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Leadership Notes

Letter from the Chair

by Scott Saylor



Greetings from Kansas City. It is an honor and pleasure to assume the position of Chair of the DRI Drug and Medical Device Committee. Congratulations and a hearty thank you to our outgoing Chair, Skip McCowan of Gordon & Rees. Skip did a fantastic job leading the Committee through several excellent years of seminars, activities, and initiatives. Our Committee's new Vice-Chair, Jim Rogers from Nelson, Mullins, and I will do our best to lead this Committee through these coming years.

A big thank you to Anne Talcott from Schwabe, Williamson for organizing, editing, and finalizing yet another excellent edition of *Rx for the Defense*. I know you will find the articles in this edition to be practical, timely, and authoritative.

After you finish reading this edition of *Rx for the Defense*, I encourage you to immediately make sure you have registered for the May 10-11, 2012, annual seminar of the DRI Drug and Medical Device Committee, to be held at the Hilton Riverside in New Orleans, LA, one of our great destination cities. If you haven't already done so, you can register on-line at the DRI's website (dri.org), or you can register using the printed meeting brochure. Our planning committee has been hard at work since last summer planning this year's annual seminar in New Orleans. The leaders of that planning committee include Program Chair Carter Thompson from Baker, Donelson; Program Vice-Chair Sara Gourley from Sidley Austin; Marketing Chair Gail Rodger from DLA Piper; Marketing Vice-Chair Sheila Boston from Kaye Scholer, and DRI Law Institute Liaison Mark Solheim from Larson & King. They, and a number of others, should be applauded for their excellent planning work.

This year's annual seminar will kick off with a number of privately held Counsel Meetings on Wednesday, May 9. We have been working hard to publicize and market the benefits associated with organizing and holding Counsel Meetings – meetings involving in-house counsel and anywhere from five to hundreds of outside counsel. If you are interested in scheduling a Counsel Meeting or learning more about them, please contact either Sara Gourley (sgourley@sidley.com) or Rick Richardson of GlaxoSmithKline (rick.e.richardson@gsk.com). Wednesday evening May 9 will begin with the 6:00 p.m. opening of Registration and a 6:00 p.m. DRI Networking Reception at the hotel, after which many will choose to go enjoy the unparalleled food and entertainment available in New Orleans.

Our annual seminar substantive program kicks off at 8:00 a.m. on Thursday, May 10, 2012. We will begin the program with two separate panel discussions featuring judges, outside counsel, and in-house counsel. The first panel featuring the Honorable Eldon E. Fallon, Russ Herman, and James Irwin will discuss MDLs and will focus specifically on some of the historic MDL experiences centered in and around New Orleans. The second panel will feature two state court judges (the Honorable Carol E. Higbee and the Honorable Sandra Mazer Mass), in-house counsel (Stacey Dixon Calahan of Takeda Pharmaceuticals), plaintiff's counsel (David Buchanan) and outside defense counsel (Ray Williams) – all of whom have been involved in and will discuss issues relating to the coordination of state court pharmaceutical mass tort litigations.

Our seminar will continue through Thursday afternoon, May 9, with presentations on a variety of timely and topical subjects in pharmaceutical and medical device litigation, including defending medical device cases on grounds other than causation, handling the mediation process, defending actions involving OTC medications, evaluating preemption post-*Levine* and post-*Mensing*, and assessing aggregate litigation.

On Thursday, May 10, the Drug and Medical Device Committee will be pleased to once again hold a diversity luncheon. Thanks to the good efforts of Sheila Boston, this year's featured speaker at the diversity luncheon will be Maria Pabon Lopez from Loyola University New Orleans College of Law who will speak on the importance of diversity in the legal profession.

Following a Thursday evening of food and fun in the French Quarter and elsewhere, our annual seminar substantive program will resume on Friday, May 11, at 8:00 a.m. The Friday program will feature speakers, demonstrations, and presentations on a variety of drug and device defense issues including e-discovery, jury selection, medical device preemption, prescriber depositions, warning defenses, and ethical issues. We are ending the seminar at 1:30 p.m. this year, about three hours earlier than in past years, so that attendees can either make a flight home on Friday afternoon or get an early start on a fun weekend of activities in the Big Easy.

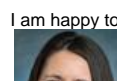
The DRI Drug and Medical Device Steering Committee held its first fly-in meeting in over ten years this past November 2011 in Chicago. Over 30 steering committee members attended. We discussed a number of new activities and initiatives, which I will address more fully in subsequent Letters from the Chair. For present purposes, if you are interested in getting involved in Committee activities, I encourage you to go to the Committee's webpage on the DRI website (dri.org). On that webpage, you will find the names and contact information for steering committee members holding leadership positions relating to all of the committee's activities (e.g., annual committee seminar, DRI annual meeting, committee newsletter (*Rx for The Defense*) publishing opportunities, *For the Defense* publishing opportunities, webpage, webinars, young lawyers primer, membership, diversity, etc., etc.). If you want to get involved in a specific area or activity, please reach out to the appropriate committee leader. If you want to get involved, I also encourage you to attend the Committee's business meeting, which will be held at 5:15 p.m. on Thursday, May 10, at the annual seminar. I wish everyone the best and look forward to seeing you in New Orleans!!

Scott Saylor

February 2012

Letter from the Editor

by Anne Talcott



I am happy to announce that that *Rx for the Defense* is moving to a quarterly publication schedule. Doubling the number of newsletters we publish allows the Committee to provide more frequent updates on issues affecting the pharmaceutical and device field. An expanded publication schedule will also offer twice as

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Seminars

DRUG AND MEDICAL DEVICE SEMINAR
MAY 10-11, 2012
HILTON NEW ORLEANS RIVERSIDE
NEW ORLEANS, LOUISIANA

IN-HOUSE SPEAKERS INCLUDING:
BARBARA ASHLEY, MEDTRONIC INC.
STACEY DIXON CALAHAN, Takeda Pharmaceuticals North America Inc.
JILL HARRISON, W.L. GORE & ASSOCIATES INC.
TIMOTHY K. HOWARD, MERRILL LYNCH PIERCE FENNER SMITH
MALINI MOORETY, PFIZER INC.
DAVID K. ORENSTEIN, CARDINAL HEALTH INC.

REASONS TO ATTEND:
• Participate in the premier networking and educational event for pharmaceutical and device practitioners in the area and enjoy 12.5 hours of CE, including 1 hour of ethics credit.
• Hear from 200+ and feature speakers providing you with the latest news and device coverage.
• Hear from 200+ practitioners, including a leading plaintiff and 200+ defense practitioners in the area.
• Activities to be held around with breakfast meals.

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May 10-11, 2012
New Orleans, Louisiana

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many authorship opportunities for those members interested in writing articles. *Rx* is circulated to all members of the DRI Drug and Medical Device Committee, so writing for the newsletter is an excellent way to get better known in the DRI community and bolster your credentials in this field.

The expansion of the *Rx* publication schedule prompted Committee Chair, Scott Sayler, to appoint a Co-Editor for *Rx*. I am happy to report that Melissa Roberts Tannery of Troutman Sanders in Richmond, VA has agreed to serve in this capacity. Melissa is a long time Drug and Medical Device Steering Committee Member, past Chair of the DRI Young Lawyers Committee and an active member of the DRI Women in the Law Committee. Welcome aboard Melissa!

We are proud to have six excellent articles in this issue—a record number for this publication. I know you will enjoy the wide range of topics featured, from tips on handling plaintiff's treating physician to a discussion of whether FDA regulations encroach on free speech. We also have an update on *Mensing*, an analysis of *Milward* and the First Circuit's weight of the evidence approach, recommendations concerning fraudulent joinder and an examination of the interplay between FDA regulations and social media.

We are still collecting articles for the summer, fall and winter issues which have due dates of May 18, August 24 and November 30, 2012, respectively. If you are interested in submitting an article please contact me at atalcott@schwabe.com. Case reports, litigation tips, state statutory changes or other drug or device related topics are all appropriate for *Rx for the Defense*. Newsletter articles range from 1000 to 1500 words in length.

I look forward to hearing from you.

From the Marketing Committee

by Gail Rodgers and Sheila S. Boston

TOP TEN REASONS to Attend the DRI Drug and Medical Device Seminar in New Orleans --"The Big Easy" -- on May 10-11, 2012:



10. Earn up to 12.25 hours of CLE credit, including 1 hour of ethics credit.
9. Hear from Federal and State Court Judges about their views concerning coordinated mass tort proceedings.
8. Witness, electronically vote on, and learn how to pick a winning jury in a live and interactive jury *voir dire* presentation.
7. Enjoy the delectable food, lively music, and beautiful sights the exciting city of New Orleans has to offer.
6. In-House Counsel can attend the Seminar for FREE! (Simply contact DRI Customer
5. Defense counsel will have the opportunity to meet and discuss drug and medical device issues in an educational, but informal, setting.
4. In-House Counsel can hold a very cost-efficient in-person outside counsel meeting. (Simply contact Beth DeMars at 312-698-6234 or demars@dri.org.)
3. In-House Counsel can attend the seminar's first-ever "For In-House Counsel Only" breakout discussion.
2. Engage in networking, networking and more networking.
1. Participate in THE premier educational and networking event for practitioners in Drug and Medical Device litigation.

WE HOPE TO SEE YOU SOON IN NEW ORLEANS!!!

Featured Articles

FDA Regulations and the Regulation of Constitutionally Protected Speech

by Ralph S. Tyler and Bruce R. Parker

Introduction



"Speech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2659 (2011). That sentence, which appears prominently in the first paragraph of the Court's decision last Term in *Sorrell*, doomed a Vermont law restricting the sale of pharmacy records of individual doctors. The principles which underlie that sentence sweep more broadly than that, however, to cast a First Amendment shadow over a range of governmental regulatory activities, including those of FDA. This shadow may well have important implications for product liability tort litigation.

