview of the FDA's policy is that companies should include risk information along with benefit claims regardless of character space constraints, while also providing a link to allow direct access of a more complete description of the risks associated with a drug or device. Companies should heed the FDA's hardline approach: "If an accurate and balanced presentation of both risks and benefits of a specific

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product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message." Put simply, it might be best to stay away from promoting a drug or device via Twitter. The FDA used the example of a company considering the following post to Twitter, "NoFocus is indicated for mild to moderate memory loss. [40/140 characters]," suggesting that the company consider whether the remaining 100 characters are sufficient to convey the necessary risk and other required information. Interestingly, the FDA has failed to comment on similar tweets, such as Pfizer's 2012 tweet stating, "FDA Approves Lyrica® (pregabalin) capsules CV for Management of Neuropathic Pain Associated w/Spinal Cord Injury on.pfizer.com/M80A5M."

What is confusing is that the FDA does not necessarily follow the same guidance that it is requiring the industry to follow. In the above example from the FDA's guidance, the FDA clearly questioned the sufficiency of a tweet that only included the name of the drug and the indication; however, in an October 10, 2014, post, the FDA tweeted, "FDA approves Akynzeo (nteupitant and palonosetron): go.usa.gov/wyX5." It is unclear whether the manufacturer of Akynzeo could post this same tweet without any repercussions. At a minimum, companies should include a link to a site that contains the full discussion of the risks associated with the drug or device at issue.

CORRECTING INDEPENDENT THIRD-PARTY MISINFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES:

Fortunately, drug and device companies are not responsible for policing the Internet universe in order to correct any misinformation about their products when the user-generated content is truly independent of the company. Companies are, however, on the hook for statements made on the Internet or through social media by "its employees or any agents acting on behalf of the firm to promote the firm's product."

The FDA's 2014 guidance clearly requires fair balance and that the company correct misinformation when statements on a website include some form of "control over, involvement with or influence over a product-related communication" by the company. In other words, companies are responsible for content on third-party sites if the company has any control or influence over the site, collaborates or has editorial privileges, or influences the placement of its promotion within the third-party site. For instance, a company is not obligated to correct misinformation if a blogger posts "misinformation" about a drug if the company did not host the website, have review privileges, place an advertisement on the blog's website or have a relationship with the blogger. Keeping in line with the FDA's guidance, if a company decides to correct a third party's Internet post containing misinformation, then the company should clearly identify the misinformation that it is correcting, provide a statement that it is responding only to the specified information, and provide a direct link to the FDA-required labeling. While companies have an incentive to correct misinformation about overexaggerated risks of their drugs or devices, they should also correct misinformation about exaggerated benefits. Companies are expected to keep records of instances where they correct misinformation from nonrestricted sites, but they are not expected to report corrections to the FDA. The FDA also recommends that companies submit an updated listing on a monthly basis of all nonrestricted sites for which the company is responsible or remains an active participant.

