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PRO TE: SOLUTIO

SOLUTIONS FOR YOU

FORUM NON CONVENIENS

How American Companies Stay Watchful For Foreign Lawsuits

LAW ELEVATED

DEAR CLIENT

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The pharmaceutical industry moves faster every day, as do the real-life legal issues facing it. Since becoming the first publication of its kind in January 2008, *Pro Te: Solutio* has provided scenarios, solutions, and successes to help you stay ahead of the curve.

With this issue, we've taken that commitment to another level. Our new, modernized design was created to help you focus faster on the topics most important to you. Complementing it will be a new, easier-to use, mobile-friendly butlersnow.com.

Why the changes? At Butler Snow, we think change is not only good, but long overdue in the practice of law.

For decades, the very companies that built their successes by not accepting the status quo became dependent on law firms whose practices remained virtually unchanged. Butler Snow is rising above those outdated approaches with more determination than ever. We're building teams with more industry-specific experience united around your goals. We're expanding our offices and equipping them with more ways to collaborate. And our innovative fee structures will continue to protect your bottom line, not our billable hours.

That's why Butler Snow can say that we've let go of law outdated, so you can experience Law Elevated.

In this issue, we offer insights on four timely topics: avoiding the tide of lawsuits brought by foreign nationals seeking jackpot verdicts in the U.S., federal teams dedicated to uncovering fraud in the healthcare industry, the use of FDA compliance in product defense, and progress in improving diversity in clinical trials.

We hope you'll enjoy your new *Pro Te: Solutio* as much as we've enjoyed improving it.

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FORUM NON CONVENIENS:

HOW TO AVOID

THE TIDE

OF LAWSUITS BROUGHT BY

FOREIGN NATIONALS

British jurist Lord Alfred Denning famously remarked that, "[a]s a moth is drawn to the light, so is a litigant drawn to the United States."[1] Because remedies and procedures available in U.S. courts are generally more attractive to plaintiffs than those available in other countries, foreign litigants frequently file suit in the U.S. with dreams of "striking it rich" with "jackpot verdicts." Thus, on many occasions, foreign nationals claiming to have been harmed by drugs or medical devices have chosen to bring suit against the manufacturers and/or their parent companies in the U.S., rather in their own country.

Suppose, for example, that "Alice," "Simon," "Maria," and "Patrick," are citizens and residents of foreign countries who all file suit in the U.S., claiming to have sustained injuries from a drug manufactured in the U.S. by "Acme," but that was prescribed and ingested in their own respective countries, where they all received subsequent medical treatment. Alice, a Canadian, would prefer to file suit in the U.S., because she cannot recover punitive damages under Canadian law. Simon, a United Kingdom (U.K.) resident, would prefer to file suit in the U.S. because of more favorable remedies and because he is having difficulty finding legal counsel in the U.K., where the prevailing party is entitled to attorney's fees.

Maria, a resident of Mexico, would prefer to file suit in the U.S., because there is no right to a jury trial in Mexico, the Mexican court process is slower, and the right to discovery is more limited. Finally, Patrick, a resident of New Zealand, would prefer to pursue his claims in the U.S., because he cannot even file a lawsuit for compensatory damages in his home country; instead, New Zealand has a statutory administrative no-fault compensation system, which allows compensation to the injured parties without finding fault or negligence and reduces the legal process to a matter of weeks.

American courts have frequently relied on the doctrine of *forum non conveniens* to weed out lawsuits that ought to be pursued in another country.

The U.S. court has jurisdiction over all of these lawsuits, because Acme, a U.S. company, manufactured the drug in the U.S. and made other similar decisions in the U.S. Ironically, traditional maneuvering to obtain a "home field advantage" is completely thrown out the window, as none of the parties wants the case to be tried in his/her/its own countries. Would the U.S. court, even though it has jurisdiction, grant a request by Acme to dismiss the lawsuits and require these plaintiffs to pursue remedies in their own countries? Quite probably.