Various government regulations impact speech, sometimes compelling speech and sometimes prohibiting or restricting speech. Government compels speech when, for example, a statute or an agency rule requires warnings or disclosures on packages or other materials. Government limits or prohibits speech when, as in *Sorrell*, a statute restricts the sale of information or when a regulatory regime prohibits the off-label promotion of an approved drug.

Tobacco warnings and compelled speech

A current example of a regulation which compels speech is FDA's rule requiring cigarette companies to display graphic warnings on cigarette packages. In the Family Smoking and Prevention Act, Congress directed FDA to promulgate a rule mandating the display on cigarette packages of graphic images depicting the negative consequences of smoking. FDA did as it was told and developed a set of dramatic images. FDA then issued a rule mandating that these images, along with blunt textual warnings, occupy 50 percent of each cigarette package.

In response to FDA's rule, several tobacco companies filed suit, challenging the rule on First Amendment Free Speech as well as Administrative Procedure Act grounds. The United States District Court for the District of Columbia (Judge

Leon) granted the companies' motion for a preliminary injunction. The court found that there was a substantial likelihood that the companies would prevail on their First Amendment claim. See *R.J. Reynolds Tobacco Co. v. FDA*, Civil Case No. 11-1482 (November 7, 2011). The government's appeal is pending.

As we await the outcome of the appeal in *R.J. Reynolds*, it is worth noting that there is other relevant precedent invalidating a regulatory regime which compels speech. In *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), for example, a case upon which the district court in *R.J. Reynolds* relied, the court invalidated an Illinois statute which required electronic video game retailers to place large warning labels on video machines and to provide other written warnings about the content of the games.

Off-label drug promotion and prohibited speech

The government has been successful in recent years in recovering substantial sums of money from pharmaceutical companies through False Claims Act settlements arising from the companies' alleged "off-label promotion" of FDA approved drugs. These settlements include Merck (\$950 million), Pfizer (\$2.3 billion), and Glaxo, Smith Kline (\$3 billion). The theory on which these cases are based needs to be examined using the lens of the First Amendment.

Only slightly oversimplified, the government's chain of logic in "off-label promotion false claim" cases is as follows: FDA approves a drug for certain specified uses (indications); those approved uses are stated on the drug's label; if a drug company makes factually true statements in generally distributed brochures or by its sales force about uses of the drug other than those which FDA has approved and as stated on the drug's label, such statements are impermissible off-label promotion of the drug; and if federal funds have been paid (through Medicare, for example) for these promoted non-approved uses, the government has received and paid "false claims" for which the government is entitled to civil penalties plus treble damages. 31 U.S.C. § 3729.

The critical point for First Amendment purposes is that the government's theory in these off-label false claims cases does not require that the companies' claims about a drug are false or misleading; rather, the government's theory allows a company to be held liable when, for example, the company's sales force promotes the fact that the drug has been used successfully in a clinical trial even if that statement is true so long as the clinical trial involves a non-FDA approved use of the drug. Under the government's theory, a company's right to speak about an FDA approved drug is limited to speech about the drug's approved uses/labeling.

The broad contours of First Amendment constraints on regulatory actions

The government may compel speech to protect consumers by requiring disclosure of "purely factual and uncontroversial information," *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985), "in order to dissipate the possibility of consumer confusion or deception." *Id.* (quotation omitted). See also *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 114-16 (2d Cir. 2001) (applying *Zauderer* rationale to uphold mandatory food labeling statute). However, even when the compelled speech satisfies this "purely factual" standard, "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech." *Zauderer*, 471 U.S. at 651.

In preliminarily enjoining FDA's graphic tobacco warnings, the district court concluded that the warnings were not entitled to the more relaxed *Zauderer* level of scrutiny because, in the court's view, the warnings were not "purely factual and uncontroversial." The court thus subjected the warnings rule to "strict scrutiny." The district court concluded that FDA's tobacco warnings regulation could not withstand "strict scrutiny." Few laws can.

Governmental prohibitions of speech, including prohibiting a pharmaceutical company from making truthful statements about a drug, raise a separate set of constitutional objections. In *Sorrell*, the Supreme Court observed that "[f]acts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs." 131 S. Ct. at 2667. That observation is hard to square with the government's efforts to restrict speech in off-label promotion false claims cases where the allegedly offending promotional statements are factually true and not misleading.

U.S. v. Caronia, 576 F. Supp. 2d 385 (E.D.N.Y. 2008) (appeal pending), is a pre-*Sorrell* case in which the court gave serious consideration to the question of the constitutionality of the government's approach to off-label promotion cases. While the court in *Caronia* ultimately denied the defendant's First Amendment based motion to dismiss an indictment for violating the misbranding provisions of the Food, Drug, and Cosmetic Act, the court noted that "the constitutional issues raised in *Caronia*'s motion are very much unsettled, not only in this circuit but nationwide." 576 F. Supp. 2d at 394. The appeal in *Caronia* will be decided in light of the Supreme Court's decision in *Sorrell*.

Given the enormous sums of money involved in pharmaceutical off-label false claim cases and the obvious seriousness with which the courts take First Amendment arguments, the question is why have these cases settled and not been litigated to determine the constitutionality of the government's approach? Certainly part of the answer to that question involves the unacceptably high reputational and business risks to a public company of being indicted. These risks create a powerful incentive to avoid indictment and settle. A closely related consideration similarly incentivizing avoiding indictment through settlement is the risk of disqualification from participation in federal health care programs (effectively the "death penalty") if convicted. See 42 U.S.C. § 1320a-7.

The Allergan company sought to thread this needle by bringing a declaratory judgment action to challenge on First Amendment grounds FDA's rules on off-label promotion. See *Allergan v. USA*, No. 09-1879 (D.D.C.). The parties in *Allergan* filed cross-dispositive motions in which the First Amendment arguments were briefed extensively; however, the case was dismissed as part of a larger overall settlement prior to the court's ruling on those motions.

Sorrell, *R.J. Reynolds*, *Entertainment Software*, *Caronia*, and *Allergan* individually and collectively reflect an increased awareness on the part of regulated entities of the constitutional implications of regulatory regimes and an increased willingness on the part of those entities to challenge those regimes on constitutional grounds. A number of the cases which have gone to judgment reflect growing judicial skepticism for the government's justifications for actions which adversely impact constitutionally protected speech.

Is tort law next?

The arguments developed in First Amendment cases have potential applicability to product liability cases involving allegations that a defendant pharmaceutical company unlawfully promoted the off-label use of a drug. Plaintiffs in these cases assert negligence claims and demands for punitive damages predicated on allegations that the plaintiff suffered injuries from off-label use of a drug as promoted by the defendant. The constitutional cloud which hangs over the government's right to restrict speech, see, e.g., *Sorrell*, may well extend to these private tort cases.

The argument would be that the requisite governmental action to implicate constitutional protections exists because the tort plaintiff's assertion that the defendant's off-label promotion is unlawful depends entirely on the web of federal statutes and regulations. But for those statutes and regulations, the plaintiff would have no basis for complaining about the defendant's truthful, non-misleading statements. If, however, the government cannot constitutionally prohibit the defendant from making truthful, non-misleading statements, then a private plaintiff should not be able to impose tort liability for the same constitutionally protected activity. The state regulates through its tort law and plaintiffs are invoking that state regulatory power to restrict speech when plaintiffs seek to impose liability and recover damages, including punitive damages, for off-label promotion of drugs and devices when that promotional activity involves truthful, non-misleading statements.

Defense counsel making these constitutional arguments should highlight the contradiction between the prohibition against off-label prohibition and the lawfulness of physicians' prescribing drugs off-label. See generally *Caronia*, 576 F. Supp. 2d at 393. Not only may a physician lawfully prescribe a drug off-label, but in certain situations such off-label use is the "medically recognized standard of care and therefore it is important for physicians to have access to accurate information about off-label uses." *Id.* at 393. The contradiction is that the manufacturer often has the most current information to provide physicians so that they may lawfully prescribe the drug, and yet the plaintiff's off-label claim seeks to severely restrict the manufacturer and its representatives from speaking truthfully about the off-label use of the drug.

As the law in this area continues to develop, defense counsel in product liability cases involving off-label promotion of drugs and devices should be mindful of the availability of constitutional defenses and, where appropriate, counsel should raise and preserve those defenses.

Conclusion

There is more to come on this entire topic. It is a virtual certainty that there will be future First Amendment challenges to federal and state regulatory statutes and rules. The cases to date suggest that a significant number of those challenges will prevail.

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Fighting Back Fraudulent Joinder in Pharmaceutical Drug and Device Cases

by Jessica Davidson Miller and Milli Kanani Hansen

Jurisdictional gamesmanship has long been a source of frustration for pharmaceutical and medical-device defendants.



Plaintiffs have frequently avoided federal jurisdiction – and by extension, inclusion in federal multidistrict litigation ("MDL") proceedings – either by joining non-diverse defendants for the sole purpose of staying in state court or by misjoining plaintiffs in a manner that defeats diversity jurisdiction. Recent case law has suggested that judges are finally growing skeptical of plaintiffs' tactics, although the success of fraudulent joinder arguments often varies based on underlying state law (such as innocent-seller statutes).

This article explores recent developments in the law of fraudulent joinder and misjoinder, with a particular focus on theories for removing cases involving distributors, sales representatives, hospitals and pharmacies. It also sets forth several practical tips for defense lawyers seeking to successfully remove pharmaceutical cases to federal court.