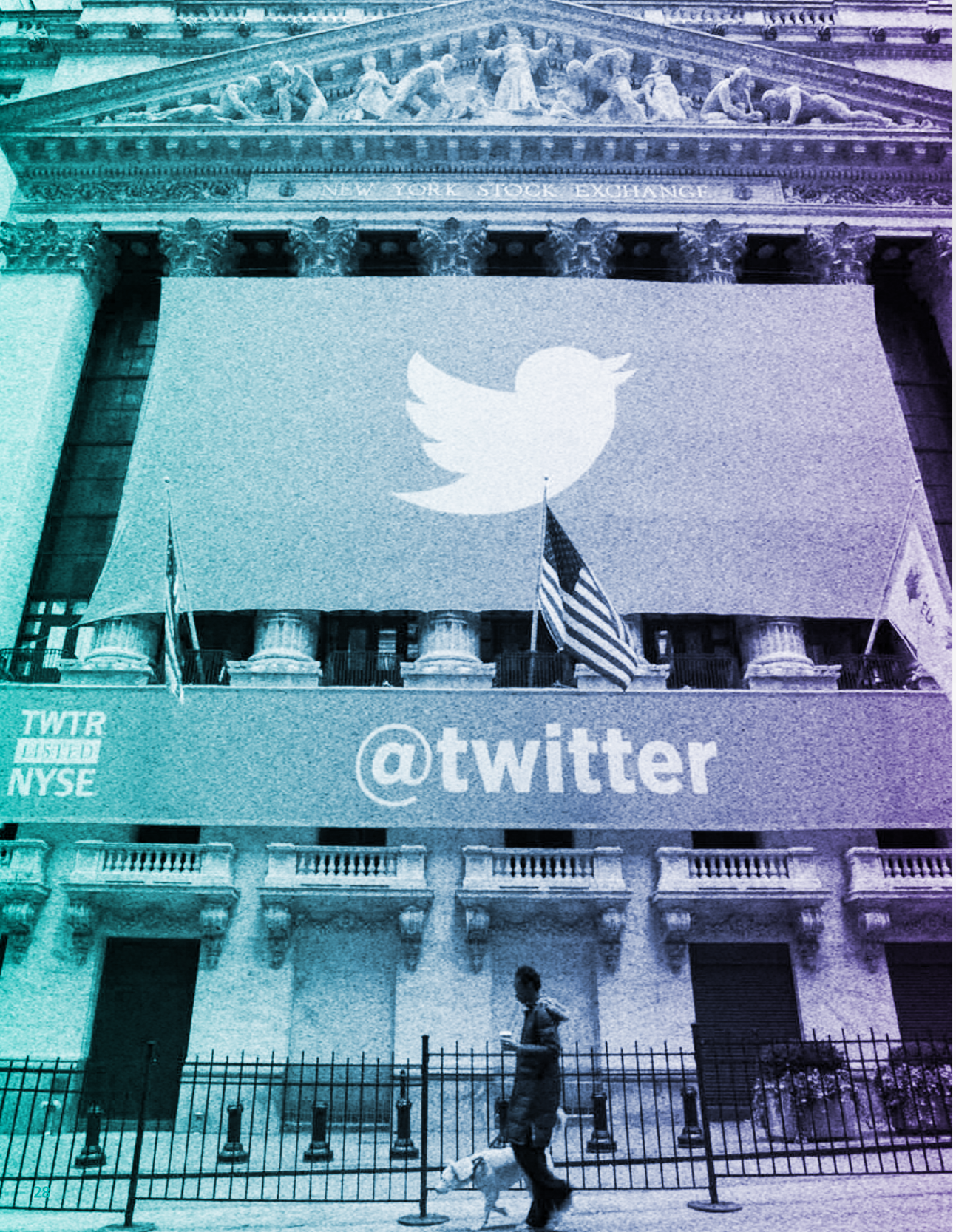
Drug and device companies should implement policies setting out strict guidelines for sales reps posting comments on social media and videos to YouTube. An example that the industry can learn from is a May 5, 2011, untitled letter the FDA issued to a drug company because of a "misleading" video about a drug that one of its sales representatives posted on YouTube. The FDA found that the video was misleading because "it makes representations about the use of Atelvia, but fails to present any risks associated with the use of Atelvia and fails to disclose the drug's indication. The video also presents dosing claims for Atelvia that omit material facts and that are misleading." The dosing statement was considered misleading because it stated "can eat and drink with in the morning" instead of the labeling which states, "should be taken in the morning."

There is nothing to "like" about receiving a Warning Letter from the FDA. The FDA issued a February 26, 2014, Warning Letter to a drug company for "liking" a customer's post on the company's Facebook wall that promoted off-label use of the drug. On March 10, 2011, the company "liked" a post that stated, "PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation..." The problem is that the company marketed the drug as a dietary supplement without ever seeking FDA approval as a drug designed to treat any specific disease.

> Put simply, it might be best to stay away from promoting a drug or device via Twitter.

HOW MANUFACTURERS CAN HANDLE THE CHALLENGES OF SOCIAL MEDIA:

Pfizer and other drug companies have utilized editorial features giving them the ability to delete Facebook users' inappropriate or misleading comments that could subject the company to an unwelcomed FDA warning letter. The "Comment Missing?" section on Pfizer's Facebook page provides a detailed list of reasons why Pfizer would delete a



user's comment. For example, Pfizer might have to delete a user's comment from its Facebook wall if it lacks fair balance when discussing a product or describes a side effect that the user has experienced. In both instances, Pfizer has linked users to the FDA website for a definition of fair balance as well as the FDA's MedWatch adverse-event reporting page.

FDA's Definition of Fair Balance:

The law requires that product claim ads give a "fair balance" of information about drug risks as compared with information about drug benefits. In other words, the content and presentation of a drug's most important risks must be reasonably similar to the content and presentation of its benefits.

This does not mean that equal space must be given to risks and benefits in print ads, or equal time to risks and benefits in broadcast ads. The amount of time or space needed to present risk information will depend on the drug's risks and the way that both the benefits and risks are presented.