Apprehensive of serving as the "courtroom to the world for adjudication of essentially foreign disputes with only nominal connections to the United States,"[2] American courts have frequently relied on the doctrine of forum non conveniens to weed out lawsuits that ought to be pursued in another country. Under this doctrine, a trial judge generally retains the discretion to dismiss a lawsuit in the event that: (a) an alternative forum is available and adequate; and (b) the alternative forum is more convenient, after considering both private and public interests. In *Gulf Oil v. Corp. v. Gilbert*,[3] the Supreme Court identified the following public interest considerations:

> Administrative difficulties follow for courts when litigation is piled up in congested centers instead of being handled at its origin. Jury duty is a burden that ought not to be imposed upon the people of a community which has no relation to the litigation. In cases which touch the affairs of many persons, there is reason for holding the trial in their view and reach rather than in remote parts of the country where they can learn of it by report only. There is a local interest in having localized controversies decided at home. There is an appropriateness, too, in having the trial of a diversity case in a forum that is at home with the state law that must govern the case, rather than having a court in some other forum untangle problems in conflict of laws, and in law foreign to itself.

Generally recognized private interests include "(1) the relative ease of access to sources of proof; (2) availability of compulsory process for attendance of unwilling and the cost of obtaining attendance of willing witnesses; (3) possibility of view of premises, if view would be appropriate to the action; and (4) all other practical problems that make trial of a case easy, expeditious and inexpensive."[4]

Piper Aircraft Co. v. Reyno

The Supreme Court's decision in *Piper Aircraft Co. v. Reyno*[5] in 1981 is the seminal case applying the *forum non conveniens* doctrine to a lawsuit brought by a foreign national. The plaintiffs in that case, representatives of estates of Scottish citizens who died in an airplane crash in Scotland, brought suit in the U.S. against the U.S. manufacturers of the aircraft and propeller. The district court concluded that the case should be dismissed for *forum non conveniens*. The Court of Appeals reversed, finding that a case should not be dismissed for *forum non conveniens* if the substantive law that would be applied in the alternative forum is less favorable. Because the plaintiffs could pursue strict liability through tort claims in the U.S., but not in Scotland, the Court of Appeals concluded that the plaintiffs were entitled to have their claims resolved in their chosen forum.

On appeal, the Supreme Court reversed and reinstated the district court's dismissal of the lawsuit. In doing so, the Court set a very low bar for considering whether a remedy is available and adequate in a foreign country. The Court found that a forum is available merely if the defendant may be served with process within that jurisdiction.[6] The Court suggested that an alternative forum is inadequate only in "rare circumstances . . . where the remedy offered by other forum is clearly unsatisfactory," such as where the alternative forum would not permit litigation of the subject matter.[7] The Court noted that, were the Court of Appeals' high standard accepted, "American courts, which are already extremely attractive to foreign plaintiffs, would become even more attractive," and "[t]he flow of litigation into the United States would increase and further congest already crowded courts."[8]

The Supreme Court found that the district court acted within its discretion in determining that it would be more convenient to litigate the case in Scotland, taking into consideration the private and public interests. The Court noted that the "the private interests point in both directions"—although important witnesses and evidence were located in Scotland, important evidence about the aircraft's design, manufacture and testing were located in the U.S.[9] The Court agreed with the district court, however, that the defendants faced challenges because certain key witnesses would not be subject to U.S. compulsory process and because the

The Court noted that, were the Court of Appeals' high standard accepted, "American courts, which are already extremely attractive to foreign plaintiffs, would become even more attractive," and "[t]he flow of litigation into the United States would increase and further congest already crowded courts.

defendants would not be able to implead potential third-party defendants in the U.S., thus increasing the risk of piecemeal litigation[10]. Turning to the public considerations, the Supreme Court recognized that "Scotland has a very strong interest in this litigation," given that the accident took place in Scotland and all of the decedents were Scottish citizens.[11] Although the plaintiffs argued that the U.S. had a strong interest in deterring its companies from manufacturing defective products, the Court concluded that "[t]he American interest in this accident is simply not sufficient to justify the enormous commitment of judicial time and resources that would inevitably be required if the case were to be tried here."[12]