I. Recent Developments in Fraudulent Joinder

A. Distributors

Cases involving non-diverse distributors have long been some of the most difficult to remove based on a fraudulent joinder argument, largely because many states have strict-liability regimes that allow claims to proceed against any defendant in the chain of distribution. Nonetheless, defendants have enjoyed some success in removing these cases, and a recent U.S. Supreme Court case has provided a new ground for these removals.

First, many states have adopted "innocent seller" statutes that limit the liability of non-manufacturing defendants as long as the seller did not have significant control over the production or design of the product, did not create the defect, and had no actual knowledge of the defect. See, e.g., Md. Code Ann. Cts. & Jud. Proc. § 5-405(b); Tex. Civ. Prac. & Rem. Code § 82.003; 735 Ill. Comp. Stat. 5/2-621. Using declarations or affidavits, removing defendants have been able to establish that the in-state distributor had no control over the product, no actual knowledge of the product defect, and did nothing to create the defect sufficient to show fraudulent joinder. See, e.g., *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336, 1339 (9th Cir. 1987) (denying remand in part based on sworn declarations submitted by fraudulently joined defendants); *Higley v. Cessna Aircraft Co.*, No. CV-103345-GHK (FMOx), 2010 U.S. Dist. LEXIS 91153, at *3-4 (C.D. Cal. July 21, 2010) (same). For example, in *Askew v. DC Medical, LLC*, the court found that the distributor was fraudulently joined when the plaintiff failed to produce any evidence rebutting a declaration by the distributor disclaiming any knowledge of the alleged defect. No. 1:11-cv-1245-WSD, 2011 WL 1811433, at *6 (N.D. Ga. May 12, 2011). In addition, some defendants have had success in opposing remand by establishing that the distributor does not meet the definition of "seller" for purposes of state liability laws. See, e.g., *Wade Transportation, Inc. v. Puckett Machine Co.*, No. 2:07CV6KS-MTP, 2007 U.S. Dist. LEXIS 38137, at *11 (S.D. Miss. May 24, 2007) (non-diverse distributor "was not a 'seller' of the Caterpillar engines at issue in this case" and therefore joinder was fraudulent); *Kite v. Zimmer US, Inc.*, No. 2:06-CV-0745-RCJ (RJJ), 2006 U.S. Dist. LEXIS 85420, at *11-12 (D. Nev. Nov. 21, 2006) (denying motion to remand on fraudulent joinder grounds where non-diverse distributor "could not be held liable in Nevada under the theories of strict product liability and warranty because it [was] not a 'seller' of the medical device at issue in the lawsuit).

Courts have also found fraudulent joinder where a plaintiff's allegations are insufficient to link the distributor to the plaintiff's injury. In *Aronis v. Merck & Co.*, for example, the plaintiff joined a distributor in a case alleging physical injury from use of the prescription drug Vioxx. No. CIV. S-05-0486 WBS DAD, 2005 U.S. Dist. LEXIS 41531, at *3-4 (E.D. Cal. May 3, 2005). But the plaintiff did not allege that the distributor had ever handled the specific pills that were the alleged cause of her injuries, and Merck had more than one distributor. Accordingly, the court found an "obvious" failure to state a claim and denied remand. *Id.* at *3; see also *In re Yasmin v. Bayer Corp.*, 2010 U.S. Dist. LEXIS 105532, at *52 (S.D. Ill. Oct. 4, 2010) (finding that non-diverse distributor was fraudulently joined because plaintiffs "do not sufficiently allege that [distributor] supplied the pills that the Plaintiffs ingested"); *Wachovia Bank, N.A. v. Bourn*, No. 7:02CV00773, 2003 U.S. Dist. LEXIS 519, at *7-8 (W.D. Va. Jan. 7, 2003) (denying remand in case involving allegedly defective weight loss supplement because non-diverse distributor defendant did not distribute the specific product that allegedly caused injury to the plaintiff). Several other California judges, however, have remanded similar cases, finding that plaintiffs have alleged a sufficient connection between the allegedly fraudulently joined distributor and their injuries. See, e.g., Order Granting Pls.' Mot. To Remand To State Court at 3, *Albright v. Merck & Co.*, No. 2:05-cv-4025 (C.D. Cal. July 5, 2005) (finding that plaintiffs' "allegations clearly connect [the distributor] to Plaintiffs' alleged injuries").

While efforts to remove cases involving distributors have met with mixed success, a recent Supreme Court decision involving preemption of claims against generic drug manufacturers may provide defendants with a foolproof ground for removing cases that name non-diverse distributors. Since the Supreme Court's ruling in *PLIVA, Inc. v. Mensing* that failure-to-warn claims against generic drug manufacturers are preempted by federal law, a number of courts have extended the rationale of *Pliva* – i.e., that generic manufacturers have no power to change FDA-approved labels – to distributors. In *In re Fosamax Products Liability Litigation*, for example, the court dismissed claims by a number of plaintiffs against the distributor of the drug. No. 3:08-cv-00008-JAP-LHG, 2012 U.S. Dist. LEXIS 5817, at *26-28

(D.N.J. Jan. 17, 2012). According to the court, such claims were preempted because the distributor had no power to change the labeling and thus "could not independently do under federal law what state law requires of it." *Id.* at *28. See also, e.g., *Stevens v. Community Health Care, Inc.*, No. ESCV200702080, 2011 WL 6379298, at *1 (Mass. Super. Ct. 5, 2011) (since a distributor has no ability to change labeling or warnings, it cannot be subject to liability in connection with a state law failure-to-warn claim). Defendants have begun removing cases on this ground, arguing that distributors are fraudulently joined because the claims against them are legally doomed, but thus far, there have not been any published rulings on this issue. See, e.g., Notice of Removal at 9-11, *Porter v. DePuy Orthopaedics, Inc.*, No. 1:12-cv-00801 (N.D. Ill. Feb. 3, 2012).

B. Sales Representatives/Employees

Plaintiffs in pharmaceutical cases also frequently join resident sales representatives or other employees of a drug or device manufacturer in an effort to defeat diversity jurisdiction. Defendants typically argue that such employees cannot be held liable for failure-to-warn because they do not owe an independent duty to the plaintiff or physician, and because they are not "sellers" for purposes of warranty law, insofar as they never have title to the products to begin with.

The Eleventh Circuit's seminal ruling in *Legg v. Wyeth*, gave defendants a significant boost in fighting this form of fraudulent joinder. 428 F.3d 1317 (11th Cir. 2005). In *Legg*, a plaintiff attempted to join a non-diverse sales representative in a product-liability case to defeat diversity jurisdiction. The defendant argued that the sales representative was fraudulently joined and submitted an affidavit from the representative stating that she had "no involvement in the development or preparation of package inserts for any of the [products], and had no control over the content or other written warnings." *Id.* at 1321. On appeal, the Eleventh Circuit agreed that the sales representative had been fraudulently joined because there was no basis to find that the sales representative "knew or should have known of [the product's] allegedly dangerous effects." *Id.* at 1324-25. The *Legg* court further explained that when a defendant presents affirmative evidence, such as declarations that are not rebutted by the plaintiff, "the court cannot then resolve the facts in the Plaintiff[s] favor based solely on the unsupported allegations" in a complaint. *Id.* at 1323. Thus, the court held, remand had been erroneously granted. *Id.* at 1325. Other courts have relied on *Legg* in finding fraudulent joinder under similar circumstances – i.e., where the sales representative defendant submits an uncontradicted affidavit that he or she did not know or have reason to know of an alleged defect. See, e.g., *Slay v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20524, 2011 WL 3052531, at *4 (N.D. Ohio July 25, 2011).

C. Pharmacies and Hospitals

The fraudulent joinder of pharmacies attracted congressional attention in the debate over the Class Action Fairness Act when Hilda Bankston, the owner of a drug store in Mississippi, testified that her pharmacy had been sued in hundreds of lawsuits brought by individual plaintiffs against a variety of pharmaceutical manufacturers. Fortunately, courts have grown highly skeptical of efforts to avoid federal jurisdiction by naming pharmacies (and hospitals) as product-liability defendants. Many courts have held that: (1) under the learned-intermediary doctrine, pharmacies have no affirmative duty to warn customers of the potential side effects of prescription medications; and (2) hospitals and pharmacies provide a "service" rather than a "sale," and are thus not subject to claims grounded in theories of breach of warranty or strict liability. See, e.g., *Walton v. Bayer Corp.*, 643 F.3d 994, 999-1000 (7th Cir. 2011) (noting that under the learned-intermediary doctrine, which is in full force in 48 states, a pharmacy has no duty to warn a customer where the physician has been warned); *Coney v. Mylan Pharms., Inc.*, No. 6:11-cv-35, 2011 U.S. Dist. LEXIS 91062, at *9-10 (S.D. Ga. Aug. 16, 2011) (finding fraudulent joinder where pharmacy had no duty to warn under state law and was protected by the learned-intermediary doctrine); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 692 F. Supp. 2d 1025, 1032-34 (S.D. Ill. 2010) (surveying a litany of policy rationales for precluding liability for pharmacies, including: (1) the duty would run contrary to public policy against expanding liability risks of health professionals; (2) potential for interference with doctor-patient relationship; (3) burden it would impose on pharmacists; and (4) lack of foreseeability of injury to a particular consumer from absence of particular warning); *Roell v. Stryker*, No. 3:06-cv-443, 2007 U.S. Dist. LEXIS 70556, at *4 (S.D. Miss. Sept. 24, 2007) (holding that the hospital was fraudulently joined because it did not meet the definition of "seller" under Mississippi's product-liability statute or under the Uniform Commercial Code); *Kavalir v. Medtronic*, No. 07 C 0835, 2007 U.S. Dist. LEXIS 30002, at *9 (N.D. Ill. Apr. 19, 2007) (denying remand in case involving allegedly defective cardiovascular implant because "plaintiff d[id] not have any possibility of succeeding" on her warranty claims against non-diverse hospital defendants insofar as the transaction was not a "sale of goods" under the applicable state law).