In the wake of the FDA's interest in monitoring social media, companies should: (1) keep a close watch over sales rep videos on YouTube, (2) constantly monitor the company's Facebook activity, (3) vigilantly correct any misinformation contained on third-party sites where the company has control or influence over the content, and (4) avoid "liking" unapproved claims contained in Facebook posts that lack fair balance or promote off-label use. Also, when hosting forums over social media, companies should monitor third-party comments, and include a clear, conspicuous statement that the company did not create the content of the forum. ■

1. Federal Register, 74 FR 48083 – September 21, 2009. http://www.gpo.gov/fdsys/pkg/FR-2009-09-21/pdf/E9-22618.pdf
2. Id.
3. Id.
4. FDA Issues Draft Guidances for Industry on Social Media and Internet Communications About Medical Products: Designed with Patients in Mind. Posted on June 17, 2014. http://blogs.fda.gov/fdavoice/index.php/2014/06/fda-issues-draft-guidances-for-industry-on-social-media-and-internet-communications-about-medical-products-designed-with-patients-in-mind/
5. Guidance for Industry. Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices. June 2014.
6. FDA Was Wrong About Google Functionality. http://regulatoryrx.blogspot.com/2014/06/fda-was-wrong-about-google-functionality.html
7. Id.
8. Guidance for Industry. Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices. June 2014.
9. Drug Industry Rips Into FDA Over Social Media Guidelines: A Summary of Industry Comments Regarding Twitter & Google Adwords. http://www.virsci.com/pmn/PMN1308-03charlimit.pdf
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11. Id.
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15. Id.
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23. Id.
24. FDA Warning Letter: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm340266.htm
25. Id.
26. FDA Targets Companies for Facebook 'Likes.' Is Twitter Next? http://www.raps.org/Regulatory-Focus/News/2014/08/12/20014/FDA-Targets-Companies-for-Facebook-Likes-Is-Twitter-Next/
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By Paul Rosenblatt

IT'S PERSONAL

THE SUPREME COURT EQUIPS CORPORATE DEFENDANTS WITH A POTENT DEFENSE FROM AN ALMOST-FORGOTTEN FRIEND

To sue in a particular forum, a plaintiff must show personal jurisdiction over the defendant(s) in compliance with that forum's long-arm statute and the Constitution's Due Process Clause. Personal jurisdiction comes in two forms – specific jurisdiction or general jurisdiction. But until recently, general jurisdiction played little or no role in the defense strategy of large companies conducting business nationally. Unless the plaintiff had named the wrong corporate entity as a defendant, most companies conceded personal jurisdiction in every state because they do business in every state; companies (and courts) usually accepted the general jurisdiction mantra of "continuous and systematic" operations to be sufficient. Even with the United States Supreme Court, general jurisdiction fell into the shadows, while specific jurisdiction took center stage. The Supreme Court issued scores of opinions featuring specific jurisdiction to a mere *three* opinions on general jurisdiction.[1] However, the Supreme Court began pulling general jurisdiction from the shadows in two recent opinions beginning in 2011 in *Goodyear Dunlop Tires Operations, S.A. v. Brown*[2] and coming into full bloom in its 2014 unanimous decision in *Daimler AG v. Bauman*.[3] Finally, general jurisdiction was fully in the spotlight. And in this new light, general jurisdiction shines as a potential rising star of corporate defense strategy.

THE BEGINNING: INTERNATIONAL SHOE AND ITS PROGENY

As its name implies, "specific" jurisdiction is premised on the relationship between the plaintiff's claims and the defendant's forum state activities. "General" jurisdiction, on the other hand, gives a court the power to require a defendant to answer all lawsuits in the state – whether or not the claims are related to the defendant's presence or activity in the forum state.

In 1945, the Supreme Court laid the foundation for general personal jurisdiction against corporate defendants in *International Shoe Company v. Washington*.[4] The Supreme Court adopted a broad interpretation of personal jurisdiction and the limits placed on it by the Due Process Clause. The Supreme Court issued the often-quoted rule that the defendant need only have certain "minimum contacts" with the forum state "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'"[5] For the corporate defendant, the Court explained that "the continuous corporate operations" in the forum state could be 'so substantial and of such a nature as to justify suit against it in causes of action arising from dealings entirely distinct from those activities.'"[6]

Seven years later, the Supreme Court formalized International Shoe's "continuous and systematic" activities in *Perkins v. Benguet Consolidated Mining Company*.[7] In *Perkins*, the foreign corporate defendant had relocated its operations temporarily from the Philippines to Ohio as a result of Japanese occupation of the Philippines during World War II. The Supreme Court held that the company was subject to general personal jurisdiction in Ohio because its wartime activities in Ohio – though limited in time – were "continuous and systematic."[8] Essentially, the company's principal place of business was temporarily in Ohio.