Sufficiency of Alternative Forums

On numerous occasions after *Piper Aircraft*, American courts have dismissed pharmaceutical products and medical device lawsuits filed by foreign nationals. Courts have very rarely, if at all, determined that the foreign plaintiff's own country did not provide an available and adequate forum. Courts typically have found a foreign forum to be available based on the defendant's stipulation that it would accept service of process and be subject to jurisdiction in that country. Given the low bar set in *Piper Aircraft*, courts have rarely found that a foreign court did not offer an adequate remedy. As noted by one court, "American courts should be wary of branding other nations' judicial forums as deficient in the substance or procedures that their laws contain," because "[s]uch denunciations . . . run counter to principles of international comity and could retard efforts to reform foreign tribunals."[13]

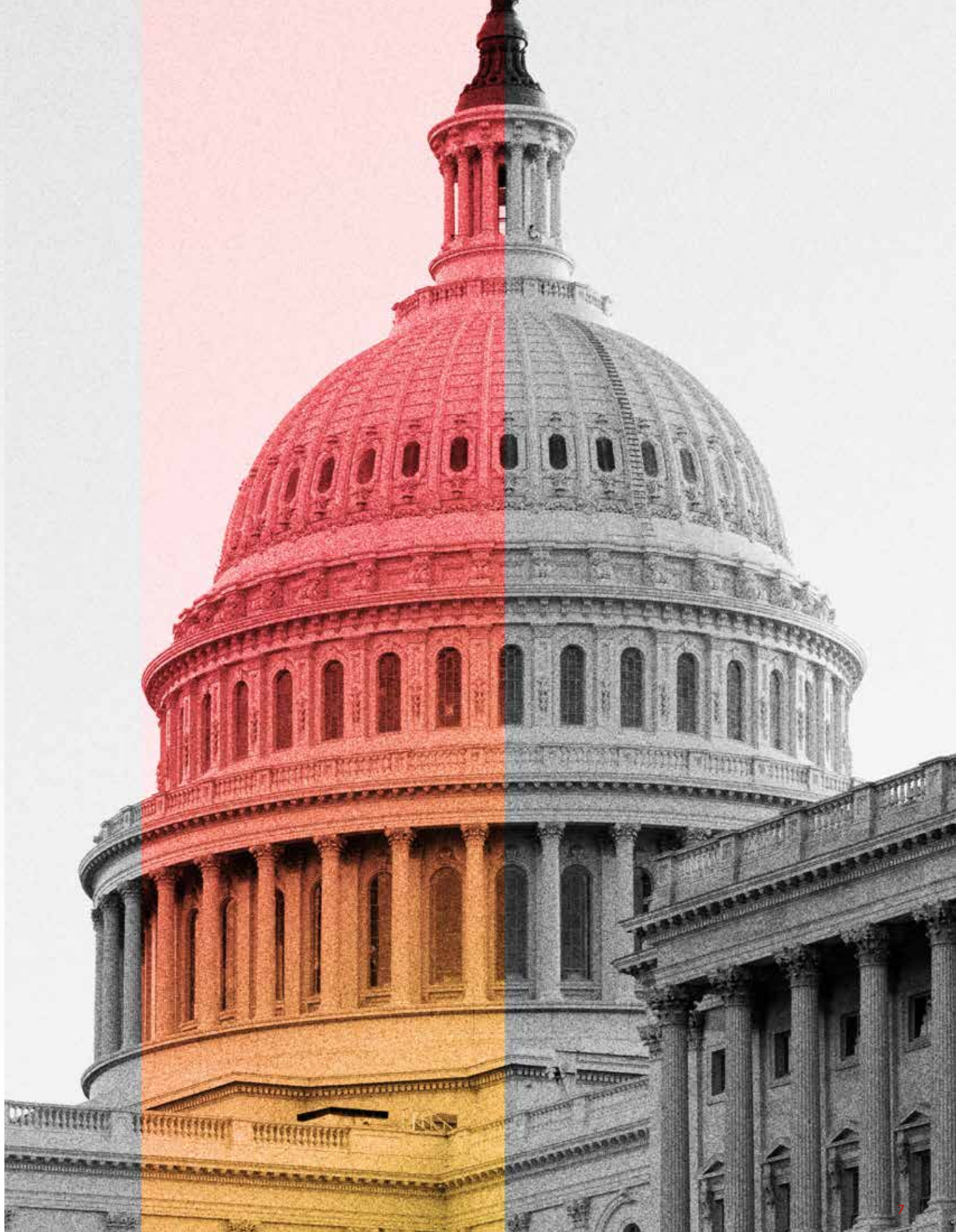
For instance, even though punitive damages are not available as a remedy in Canada and many other countries, courts have repeatedly determined that the unavailability of certain claims and remedies, "[e]ven where the award would be drastically reduced in an alternate forum," does not render the foreign forum inadequate.[14] In fact, courts have found that countries, such as New Zealand, that have enacted an administrative no-fault accident compensation scheme, afford an appropriate remedy, even though they do not permit litigation.[15]