Courts have expressed particular skepticism about suits against hospitals and pharmacies where the underlying complaint alleges that the manufacturer hid the dangers of the drug or device from the public, the healthcare community and physicians. See, e.g., *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, No. C02-423R, slip op. at 6-7 (W.D. Wash. Nov. 27, 2002) (pharmacy defendant fraudulently joined where the allegations that "manufacturer defendants concealed material facts regarding PPA through product packaging, labeling, advertising, promotional campaigns and materials, and other methods . . . directly undermines and contradicts the idea that [the resident retail defendant] had knowledge or reason to know of alleged defects"); *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 290 (S.D.N.Y. 2001) (resident retail pharmacies facing failure-to-warn claims fraudulently joined where "the theory underlying the complaint [was] that the manufacturer defendants hid the dangers of Rezulin from Plaintiffs, the public, physicians, distributors and pharmacists – indeed from everyone"). For instance, in the *Vioxx* litigation, Merck was successful in convincing several courts that plaintiffs could not defeat diversity by simultaneously alleging failure-to-warn claims against non-diverse doctors, pharmacies and hospitals. See, e.g., *Omobude v. Merck & Co.*, No. 3:03CV528LN, 2003 U.S. Dist. LEXIS 27006, at *5-6 (S.D. Miss. Oct. 3, 2003) (physician fraudulently joined where plaintiff alleged that "Merck withheld and concealed and misrepresented the true facts regarding Vioxx; and yet, without alleging any factual basis for the charge, plaintiff conclude[d] that [physician] 'knew or should have known' the truth about Vioxx"). These rulings have led plaintiffs to be more careful about their pleadings, but on the whole, defendants have nonetheless fared reasonably well in deflecting the fraudulent joinder of pharmacies and hospitals in both drug and device cases.

D. Misjoinder of Plaintiffs and Claims

Under the fraudulent-misjoinder doctrine, federal diversity jurisdiction exists "where diversity is destroyed only through misjoinder of parties." *Asher v. 3M*, No. 04-CV-522-KKC, 2005 U.S. Dist. LEXIS 42266, at *37 (E.D. Ky. June 30, 2005). The fraudulent-misjoinder doctrine applies where plaintiffs' claims are "egregiously[]" misjoined to defeat federal jurisdiction and "have no real connection" to one another. *Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353, 1360 (11th Cir. 1996), *abrogated on other grounds by Cohen v. Office Depot, Inc.*, 204 F.3d 1069 (11th Cir. 2000). Fraudulent misjoinder has not been recognized in every circuit and can still present a significant challenge to defendants.

Fraudulent-misjoinder removals usually take two forms: (1) fraudulent misjoinder of plaintiffs; and (2) fraudulent misjoinder of claims.

Misjoinder of plaintiffs occurs when multiple plaintiffs join their claims together with those of one plaintiff who is not diverse from the defendant manufacturer, arguing that all the claims in the suit are immune from removal because one plaintiff and one defendant share citizenship. Defendants typically argue in such cases that the various plaintiffs' claims do not arise "out of the same transaction, occurrence, or series of transactions or occurrences" or give rise to common questions of law or fact – and that they should therefore be severed before jurisdiction is determined. Fed. R. Civ. P. 20(a); see also *In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 144 (S.D.N.Y. 2001) ("Misjoinder of parties occurs when a party fails to satisfy the conditions for permissive joinder under Rule 20(a)."). In *Chaney v. Gate Pharmaceuticals*, for example, eleven plaintiffs from seven different states sued fourteen defendants, alleging injuries from use of the diet drugs phentermine, fenfluramine and dexfenfluramine, or some combination of those drugs. No. 98-20478, 1999 U.S. Dist. LEXIS 11414 (E.D. Pa. July 16, 1999). Seven of the plaintiffs were diverse from all the defendants and four were not. The court found that the claims of the plaintiffs who had not purchased or received diet

drugs from an identical source, such as a physician, hospital or diet center, were misjoined and, accordingly, denied the motion to remand as to the plaintiffs whose claims were fully diverse from the defendants.

Misjoinder of claims typically arises in pharmaceutical cases where a plaintiff combines product-liability claims against a manufacturer with medical-malpractice claims against a physician. In contrast to an argument based on alleged fraudulent joinder, removal is not based on the contention that the claim against the physician is meritless; rather, the argument is that the malpractice claim does not arise out of the same transaction or occurrence as the product-liability claim. For instance, in *Sutton v. Davol*, the court found that plaintiffs fraudulently misjoined their product-liability claims against the manufacturer of a medical device with medical-malpractice claims against resident physician and hospital defendants. 251 F.R.D. 500 (E.D. Cal. 2008). Similarly, in *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, the court denied remand where the plaintiff had joined product-liability claims against the manufacturer of a defibrillator and a medical-negligence claim against the physician. No. 07-1487, 2007 U.S. Dist. LEXIS 64942 (D. Minn. Aug. 30, 2007). In both cases, the courts found that the claims were misjoined because the malpractice claims were not based on – and could not be based on – the alleged negligence of the manufacturer. *Sutton*, 251 F.R.D. at 505; *In re Guidant Corp.*, 2007 U.S. Dist. LEXIS 64942, at *7.

II. Practical Tips for Defense Lawyers

In deciding how and when to pursue fraudulent joinder arguments, removing defendants should consider the following strategies:

- *Use extrinsic sources.* Although the fraudulent joinder standard is theoretically higher than that for motions to dismiss, it may be easier in practice to achieve removal based on fraudulent joinder than to succeed on a motion to dismiss. This is so because a court may look beyond the pleadings to determine whether a defendant is fraudulently joined. Indeed, courts have held that "[w]hen the Defendants' affidavits are undisputed by the Plaintiffs, the court cannot then resolve the facts in the Plaintiffs' favor based solely on the unsupported allegations in the Plaintiffs' complaint." *Legg v. Wyeth*, 428 F.3d 1317, 1323 (11th Cir. 2005); see also *Slay v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20524, 2011 WL 3052531, at *3 (N.D. Ohio July 25, 2011) ("[W]here the non-moving party has presented un rebutted evidence in the form of an affidavit or declaration, the Court will give weight to the sworn testimony rather than the unsupported allegations of the complaint."). Thus, defense counsel should always consider how an affidavit or declaration might assist removal or remand opposition efforts.
- *Effectively leverage the existence of an MDL.* Defendants may have better success with jurisdictional arguments if they are able to remove a case to federal court and then immediately "tag" the case for transfer to an existing MDL proceeding. Federal courts are much more likely to defer consideration of a remand motion if a conditional transfer order is in place, and MDL judges often have a better contextual understanding of forum-manipulation efforts and are more alert to fraudulent joinder issues.
- *Familiarity with state tort laws is critical to crafting persuasive fraudulent joinder arguments.* A choice-of-law analysis is critical to most fraudulent joinder arguments, and defendants should familiarize themselves with the underlying state statutory and common law with respect to all claims. States may preclude liability for certain types of claims or defendants, or they may require plaintiffs to exhaust administrative remedies before pursuing a civil suit (e.g., in malpractice claims), rendering claims against non-diverse defendants meritless.
- *Highlight deficiencies in the complaint.* Often, plaintiffs fail to make particularized allegations in a complaint because they cannot do so. For example, they may not know which distributor or sales representative can be tied to their specific pills or device and therefore offer only generic allegations against the non-diverse defendants. In such instances, defendants should capitalize on plaintiffs' vagueness to highlight the lack of any concrete allegations against the in-state defendants. This is particularly true in fraud-based actions, where Rule 9(b) adds a heightened pleading requirement that plaintiffs can rarely satisfy with respect to a fraudulently joined defendant.

* * *

In the end, regardless of how clear or compelling a fraudulent joinder argument might be, the outcome of these inquiries often depends on the court's perception of – and experience with – such claims. Some courts – particularly those with a lot of experience in seeing how pharmaceutical and medical device product defect claims normally play out – are highly dubious of efforts to join non-manufacturer parties. Other courts manifest a much narrower view of federal jurisdiction, leading them to more reflexively remand cases regardless of the futility of a plaintiff's state-law claims against non-manufacturer parties.

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When Will Plaintiffs Learn to Let Treating Physicians Be Treating Physicians?

by Sheila S. Boston and Ira Ginsberg

Experienced product liability practitioners know that the treating physician's testimony is often the most important testimony in a personal injury case. Thus, both plaintiff and defense counsel alike attempt to elicit favorable causation testimony from these witnesses. Plaintiff counsel, however, often go a step further: they try to convert non-party treating physicians into experts. Unable to find qualified causation experts in a particular field with the appropriate experience and publications concerning a salient issue, plaintiffs instead often opt to proffer treating physicians as causation experts. And, more often than not, differential diagnosis is the methodology employed by those treating physicians as the basis of their expert opinions.