Although *Perkins* presented unusual facts not likely to arise in other cases, in the decades that followed, many circuit courts of appeal embraced *Perkins*' holding as the definitive test for general personal jurisdiction.[9] For more than 30 years, the Supreme Court remained silent as to general personal jurisdiction. In 1984, the Supreme Court repeated its "continuous and systematic" formulation of

general jurisdiction in *Heliocopteros Nacionales de Columbia S.A. v. Hall*.[10] A single footnote in *Keeton v. Hustler Magazine, Inc.*,[11] issued by the Court that same year, suggested that its general jurisdiction decisions were largely fact-driven and that the Court maintained reservations about broad application of the "continuous and systematic" test. The *Keeton* Court emphasized that the "continuous and systematic" activities giving rise to general personal jurisdiction over the corporate defendant in *Perkins* were so pronounced that they effectively rendered the forum state "the corporation's principal, if temporary, place of business."[12]

Thus, for more than 60 years after *International Shoe*, general jurisdiction simply was not the focus of the Supreme Court's personal jurisdiction jurisprudence, and "continuous and systematic" activities persisted as the catch-phrase of general jurisdiction.

THE OTHER SHOE DROPS: *GOODYEAR AND DAIMLER*

The accepted notion of "continuous and systematic" activities creating general personal jurisdiction in a state, coupled with a growing global economy and the rise of online commerce, contributed to companies' resignation – and plaintiffs' delight – that they could be called to defend themselves against lawsuits in all 50 states. Conventional wisdom began to change in 2011 in *Goodyear*[13] when the Supreme Court finally began to formally rein in the boundaries of general jurisdiction. The underlying facts concerned two North Carolina residents who were killed in a bus accident in France. Plaintiffs sued the American parent company and several of its foreign subsidiaries in North Carolina, alleging that the defendants' tires caused the accident. Reversing the lower court, the Supreme Court declined to exercise general personal jurisdiction over the foreign corporations. Although the products of the foreign companies continuously reached the forum state of North Carolina, the Court held these contacts were not so "continuous and systematic as to render [the corporate defendant] *essentially at home* in the forum State."[14] This new "at home" rule arose from *Keeton*'s characterization of the facts of *Perkins*, but its limitations were still somewhat unclear until January of this year in *Daimler*.

> As a general rule, a corporate defendant is only "at home" and—in the absence of specific personal jurisdiction—may be sued only in two locations: its state of incorporation and the state in which its principal place of business is located.

In *Daimler*,[15] the Supreme Court clarified the "at home" standard. That clarification further limited the reach of general personal jurisdiction over corporate defendants. The Court explicitly held that a corporation is not "at home" in a forum merely because it "engages in a substantial, continuous and systematic course of business" there.[16] "That formulation," the Court held, "is unacceptably grasping."[17] The 22 plaintiffs in Daimler were Argentinian nationals, seeking damages in California for harms allegedly suffered in Argentina. "[G]iven the absence of any California connections" to the harms alleged, specific jurisdiction was lacking.[18] Thus, the plaintiffs were forced to rely upon general personal jurisdiction.

In particular, the plaintiffs alleged that Daimler's Argentinian subsidiary had collaborated with state security forces during Argentina's "Dirty War" to kidnap, detain, torture and kill certain of its employees. Plaintiffs sued Daimler – a German public stock company headquartered in Stuttgart – in California, asserting general jurisdiction there based on the unrelated activities of another Daimler subsidiary, Mercedes-Benz USA ("MBUSA") – a Delaware corporation with its principal place of business in New Jersey. The Court ruled that Daimler's contacts with California, through MBUSA who distributed Daimler-manufactured vehicles throughout the United States, were not significant enough to render it "at home" in the forum state.

As such, Daimler changed more than 60 years of conventional wisdom in measuring general personal jurisdiction. As a general rule, a corporate defendant is only "at home" and – in the absence of specific personal jurisdiction – may be sued only in two locations: (1) its state of incorporation and (2) the state in which its principal place of business is located.[19]

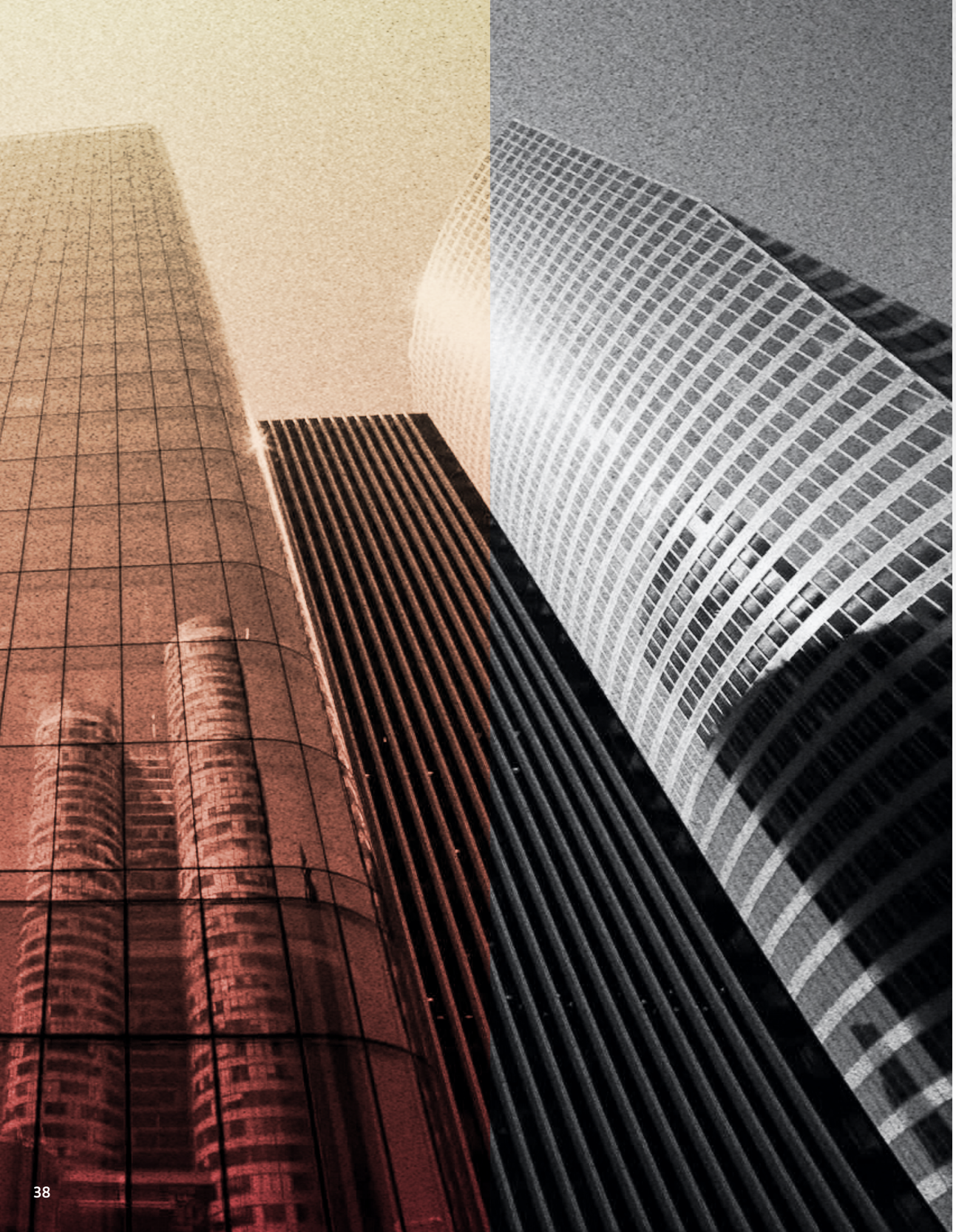
THAT'S THE RULE – AND NO EXCEPTIONS

In articulating its rule regarding general jurisdiction, the Supreme Court called the corporate defendant's state of incorporation and the state of its principal place of business the "paradigm all-purpose forums" or "exemplar bases" for general jurisdiction.[20] Plaintiffs have latched on to these phrases to push for exceptions to the general rule. Although it is theoretically possible that circumstances could give rise to another location being so similar to the "exemplar bases" or "paradigm all-purpose forums" that it could also invoke general jurisdiction,[21] the Supreme Court's additional requirement – that the volume of activities in the forum not be significantly outweighed by the defendant's operations elsewhere – makes an exception to the general rule extremely rare.