Differential Diagnosis Under *Daubert*

In product liability personal injury cases brought against drug and medical device manufacturers, the plaintiff must establish general causation and specific causation. To establish general causation, plaintiffs often retain experts in the relevant scientific field. To establish specific causation, plaintiffs often proffer the testimony of treating physicians who base their testimony on the same differential diagnosis doctors routinely employ to treat their patients. "Differential diagnosis refers to the clinical process by which doctors determine the internal disease that is causing a patient's suffering," and when used appropriately it "is an invaluable tool that guides physicians' choices among possible

diagnostic tests and treatments." Ian S. Spechler, Note, *Physicians at the Gates of Daubert: A Look at the Admissibility of Differential Diagnosis Testimony to Show External Causation in Toxic Tort Litigation*, 26 Rev. Litig. 739, 740-43 (2007) ("Spechler Note"). An overwhelming number of courts have held that a medical opinion proffered in support of specific causation, based upon a proper differential diagnosis, is permissible as expert testimony. See *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178-80 (6th Cir. 2009); *Hines v. Wyeth, Inc.*, 2011 WL 2792436, at *3 (S.D.W.V. July 14, 2011).

Expert testimony can be admitted only after careful consideration of Federal Rule of Evidence 702 and the relevant *Daubert* factors, which require district courts to assess whether proffered expert testimony is both reliable and relevant to a case. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Courts consider reliability by reviewing "whether the theory or technique had been tested, whether it had been subjected to peer review and publication, the method's known or potential error rate, and the method's general acceptance in the scientific community." *Meister v. Med. Eng'g Corp.*, 267 F.3d 1123, 1127 (D.C. Cir. 2001). Although a treating physician need not be "among the world's foremost authorities" on the causation matter at issue to provide expert testimony regarding a patient's illness, the appropriate diagnosis, and the cause of the illness, a treating physician's expert opinion on causation is subject to the same rigorous standards of scientific reliability that govern the expert opinions of physicians hired solely for purposes of litigation. *Thomas v. Novartis Pharm. Corp.*, 443 Fed. App'x 58, 61 (6th Cir. 2011); see *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *Bland v. Verizon Wireless, L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008). Consequently, the admissibility of a treating physician's "expert" testimony rendered on behalf of a plaintiff is far from a *fait accompli*. Recent published federal case law demonstrates that plaintiffs in drug and medical device litigations have often struggled to parlay treating physician testimony into admissible expert testimony under *Daubert*. See *Thomas v. Novartis* (affirms exclusion of causation testimony of plaintiffs' treating doctors); *Hines v. Wyeth* (excludes causation testimony of one of plaintiff's surgeons); see also *Bland v. Verizon Wireless* (affirms exclusion of treating physician's differential diagnosis with a good discussion of *Daubert*); but see *In re Fosamax Prods. Liab. Litig.*, 647 F.Supp.2d 265 (S.D.N.Y. 2009). Furthermore, although courts find that, at least in theory, a treating physician's differential diagnosis survives *Daubert* to show specific causation, courts generally find this approach insufficient to demonstrate general causation. See *Bickel v. Pfizer, Inc.*, 431 F.Supp.2d 918, 923 (N.D. Ind. 2006) ("the Plaintiff cannot rely on [differential] diagnosis to establish general causation"); see also *In re Rezulin Prods. Liab. Litig.*, 2004 WL 2884327, at *4 (S.D.N.Y. Dec. 10, 2004) ("differential diagnosis does not 'speak to the issue of general causation. [It] assumes that general causation has been proven for the list of possible causes' that it rules in and out in coming to a conclusion." (quoting *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1413 (D.Or. 1996))); but see *Perkins v. Origin Medsystems Inc.*, 299 F.Supp.2d 45, 57-61 (D. Ct. 2004).

Differential Diagnosis vs. Differential Etiology

While courts allow treating physicians to testify as experts based on differential diagnosis, such rulings have been based on a misunderstanding of a physician's role. Doctors treat symptoms and diseases, so they try to figure out the source of the symptoms and identify the disease or injury so that they may properly treat the patient. Physicians do not, however, routinely engage in differential etiology or an attempt to figure out what external factor caused a disease. Doctors like the one portrayed by actor Hugh Laurie in the Fox network television medical drama "House" are an anomaly. How many doctors make house calls or inspect work and/or home environments as part of their diagnostic practice? There is a significant difference between differential diagnosis and differential etiology. "In a differential diagnosis, a doctor isolates a disease that is causing the patient's symptoms, whereas differential etiology isolates an external factor that has caused the internal disease." Spechler Note at 743. Recently, some courts have demonstrated a clearer understanding of these concepts, and, in assessing the reliability of treating physician testimony, have inquired whether the doctor's differential diagnosis procedure included an emphasis on external causes. See, e.g., *Bickel*, 431 F.Supp.2d at 923-924; *In re Rezulin Prods. Liab. Litig.*, 2004 WL 2884327, at *3-4.

Instructive Defense Victories in 2011

In *Thomas v. Novartis*, three plaintiffs alleged that the defendant's prescription bisphosphonate drugs caused them to develop osteonecrosis of the jaw ("ONJ"). To prove specific causation, plaintiffs proffered the testimony of their respective "expert" treating physicians. The experts of two of the plaintiffs were experienced in the relevant field of medicine, had treated many patients with ONJ, and had engaged in differential diagnosis in support of their specific causation opinions. Furthermore, the plaintiffs presented evidence that the treatment ordinarily used for ONJ actually worsens the condition when used on patients with bisphosphonate-induced ONJ, thus emphasizing the importance of the treating physician properly determining ONJ's cause. Nonetheless, the court excluded both experts stating that they lacked an adequate basis for showing the defendant's products caused plaintiffs' ONJ. The court noted that "the importance of correctly determining the cause of the osteonecrosis ... does nothing to establish that [the doctor] can in fact, reliably determine the cause of a patient's [ONJ]." *Id.* at 62. The court also stated that showing a doctor could recognize and treat ONJ was insufficient to show that he could adequately determine the condition's external cause. Moreover, the court noted that one of the experts did not consider himself to be an expert in the causes of ONJ, which although not dispositive, did impact the court's assessment of the testimony. The testimony of the third plaintiff's experts were excluded on simpler grounds: both doctors stated that they did not form an opinion about the cause of their patient's condition to a reasonable degree of medical certainty. Furthermore, neither doctor considered himself an expert on the relevant issue.

In *Hines v. Wyeth*, a plaintiff alleged that her ingestion of defendants' hormone replacement therapy (HRT) drugs caused her development of breast cancer. The defendants successfully moved to exclude one of plaintiff's treating physicians from testifying as a specific causation expert. Although the treating physician conducted a differential diagnosis, the court found that his testimony failed to pass the *Daubert* threshold because in addition to not properly ruling out alternative causes of the plaintiff's condition, he did not reliably rule in alternative causes by considering the possibility of such alternatives.

Tips for Defense Counsel

Based on recently published *Daubert* decisions, there are several strategies defense counsel should consider when opposing a plaintiff's attempt to proffer treating physician testimony as expert causation testimony. In addition to arguing that a treating physician lacks certain qualifications and that differential diagnosis is not a suitable methodology for establishing general or specific causation, defense counsel should also:

- Capitalize upon a treating physician's own acknowledgement that he or she is not an expert. See, e.g., *Thomas v. Novartis*.
- Establish that the treating physician has never published or otherwise presented the causation opinion to professional peers. See, e.g., *Bickel v. Pfizer*.
- Establish that the treating physician is unable to cite any published medical textbook or article that concludes there is a validated medical test, procedure or protocol as the basis for his or her specific causation opinion. See, e.g., *Bickel v. Pfizer*.
- Obtain an admission from the treating physician that the goal of the differential diagnosis is to determine from what disease a patient suffers, not to determine the external cause of that disease. See Spechler Note.
- Demonstrate that the treating physician failed to adequately "rule in" and "rule out" alternative causes. See, e.g., *Hines v. Wyeth*.
- Demonstrate that the treating physician not only failed to attempt to rule out other possible causes of the condition but also is unable to rule them out. See, e.g., *Meister v. Med. Eng'g*.
- Argue that the importance of correctly determining the cause of an alleged injury or disease does nothing to establish that the treating doctor could in fact reliably determine the cause of a patient's injury or disease. See, e.g., *Thomas v. Novartis*.
- Always make sure that the treating physician offers more evidence than just a temporal link; reliance on temporal proximity, without more, is insufficient to establish causation. See, e.g., *Meister v. Med. Eng'g*; but see *Perkins v. Origin*.

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Milward and the First Circuit's Weight-of-the-Evidence Approach

by Eric Swan

In one of the most controversial *Daubert* rulings in recent memory, the First Circuit in *Milward v. Acuity Specialty Products Inc.* recently held that an expert's opinion was reliable based on a "weight-of-the-evidence" approach. 639 F.3d 11 (1st Cir. 2011), cert. denied sub nom *U.S. Steel Corp. v. Milward*, No. 10A1263, 2012 WL 33303 (Jan. 9, 2012). Because this approach is contrary to existing precedent and scientific principles, and will likely be coming to a court near you soon, I analyze some of the problems with the decision.



I. Background

The background facts of the case were recently well summarized by Julie A. Brennan in an article published in the DRI Young Lawyers Committee's online newsletter, *The Whisper*. <http://clients.criticalimpact.com/newsletter/newslettercontentshow1.cfm?contentid=9645&id=1080>. Therefore, I only briefly summarize them here.

The Plaintiffs in *Milward* sued multiple Defendants alleging that Mr. Milward's exposure to benzene caused him to develop a blood cancer called Acute Promyelocytic Leukemia (APL), a rare subtype of a more general category of leukemia known as acute myeloid leukemia (AML). In formulating his opinion, Plaintiffs' expert toxicologist relied on several lines of evidence:

- The scientific consensus "that benzene can cause AML as a class";
- Literature suggesting that AML and APL both arise from stem cells;
- Evidence that both APL and AML are often accompanied by chromosomal translocations—chromosomes that have broken and improperly recombined;
- The ability of metabolites of benzene to cause chromosomal translocations by a variety of mechanisms; and
- Statistically insignificant epidemiologic studies that "suggest" a link between benzene and APL.