The Supreme Court has expressly rejected the arguments that plaintiffs typically have asserted to gain access to a forum based on general jurisdiction. For example, substantial revenues from in-state sales are insufficient; MBUSA's "substantial" in-state revenue, which accounted for 2.4% of Daimler's worldwide sales, or $4.6 *billion*, did not make Daimler "at home" there. Likewise, numerous sales representatives and multiple offices did not warrant an exception to the new rule. To date, no courts have found the factual circumstances of any case warranted an exception to the rule articulated in *Daimler*.[22]

> Domestic companies with operations in many states no longer need to resign themselves to assertions of personal jurisdiction in each of those states.

In the first post-*Daimler* opinion on general jurisdiction from a U.S. Circuit Court of Appeal, *Monkton Insurance Services, Ltd. v. Ritter*, the Fifth Circuit expressly stated that *Daimler's* rule makes it "incredibly difficult to establish general jurisdiction in a forum other than the place of incorporation or principal place of business."[23] The plaintiff in *Monkton*, an insurance manager, was a Texas resident who at all relevant times remained in Texas.[24] The third-party defendant was a bank organized and regulated under Cayman Islands law and located on the island of Grand Cayman. Plaintiff based its "continuous and systematic" argument on the bank's website, phone conversations with the defendant in Texas (initiated by defendant, not the bank) and its wire transfers to Texas banks. *Id.* at *5. But the Fifth Circuit – applying



Daimler – rejected plaintiff's argument that the Grand Cayman bank's contacts were continuous and systematic enough to establish general jurisdiction in Texas. The court affirmed the district court's dismissal of the Grand Cayman bank for lack of personal jurisdiction.[25]

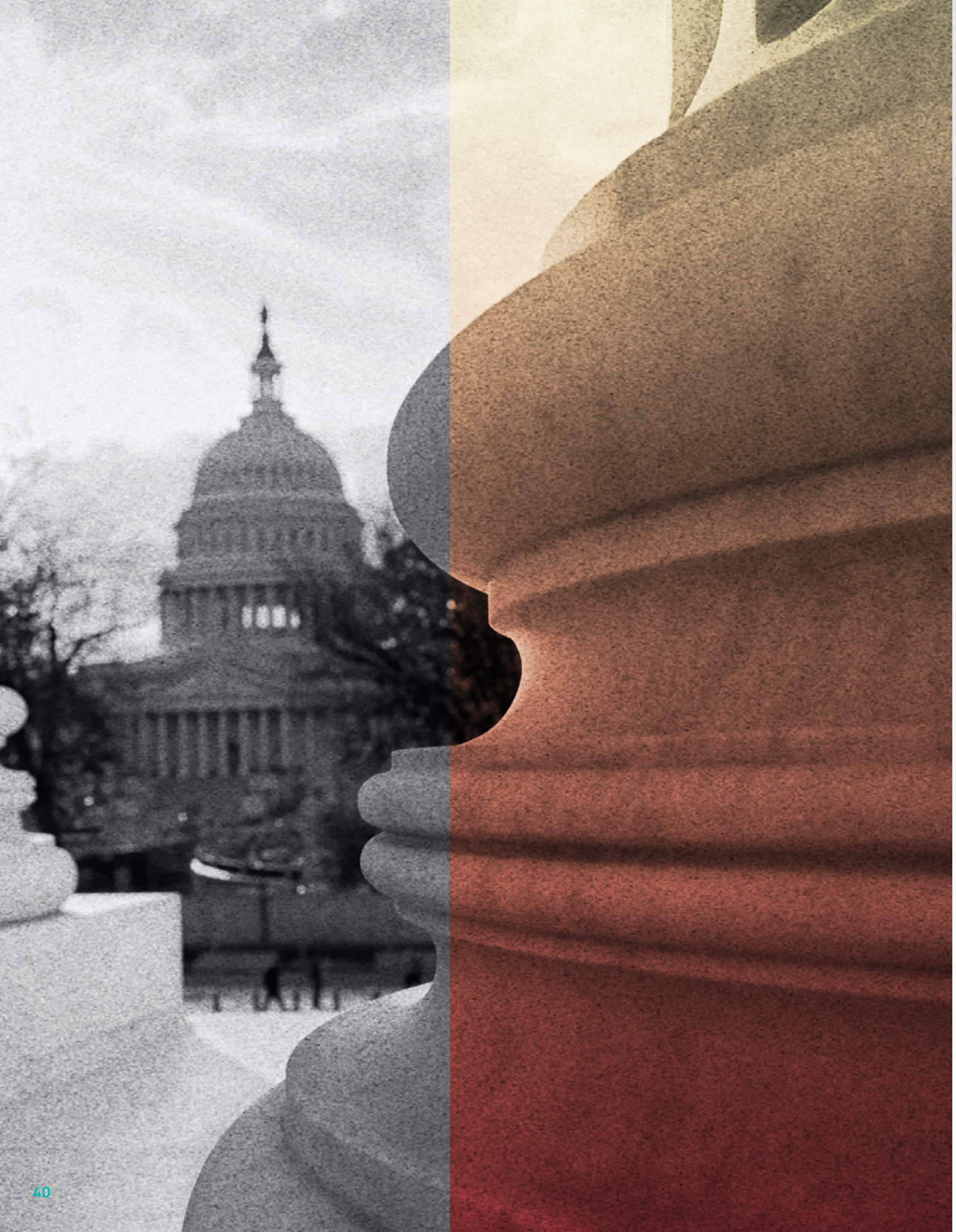
NOT JUST THE STAR FOR NON-US SUBSIDIARIES

The change in the test for general jurisdiction does not just affect foreign subsidiaries in the colloquial sense of non-U.S. corporations. A mass tort judge in Cook County, Illinois – a longstanding plaintiff-friendly jurisdiction – noted that "international relations," a public policy reason cited by the Supreme Court in support of its rule in *Daimler*, was not a basis for distinguishing *Daimler*.[26] Domestic companies with operations in many states no longer need to resign themselves to assertions of personal jurisdiction in each of those states. Indeed, the Supreme Court's decision has the potential to significantly impact litigation against corporate defendants in a number of positive ways from restricting forum-shopping to providing new avenues for removal of multi-plaintiff actions.

Corporate defendants have become intimately familiar with the handful of "magnet jurisdictions" that forum-shopping plaintiffs flock to by the hundreds or thousands. The new general jurisdiction rule, however, means that doing business in that state – no matter how much revenue those operations bring – is no longer dispositive for personal jurisdiction. Unless the facts of a particular plaintiff's case establish specific personal jurisdiction, general personal jurisdiction challenges should be considered in all states other than the state of incorporation and the company's principal place of business.

And personal jurisdiction is a claim- and plaintiff-specific inquiry;[27] therefore, corporate defendants need not concede personal jurisdiction in multi-plaintiff cases in which only one (or some) of the plaintiffs can connect the alleged tort with the forum state. Accordingly, *Daimler* also provides a removal tool to combat the common practice by plaintiffs' lawyers of joining dozens of unrelated, out-of-state plaintiffs with one or two in-state plaintiffs and bringing all claims in a single lawsuit in an attempt to thwart the defendant's right to remove the case to federal court. In these cases, none of the out-of-state plaintiffs alleges taking the drug or being implanted with the medical device in the forum state, one or two resident plaintiffs are diversity-destroyers, sharing their citizenship with the corporate defendant. In such a situation, corporate defendants now can move to dismiss the out-of-state plaintiffs for lack of personal jurisdiction and simultaneously remove the case to federal court on the basis of fraudulent or sham joinder. Because there is no personal jurisdiction in that forum state over the claims alleged by the out-of-state plaintiffs against the defendants, the plaintiffs cannot establish a cause of action against those defendants in that state.

For example, in the *In re Plavix* mass tort litigation in Cook County, Illinois, 486 non-resident plaintiffs whose claims had nothing to do with the forum state were dismissed on this basis. The court rejected plaintiffs' arguments that the corporate defendants' contacts with the forum – which included a branch office, sales reps and other employees, as well as $1.7 billion in revenue from sales of Plavix to Illinois residents – gave rise to general personal jurisdiction over the defendants. And the removals and associated briefing in at least a dozen cases currently pending in, or pending



transfer to, the six Pelvic Repair System Products Liability MDLs in the Southern District of West Virginia likewise rely upon Daimler as the basis for removal and dismissal or severance of the out-of-state plaintiffs.[28] Similarly, this basis for removal was recently endorsed by a United States District Judge for the Southern District of Texas. In his November 10, 2014, order, the judge denied plaintiffs' motion to remand and granted the corporate defendants' motion to dismiss the 76 out-of-state plaintiffs and retain jurisdiction over the one remaining plaintiff, a Texas resident.

CONCLUSION: WILL THE RESURGENCE OF GENERAL JURISDICTION END SUCCESSFUL FORUM SHOPPING?