Based on the weight of this evidence, Plaintiffs' expert concluded that benzene is capable of causing APL. *Milward*, 639 F.3d at 20.

II. Weight-of-the-Evidence Approach

The precise contours of the weight-of-the-evidence methodology that the Court accepted are not altogether clear. According to the Court, the expert's analysis began with the nine factors identified in the Bradford-Hill criteria. From there the expert added a second layer of analysis. Under this methodology the expert must:

1. identify an association between an exposure and a disease,
2. consider a range of plausible explanations for the association,
3. rank the rival explanations according to their plausibility,
4. seek additional evidence to separate the more plausible from the less plausible explanations,
5. consider all relevant available evidence, and
6. integrate the evidence using professional judgment to come to a conclusion about the best explanation.

Id. at 18. The Court ultimately held that this approach was "scientifically sound and methodologically reliable" per *Daubert*, *id.* at 20, and, as a result, it reversed the lower court's exclusion of the expert's testimony.

III. Analysis of the Court's Reasoning

The Court's analysis is fraught with problems. First, and most importantly, by accepting this weight-of-the-evidence methodology, the Court subtly but profoundly shifted the *Daubert* inquiry from whether the evidence *standing alone* is sufficiently reliable scientific evidence of causation, to whether *on balance* the evidence supports an expert's theory. Second, the Court jettisoned one of the most accepted standards for making causal judgments—the hierarchy of evidence—and replaced it with a scientific standard that has no *Daubert* precedent. Finally, the Court's weight-of-the-evidence approach creates an analytic conundrum for judges: How are judges to reconcile their role as gatekeepers in cases involving weight-of-the-evidence opinions, when they are admonished that the "evaluation of the weight of the evidence...is the province of jury"? *Id.* at 20.

A. Altering the *Daubert* Inquiry

Although the Court tried to cloak its opinion in established authority, most notably the Bradford-Hill criteria, its analysis diverges significantly from both Bradford-Hill and established *Daubert* precedent. One of the most fundamental problems with the Court's analysis is that it shifted the *Daubert* inquiry from the reliability of the plaintiff's evidence vis-à-vis an external standard, to the strength of the expert's evidence vis-à-vis other competing evidence. This can be seen in steps 2-6 of the methodology, which permit the expert to rank competing plausible explanations and then weigh their relative strength. *Id.* at 18. Whereas Hill looked at a specific theory and asked whether there was sufficient evidence to say the association was causal, the Court's weight-of-the-evidence approach asks how the theory stacks up against competing theories.

The result is that there is no threshold level of evidence before an expert's opinion can be deemed admissible. For example, what if the available evidence consists entirely of one animal study and a single paper hypothesizing a mechanism of action? And what if no scientist had bothered to publish or conduct contrary studies? Under existing *Daubert* case law, most courts would find this to be insufficient evidence of general causation. Under a weight-of-the-evidence approach, it might be admissible because the "weight" of the evidence supports the conclusion. There is no doubt plaintiffs' lawyers will press this angle in future litigation.

B. Rejecting the Hierarchy of Evidence

Perhaps the most disconcerting portion of the opinion is the suggestion that there is no hierarchy of evidence in causal inference. At the end of its brief discussion of Bradford-Hill, the Court wrote: "[I]t is generally agreed that this list is not exhaustive and that no one type of evidence must be presented before causality may be inferred. For example, when a

group from the National Cancer Institute was asked to rank the different types of evidence, it concluded that "[t]here should be no such hierarchy." *Id.* at 17. The full quote from the NCI panel is as follows:

6. What is the hierarchy of state-of-the-art approaches needed for confirmation criteria, and which bioassays are critical for decisions: epidemiology, animal testing, cell culture, genomics, and so forth? There should be no such hierarchy. Epidemiology, animal, tissue culture and molecular pathology should be seen as integrating evidences in the determination of human carcinogenicity.

Michele Carbon et al., *Modern Criteria to Establish Human Cancer Etiology*, 64 *Cancer Res.* 5518, 5522 (2004). The implication that there is no hierarchy of evidence in causal inference, and that tissue culture studies are as relevant as epidemiology, is patently absurd. Whatever value this may have in the context of regulatory decisions for the purpose of cancer prevention, it has no value and no precedent in tort law. See, e.g., *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005). (holding that epidemiology is the "best evidence"—and therefore better evidence—of causation). Indeed, if there is no hierarchy one must ask why the FDA requires clinical trials for drug approval? After all, by this logic, clinical trials are no better than in vitro studies and animal studies at showing safety and efficacy.

C. Creating an Analytical Conundrum

Lastly, the Court's weight-of-the-evidence approach creates analytic problems for courts assessing the reliability of expert testimony. The lower court noted three principle inferential leaps in the Plaintiffs' expert's analysis that it believed rendered his opinion unreliable. The First Circuit responded by saying these were of the lower courts own making, *id.* at 22, and went on to chastise the lower court for crossing "the boundary between gatekeeper and trier of fact." *Id.* According to the Court, "the alleged flaws [went] to the weight of Dr. Smith's opinion, not its admissibility." *Id.* Of course, this begs the question: When the methodology is expressly predicated on weighing the evidence how is a lower court to evaluate the reliability of the opinion if it cannot in fact weigh the evidence?

Whether it is called "weighing the evidence" or analyzing the inferential leaps in the expert's methodology, what the lower court did is consistent with the Supreme Court's admonition to courts in *Joiner* not to rely simply on the expert's *ipse dixit*. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The First Circuit recognized this and even cited the relevant language from *Joiner*: "following *Joiner*, a district court properly may exclude expert testimony if the court concludes too great an analytical gap exists between the existing data and the expert's conclusion." *Id.* (internal citations omitted). By likening the lower court's analysis of those gaps to an improper weighing of the evidence, the First Circuit gave ammunition to plaintiffs in future cases to liken all defense criticisms of their expert's inferential leaps to an inappropriate call to "weigh the evidence." It would have been better if the First Circuit simply acknowledged what it did: replace its judgment of the evidence for that of the lower court's.

IV. Conclusion

The First Circuit was correct when it said that "[n]o matter what methodology is used, 'an evaluation of data and scientific evidence to determine whether an inference of causation is appropriate requires judgment and interpretation.'" *Id.* at 18 (internal citations omitted). However, it was wrong to adopt a standard that shifts the focus from a judgment of the evidence vis-à-vis an external standard, to a judgment vis-à-vis whatever information is available. It compounded this mistake by jettisoning the hierarchy of evidence, which provides a framework for making those judgments, and by characterizing the lower court's analysis of the expert's inferential leaps as an invasion on the fact finding role of the jury. In the end, the First Circuit obfuscated rather than elucidated the requirements for the admissibility of expert testimony and added more confusion to an already confusing area of law.

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Product Liability Claims Against Generic Pharmaceutical Manufacturers in a Post-*Mensing* Environment

by Beth S. Rose and Vincent Lodato



Generic pharmaceutical manufacturers scored a major victory in June 2011 when the United States Supreme Court decided *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *Mensing*, the Court held that state law failure to warn claims against generic pharmaceutical manufacturers were impliedly preempted by federal law. The Court's decision was premised on its conclusion that generic manufacturers "have an ongoing federal duty of sameness" which requires that the labeling and warnings for generic products be identical to those of their brand-name counterparts. *Mensing*, 131 S. Ct. at 2574-75. Because the Court accepted the FDA's conclusion that the changes being effected (CBE) regulations were not available to generic manufacturers, the Court held that the state law failure to warn claims were preempted as it was impossible for a generic manufacturer to unilaterally change its label to strengthen or add new warnings without violating FDA regulations. *Id.* at 2575.

Since *Mensing* was decided, several trial courts have been asked to interpret the breadth and scope of the Court's decision. Plaintiffs have typically argued that *Mensing* preempts only a very narrow category of failure to warn claims against generic manufacturers, *i.e.*, where plaintiff is alleging that the labeling for the generic product should have included new or additional warnings beyond those required by the FDA. Most generic manufacturers, on the other hand, have taken the position that *Mensing* should be broadly applied and that failure to warn claims are not the only types of claims which are now preempted. These competing theories are forcing courts to address the contours of *Mensing*.

Failure to Warn Claims

To the extent that a plaintiff is alleging that a generic manufacturer should be held liable because it failed to include additional or different warnings from those required by the FDA to be in the brand name product's label, the courts have held that such claims are impliedly preempted by *Mensing*. See, e.g., *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, MDL No. 2243, 2011 U.S. Dist. LEXIS 135006, at *34 (D.N.J. Nov. 21, 2001) (dismissing plaintiffs' failure to warn claim that the defendant should have changed its label "to provide new, different, and stronger warnings"); *In re Pamidronate Products Liability Litigation*, No. 09-md-2120, 2012 U.S. Dist. LEXIS 10901, at *10-11 (E.D.N.Y. Jan. 30, 2012) (dismissing plaintiffs' failure to warn claim that the "defendants should have altered the labeling of pamidronate to provide stronger warnings about the drug's possible adverse side effects").