While it is still too early to tell whether *Daimler* has sounded the death knell for forum-shopping or just how big of a star general jurisdiction will be for corporate defendants, one takeaway is clear: From this point forward, lack of personal jurisdiction should be back on the shortlist of defense strategies to consider if the company is sued *anywhere* other than the location of the alleged tort, the company's principal place of business or its state of incorporation. ■

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1. *Daimler* at 755 ("Since *International Shoe*, 'specific jurisdiction has become the centerpiece of modern jurisdiction theory while general jurisdiction [has played] a reduced role.'" "Our post-*International Shoe* opinions on general jurisdiction, by comparison, are few.")
2. 131 S. Ct. 2846 (2011).
3. 134 S. Ct. 746 (2014).
4. 326 U.S. 310 (1945).
5. 362 U.S. 310, 316 (1945) (quoting Milliken v. Meyer, 311 U.S. 457, 463 (1940)).
6. *Id.* (citing *Missouri, K. & T.R. Co. v. Reynolds*, 255 U.S. 565 (1921) and collecting cases).
7. 342 U.S. 437, 438, 449 (1952).
8. *Id.* at 438.
9. *See, e.g., Harlow v. Children's Hospital*, 432 F. 3d 50, 57, 64 (1st Cir. 2005); *Metropolitan Life Ins. Co. v. Robertson-Ceco Corp.*, 84 F.3d 560, 568 (2d Cir. 1996); *Gorman v. Ameritrade Holding Corp.*, 293 F.3d 560, 568 (D.C. Cir. 2002).
10. 466 U.S. 408, 416 (1984).
11. 465 U.S. 770 (1984).
12. *Id.* at 779 n. 11.
13. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846 (2011).
14. *Id.* (emphasis added).
15. 134 S. Ct. 746 (2014). The decision was authored by Justice Ginsburg and was joined by all except Justice Sotomayor, who wrote a concurring opinion.
16. *Id.* at 761.
17. *Id.*
18. *Id.* at 751.
19. *See id.* at 760-61; *see also Earnest v. Boston Scientific Corp.*, 2:12-cv-6521, 20134 WL 1566734 (S.D.W. Va. Apr. 15, 2013) (Goodwin, J., presiding).
20. *Daimler*, 134 S. Ct. at 760-61.
21. *See id.* at 761 n. 19 ("We do not foreclose the possibility that in an exceptional case, see, *e.g. Perkins*, . . . But this case presents no occasion to explore that question, because Daimler's activities in California plainly do not approach that level.")
22. Even in Texas—home to numerous favorite venues of plaintiffs—federal district courts thus far have rejected plaintiffs' arguments of general jurisdiction over corporate defendants not incorporated in Texas and with their principal places of business in other states. *See, e.g., Air Tropiques, SPRL v. Northern & Western Ins. Co.*, 2014 U.S. Dist. LEXIS 44255, at *23, 28-31 (S.D. Tex. Mar. 31, 2014) (noting that "the Supreme Court has stepped away from the continuous-and-systematic-contacts test in favor of an even more stringent test" and holding that plaintiffs could not establish general personal jurisdiction in Texas over foreign insurance company with its principal place of business in St. Kitts, even though defendant has an "administrative office" in Texas and its "managing agent" was a Texas corporation).
23. *Monkton* Ins. Servs., *Ltd. v. Ritter*, No. 13-50941, --F.3d--, 2014 WL 4799716, at *2 (5th Cir. Sept. 26, 2014).
24. *Monkton*, 2014 WL 4799716, at *1.
25. *Id.*
26. *See In re Plavix*, 2014 WL 3928240, at *6 (Ill. Cir. Cook Co. Aug. 11, 2014).
27. *See Heliocopteros*, 466 U.S. 408, 414 n. 8 (1984) (noting that each plaintiff must show that his or her claims arise out of or related to the defendant's contacts with the forum state); *see also Phillips Exeter Academy v. Howard Phillips Fund, Inc.*, 196 F.3d 284 (1st Cir. 1999) (examining plaintiff's contract and tort claims separately in its specific jurisdiction analysis and noting, "[q]uestions of specific jurisdiction are always tied to the particular claims asserted"); *McFadin v. Gerber*, 587 F.3d 753, 759 (5th Cir. 2009) (noting that "specific personal jurisdiction is a claim-specific inquiry").
28. The Judicial Panel on Multidistrict Litigation ("JPML") has announced that it will consider transfer of five such cases at its December 4, 2014, hearing. *See* 12/4/14 Hearing Session Order, available on the JPML's website, http://www.jpml.uscourts.gov/sites/jpml/files/Hearing_Order-12-4-14.pdf (last accessed Nov. 6, 2014).
29. Locke et.al. v. Ethicon (USDC, SDTX) 4:14-CV-2648 (November 10, 2014)

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