Despite *Mensing's* clear holding, some plaintiffs have tried to keep their failure to warn claims alive by raising two

"creative" arguments. First, some plaintiffs have argued that *Mensing* does not preempt failure to warn claims where plaintiff is alleging that the generic manufacturer failed to update its product label to match that of the brand name product. For the most part, trial courts have been receptive to this "failure to update" argument because *Mensing* is premised on the theory that a generic manufacturer is under a "duty of sameness" and must ensure that its product label and warnings are identical to those of the brand name product. See, e.g., *Fisher v. Pelstring*, No. 09-cv-252, 2011 U.S. Dist. LEXIS 116162, at * 10-13 (D.S.C. Sep. 30, 2011) (holding that defendant's failure to timely update its label was sufficient grounds to deny its motion to dismiss on preemption grounds); *Phelps v. Wyeth, Inc.*, No. 09-cv-6168, at pp. 7-8 (D. Or. Nov. 30, 2011) (dismissing all of plaintiff's failure to warn claims except for the claim that the generic manufacturers failed to timely update their label); *Couick v. Wyeth, Inc.*, No. 09-cv-210, 2012 U.S. Dist. LEXIS 3699, at *9-14 (W.D.N.C. Jan. 11, 2012) (denying the generic defendants' motion to dismiss on preemption grounds because they failed to establish that their product labels matched the label of the brand name product). Furthermore, courts have held that generic manufacturers are entitled to use the CBE process to unilaterally update their labels and warnings so that they match those of the brand name product. *Del Valle v. Pliva, Inc.*, No. 09-cv-6168, at p. 13 (S.D. Tex. Dec. 21, 2011) (noting that a generic manufacturer may use the CBE process to "match an updated brand-name label") *Fisher*, 2011 U.S. Dist. LEXIS 116162 at *13 (holding that a CBE supplement "is the appropriate process" for a generic manufacturer to update its label to conform to the brand name product's label). A few courts, while accepting that failure to update claims may not be preempted, have rejected those claims on other grounds. See, e.g., *Del Valle*, No. 09-cv-6168 at pp. 7-8 (declining to address the validity of plaintiff's failure to update argument because plaintiff failed to identify any harm that resulted from defendant's alleged failure to update its label to match the brand name product); *Gross v. Pfizer, Inc.*, No. 10-110, 2011 U.S. Dist. LEXIS 134895, at *11-12 (D. Md. Nov. 22, 2011) (rejecting plaintiff's claim that the defendant's label differed from the brand-name label because Maryland law did not recognize such a cause of action).

Second, some plaintiffs have argued that *Mensing* only preempts claims that the generic manufacturer should have made content changes to the product's label. They have argued that *Mensing* does not preempt claims that the manufacturer should have communicated FDA-required warnings through more effective modes of communication than the product's label including sending Dear Doctor letters, holding physician seminars or publishing warnings in professional publications like the Physician's Desk Reference. See, e.g., *Grinage v. Mylan Pharmaceuticals, Inc.*, No. 11-1436, 2011 U.S. Dist. LEXIS 149667, at *9-10 (D. Md. Dec. 30, 2011). Most courts have rejected these arguments with some concluding that the *Mensing* Court held that generic manufacturers were not free to unilaterally send Dear Doctor letters without prior FDA approval. *Guarino v. Wyeth LLC*, No. 10-cv-2885, 2011 U.S. Dist. LEXIS 128630, at * (M.D. Fla. Nov. 7, 2011) (holding that the *Mensing* Court "specifically rejected Plaintiff's failure-to-communicate argument"); *Del Valle*, No. 06-cv-6168 at p. 10 (holding that plaintiff's "Dear Doctor letter" argument was precluded by *Mensing*). Other courts have rejected such claims because plaintiffs were unable to allege how a Dear Doctor letter, which included the same information as the product label, would have prevented plaintiff's injuries. *Grinage*, 2011 U.S. Dist. LEXIS 149667 at *12-13; *Metz v. Wyeth, LLC*, No. 10-cv-2658, 2011 U.S. Dist. LEXIS 121549, at *5 n.2 (M.D. Fla. Oct. 20, 2011). A few courts, however, have permitted such claims to proceed, holding that the *Mensing* Court never addressed whether generic manufacturers could be held liable for failing to send Dear Doctor letters that are consistent with the product labeling, and that no FDA regulations prohibit generic manufacturers from issuing such letters. *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc.*, No. 10-031, 2011 U.S. Dist. LEXIS 102858, at *6-8 (S.D. Ala. Sep. 12, 2011); *Sacks v. Endoscopy Center of Southern Nevada, LLC*, No. 08A572315, 2011 WL 4915174, at *1-2 (Nev. Dist. Ct. Jul. 28, 2011) (holding that plaintiff's claim that the defendant could have sent a Dear Doctor letter containing warnings consistent with the product label did not violate *Mensing*); *Keck v. Endoscopy Center of Nevada, LLC*, No. A575837, 2011 WL 3921690, at *4 (Nev. Dist. Ct. Aug. 19, 2011) (holding that the "Supreme Court did not indicate that 'Dear Doctor' letters that were 'consistent and not contrary' to the labeling, were preempted").

Design Defect Claims

In most jurisdictions, plaintiffs are precluded from asserting design defect claims against pharmaceutical manufacturers because they have adopted Comment K to the Restatement (Second) of Torts, § 402A, which immunizes manufacturers of "unavoidably unsafe" products from design defect claims. See, e.g., *Grinage*, 2011 U.S. Dist. LEXIS 149667 at *15; *Gross*, 2011 U.S. Dist. LEXIS 134895 at *7. Despite Comment K, most plaintiffs still assert design defect claims in pharmaceutical product liability cases. Although *Mensing* only specifically addressed failure to warn claims, some courts have recently held that the same principles also impliedly preempt design defect claims against generic manufacturers. These decisions have expanded on *Mensing's* "duty of sameness," holding that federal law not only requires generic and brand-name pharmaceutical products to have identical labeling, but they must also share the same design, i.e., the same active ingredient, bioequivalence and safety and efficacy profile. Because generic manufacturers cannot unilaterally change the design of their generic drug products without FDA approval, these courts have held that design defect claims are also impliedly preempted under *Mensing*. See, e.g., *In re Pamidronate*, 2012 U.S. Dist. LEXIS 10901 at *11-12; *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *32-34; *Stevens v. Pliva, Inc.*, No. 10-0886, 2011 U.S. Dist. LEXIS 147684, at *5-6 (W.D. La. Nov. 15, 2011). Along these same lines, a few courts have dismissed design defect claims because the brand-name manufacturer rather than the generic manufacturer that actually "designed" the product. *Metz*, 2011 U.S. Dist. LEXIS 121549 at *10; *Fullington v. Pliva, Inc.*, No. 10-cv-236, 2011 U.S. Dist. LEXIS 142931, at *15-16 (E.D. Ark. Dec. 12, 2011).

Negligence, Warranty and Fraud Claims

Plaintiffs have not fared much better on their non-product liability claims. For example, several courts have dismissed claims which allege that the generic manufacturer was negligent or committed fraud in connection with the labeling, marketing, promotion or distribution of their products because such claims were essentially failure to warn claims. *In re Pamidronate*, 2012 U.S. Dist. LEXIS 10901 at *12-13; *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *40, 42-43; *Grinage*, 2011 U.S. Dist. LEXIS 149667 at *15; *Gross*, 2011 U.S. Dist. LEXIS 134895 at 22; *Metz*, 2011 U.S. Dist. LEXIS 121549 at *11; *Del Valle*, No. 11-cv-113 at pp. 8-9. Some courts have also dismissed express warranty claims on the same grounds. *In re Pamidronate*, 2012 U.S. Dist. LEXIS 10901 at *13-14; *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *42-43. Furthermore, claims that the defendant was negligent in designing or testing a product have also failed because they were akin to design defect claims which are also preempted. *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *41. Many courts have also dismissed implied warranty claims because they were just repeats of plaintiffs' failure to warn or design defect claims. *In re Pamidronate*, 2012 U.S. Dist. LEXIS 10901 at *14-15; *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *41-42; *Grinage*, 2011 U.S. Dist. LEXIS 149667 at *15; *Gross*, 2011 U.S. Dist. LEXIS 134895 at *19-20. *But see Couick*, 2012 U.S. Dist. LEXIS 3609 at *18-19 (refusing to dismiss plaintiff's implied warranty claim on preemption grounds because the claim did not exclusively relate to the product's labeling).

Conclusion

Post-*Mensing*, plaintiffs are trying to develop more creative arguments in order to maintain claims against generic manufacturers. For the most part, generic manufacturers have been successful in defeating these arguments and having cases dismissed in their entirety. Whether lawsuits against generic manufacturers will completely fade away still remains to be seen.

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Taken

by Michael A. Walsh

The Internet revolutionized how we obtain information, and social media has revolutionized how we share it. However,



the current regulatory landscape created by the Food and Drug Administration (FDA) for medical product manufacturers is comprised of old rules designed for old media, wherein a medical product manufacturer's online speech and active participation in the dissemination of truthful product information creates an enormous risk of civil and criminal prosecution. This lack of clear regulatory guidance constrains manufacturers from providing meaningful and reliable product information.

In defending FDA's regulatory approach, its Commissioner recently stated:

Now I know that in some circles regulation is viewed as a roadblock to innovation and economic growth. But in actuality, when done right, regulation isn't a roadblock; it's the actual pathway to achieving real and lasting innovation... Going forward, smart regulation requires regulatory flexibility that responds to changing situations, new information and new challenges.

Margaret Hamburg, M.D., 50 Years after Thalidomide: Why Regulation Matters, FDA Voice (February 7, 2012), <http://blogs.fda.gov/fdavoices/index.php/2012/02/>.

Unfortunately, FDA may be failing to respond to "changing situations" and its opportunity to do it "right" is passing. There remains an immediate need for regulations that comport with the new era in information gathering.

For medical product manufacturers, three main questions arise concerning their use of the Internet and social media: (1) what can they say?; (2) what are they responsible for (i.e., third-party content and adverse event reporting)?; and (3) what are the consequences of not participating?

In 2009, approximately 158 million users looked online for health information, and 50 million people used the Internet as their first source for healthcare information. Mark Bard, *Wired for Health: Consumer and Physician Demand for Digital Health, Pharma and Social Media Resources*, ePharma Physician (2009), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM195751.pdf>.

In the last quarter of 2007 alone, there were "4.6 billion health-related searches across all search engines in the U.S." Mary Anne Belliveau, Amy Cowan, *A Proposal for Sponsored Links – Connecting Consumers to Important Health Information*, Google (Nov. 2009), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM195758.pdf>.

As patients are increasingly managing their healthcare online, social media are quickly surpassing television and print media as the primary source of health-related information.

Consumer health-related searches are driven by medical events, with users looking for a "truth-risk value proposition," and consumers find "personal experience" content most useful. See *Promotion of FDA Regulated Medical Products – Using the Internet and Social Media Tools: Public Hearings before the Food and Drug Administration*, p. 391 (Nov. 12, 2009)(statements of Kathleen Fourte). It is estimated that 78 percent of people "suffering" use the Internet, *id.* at 352 (statements of John Mangano), and two-thirds of them say online information has improved the physician-patient dialogue. *Id.* at 418 (statements of Larry Mickelberg). In one survey, 46 percent of respondents said social media helped but they thought the content was unreliable. *Id.* at 362. According to the research, users search online first, then 86 percent ask their physicians about the information they found online. See *id.* at 73 (statements of Jeff Francer).

Patients are not the only ones managing health information online. According to survey data, 90 percent of physicians are online, and 75 percent are online daily. Physicians no longer simply rely on professional society meetings, journals, sales representatives, and interactions with colleagues in hospital hallways to gain information. Now, this exchange of information is being conducted on a grand scale online.

Consumers and healthcare professionals are not changing how they think because of social media – rather, social media is adapting to work the way people think. Health-related communities are forming and evolving, making interactions more productive, informative, and immediate.

In 1996, FDA held hearings to address the then newly-forming Internet, which was capable of delivering health information without the time limitations of TV or the space limitations of print media. Since 1996, the Internet has become the primary choice of both consumers and healthcare professionals seeking health and medical product information. See e.g. Bard, *Wired for Health: Consumer and Physician Demand for Digital Health, Pharma and Social Media Resources*.

In November 2009, FDA held additional hearings regarding the use of the Internet and social media by manufacturers of FDA-regulated products. See *Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools*, Food and Drug Administration, available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm> (last updated Dec. 27, 2011). In connection with those hearings, FDA stated that "[p]olicy and guidance development for promotion of FDA-regulated medical products using the Internet and social media tools are among our highest priorities." See *id.* Since that time, FDA has done little to update the regulatory landscape to (1) allow manufacturers to disseminate truthful health-related information regarding its products or (2) provide guidance on what, if anything, a manufacturer must do to monitor third-party information concerning its products.

In December 2011, FDA issued its draft Guidance on Unsolicited Requests, which addressed new media but provided minimal guidance in this regard. See *Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*, Food and Drug Administration (Dec. 2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>. Also in December 2011, FDA posted two notices: (1) Examination of On-Line Direct-to-Consumer Drug Promotion, which is an effort designed to conduct a series of studies to determine how best to present risk and benefit information on branded drug websites (76 Fed. Reg. 243, 78663-78667 (Dec. 19, 2011)) (<http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/html/2011-32275.htm>); and (2) Communications and Activities Related to Off-Label Uses of Marketed Products and Use of Products not Yet Legally Marketed (i.e., Scientific Exchange) (76 Fed. Reg. 249, 81508-81510 (Dec. 28, 2011)) (<http://www.gpo.gov/fdsys/pkg/FR-2011-12-28/html/2011-33188.htm>). While these current initiatives may bear on the use of the Internet and social media by manufacturers of FDA-regulated products, it is uncertain when, or if, FDA will take meaningful action. Because FDA cannot regulate the online communications or content of the consuming public or healthcare professionals, FDA is standing on the sidelines, confounded by how to fashion new rules to allow its most potent participant, the manufacturer, to participate meaningfully.

The absence of clear rules regarding online communications, particularly any clearly guiding manufacturers as to how they can provide truthful information concerning their products, has left manufacturers uncertain about what they are permitted to do. This regulatory void hinders the most potent source of reliable health information specific to medical products, both for consumers and healthcare professionals. A number of speakers at FDA's 2009 hearings expressed the inherent problems in this lack of direction as follows:

- "[I]t is a travesty in this day and age when we have the technology to provide the most comprehensive and transparent medical information to those who can rely on it daily – the healthcare professional." *Promotion of*

FDA Regulated Medical Products – Using the Internet and Social Media Tools: Public Hearings before the Food and Drug Administration, p. 267 (Nov. 13, 2009)(statement of David Saggio).

- "[T]he vacuum created by the absence of manufacturer activity within the social media ecosystem has been quickly filled by...user-generated [content]." *Promotion of FDA Regulated Medical Products – Using the Internet and Social Media Tools: Public Hearings before the Food and Drug Administration*, p. 426 (Nov. 12, 2009)(statement of Dr. John Reeves).
- Google testified that after FDA issued 14 Notices of Violation on April 2, 2009, which claimed "misbranding" based on FDA's assessment that sponsored links on company websites failed to communicate risk information, the "click through rate" (i.e., the number of times an ad was delivered divided by the number of times it was clicked on) fell off precipitously. This illustrates that FDA's approach to restricting industry conduct reduced the availability of manufacturer-generated content to searchers. *Promotion of FDA Regulated Medical Products – Using the Internet and Social Media Tools: Public Hearings before the Food and Drug Administration*, pp. 436-38 (Nov. 12, 2009)(statements of Mary Ann Belliveau and Amy Cowan).

Industry should be an active participant in any dialogue concerning its products. But fear of FDA's criminal and civil enforcement and penalties has led the industry to take the FDA's threats seriously and manufacturers anxiously sit as bystanders. Rather than permitting industry to step in (no matter how imperfectly) to inject truthful, reliable, scientific information, the regulations instead restrict participation and punish missteps.

While FDA's concern for "fair balance" in presenting risk and benefit information may intuitively seem to promote the public health, a recent analysis of literature suggested that injecting too much risk data can be as harmful as providing no risk data at all:

"[U]nintended consequences from regulatory warnings...demonstrate[] the challenge that [FDA] face[s] to design risk messages...that don't become risks themselves." Dusetzina SB, et al. *Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review*, *Med Care*, Jan. 18, 2012.

The study surveyed 20 years of literature on the impact of FDA risk communications on healthcare utilization. Most of the studies reviewed demonstrated a "spillover" effect, where non-target populations were impacted. Most notable among the examples cited was that warnings provided regarding a particular drug related to suicide risks in adolescents resulted in both a decrease in use of the drug by adults and an increase in suicide rates after the decline in prescriptions. The authors concluded that their "review indicates the varied and unpredictable impact that [warnings] can have and suggest the importance of continuing to characterize the effect of advisories and warnings on a variety of behaviors to enhance the science of risk communications regarding prescription drugs." See *id.*

Consumers expect manufacturers to not only know what is being said about their products online but also to provide useful information. Yet, consumers are unaware that manufacturers are constrained from meaningfully participating in the online dialogue. The absence of reliable product information results in the public trusting "digital strangers" to provide important healthcare information.

Many manufacturers take the "ostrich approach" or the "we weren't required to monitor" approach. While this may avoid regulatory enforcement action, it could prove to be a weak defense in the product liability context. Fundamental to all product liability cases is the question of what the manufacturer knew and when it knew it. The online "social revolution" and consumer assumptions that manufacturers are present and monitoring online communications will raise the question of where did you look and what did you do about it? Moreover, this industry stance, driven by fear of civil and criminal enforcement, may not be well-received by an already skeptical consuming public, and, most importantly, it leaves an information void where useful health-related information could be provided.

At the hearings in 2009, precious few suggestions were made by manufacturers. See *Promotion of FDA Regulated Medical Products – Using the Internet and Social Media Tools: Public Hearings before the Food and Drug Administration* (Nov. 12 and 13, 2009).

Among the suggestions made by a number of the speakers include the following:

- Hire people to monitor the Internet using Internet monitoring tools
- Manufacturers should correct third-party content
 - survey data reflected that 59 percent of the public agree
 - "companies are big enough and have enough money to make sure the Internet is accurate."
- Use "widgets" to convert public conversations to private communications
- Create an FDA logo or "seal of approval" for reliability
- Standardize the presentation of product information
- MedWatch Adverse Event reporting should be easy to use and hard to miss on the Internet
- Establish SOPs for monitoring for Adverse Events on Social Media
- Relax prior FDA approval and oversight requirement at time of dissemination. Current rules hinder the flow of information and are inconsistent with the way users are searching.
- "End the culture of fear" – reverse the "see no evil hear no evil" approach to avoiding Federal enforcement

As FDA ponders its options, the Internet has morphed into a platform for personal interaction regarding healthcare issues on a global scale. With no new guidance from FDA in sight, industry is left with rules designed for old-world media that restrict and severely punish "incorrect" participation. As it stands now, both the public and manufacturers must read tea leaves when navigating their way through online health information.

Because the electronic communication frontier cannot be contained, FDA will eventually pave the way and establish rules to allow those who know the most about their healthcare products to provide truthful, reliable information to those who have a real and immediate need for it. The scope and tools for social media are changing more quickly than FDA can act, and the resulting absence of manufacturer presence in social media may represent a lost opportunity to an entire generation of Americans for advancement in providing important health information.

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