Many courts have also refused to deem a foreign forum inadequate merely because discovery procedures are less generous than in the U.S.,[16] or because there is no right to a trial by jury in the foreign forum.[17] Courts have generally not afforded much credence to any practical challenges faced by plaintiffs in pursuing remedies in a foreign forum. For instance, in *In re Vioxx Litig.*,[18] the New Jersey court rejected the plaintiffs' argument that the U.K. offered an inadequate forum due to the "English system" of attorney's fees recovery and other financial challenges of bringing mass tort litigation in that country. Courts have even found that a forum is adequate in countries with systems "well below international standards for law or human rights."[19]

Resolution of the case in the foreign forum is often more convenient if much of the discovery must take place in that country.

Balancing Private and Public Interests

Upon recognizing that a foreign forum is both available and adequate, courts on many occasions have determined that the balancing of public and private interests weighs in favor of requiring foreign plaintiffs to pursue drug or medical device products liability claims in their own countries. In most of these cases, the consideration of private interest factors has been a relatively close call. Resolution of the case in the foreign forum is often more convenient if much of the discovery must take place in that country. This is particularly



true if important sources of evidence, such as healthcare providers and pharmacies, are located in the foreign country, and therefore, are immune from a U.S. court's subpoena. If a defendant wishes to pursue an indemnity action against a foreign third party, this would also weigh in favor of a dismissal so that litigation is not pursued piecemeal.[20]

Foreign plaintiffs often argue that it is more convenient to litigate in the U.S. because important documents and witnesses concerning the product at issue are located in the U.S. Although courts have been sympathetic to this argument, many courts have noted that this is less of a concern because the evidence is generally within the defendant's control. Therefore, it would be expected that this evidence could be readily obtained by the plaintiff in a foreign court proceeding. Moreover, "[i]n ongoing multidistrict litigation actions in which a U.S. pharmaceutical company has already produced voluminous amounts of documentary evidence, courts may accord the company's location less weight in the private interest analysis."[21]

In drug and medical device product liability actions, public interest considerations typically tip the scales in favor of dismissal on *forum non conveniens.* This is based largely on the fact that such products are usually marketed and sold subject to unique and comprehensive statutory and regulatory schemes in other countries. As noted by the Sixth Circuit, "[w]hen a regulated industry, such as pharmaceuticals . . . is involved, the country where the injury occurs has a particularly strong interest in product liability litigation."[22] A federal district court in Louisiana recently stressed the importance of deferring to a foreign sovereign government in such instances:

> As one court noted, "[t]he forum whose market consumes" a regulated product has a "distinctive interest in explicating the controlling standards of behavior" related to that product. *Doe v. Hyland Therapeutics Div., 807* F. Supp. 1117, 1129 (S.D.N.Y. 1992). Indeed, trying the plaintiffs' claims in the United States would risk disrupting the judgments of foreign regulatory bodies by imposing an American jury's view of the appropriate standards of safety and labeling on companies marketing and selling drugs in the plaintiffs' respective home forums. *See Vasquez*, 325 F.3d at 674 ("If accepted, plaintiffs' argument would curtail the rights of foreign governments to regulate their internal economics and threaten to engulf American courts with foreign claims.")[23]

In drug and medical device products liability actions, public interest considerations typically tip the scales in favor of dismissal on *forum non conveniens*.

A Pennsylvania federal court similarly found as follows:

> Questions as to the safety of drugs marketed in a foreign country are properly the concern of that country; the courts of the United States are ill-equipped to set a standard of product safety for drugs sold in other countries. . . . The United States should not impose its own view of the safety, warning, and duty of care required of drugs sold in the United States upon a foreign country when those same drugs are sold in that country. . . . [I]t is manifestly unfair to the defendant, as well as an inappropriate usurpation of a foreign court's proper authority to decide a matter of local interest, for a court in this country to set a higher standard of care than is required by the government of the country in which the product is sold and used.[24]

Otherwise, there is a danger that a U.S. court would impose on the defendant a higher standard of care than is required in the country where the product was sold.[25] Moreover, U.S. courts are reluctant to apply unique and unfamiliar foreign law and to burden U.S. courts and juries.[26]

A decision by a New York federal district court in *In re: Fosamax Products Liab. Litig.*,[27] offers an insightful example of how courts have typically balanced public and private considerations in drug and medical device products liability actions. The British plaintiff in that case sought to pursue a products liability claim in a U.S. MDL against several pharmaceutical companies. The plaintiff's claims involved drugs that were prescribed, marketed, sold, and ingested in the U.K., where she also received medical treatment. The court found that the plaintiff's choice of forum deserved "little deference" given that she has "no apparent connection to the United States" other than her legal counsel.[28] After finding that the U.K. was an adequate alternative forum, the court turned to the private and public considerations.

The court found that private factors weighed in favor of the case being litigated in the U.K.[29] The court noted that the "overwhelming majority of evidence regarding injury, causation, and damages is located there," and that the plaintiff's physicians were not subject to U.S. compulsory process.[30] Although many of the defendants' materials were located in the U.S., the court noted that these materials would already be available to the foreign plaintiff through the U.S. MDL discovery process.[31]

The court also found that public interest factors warranted dismissal. The court noted that "[p]harmaceutical products liability cases involving an allegedly unsafe drug that was sold in a foreign country subject to its regulatory scheme, and then later ingested by plaintiff in that foreign country, are especially susceptible to *forum non conveniens* dismissal due to the foreign country's strong interest in the matter."[32] The court stated that "the foreign nation has an interest in protecting its citizens from alleged injuries caused by events occurring within its borders," as well as "the foremost interest in defining the standard of conduct which pharmaceutical companies must follow in distributing products under its regulatory scheme."[33] Quoting *Doe v. Hyland Therapeutics Div.*,[34] the court stated:

> The forum whose market consumes the product must make its own determination as to the levels of safety and care required. That forum has a distinctive interest in explicating the controlling standards of behavior, and in enforcing its regulatory scheme. The standards of conduct implemented, and the level of damages

assessed, will reflect the unique balance struck between the benefit each market derives from the product's use and the risks associated with that use; between the community's particular need for the product and its desire to protect its citizens from what it deems unreasonable risk. The forum's assessment will affect not merely the quality of the product, but also the price, quantity, and availability to its public. Such an assessment must remain the prerogative of the forum in which the product is used.[35]

Although the court acknowledged that the U.S. had an interest in the defendants' conduct given that they were U.S. companies, the court found that "[t]he presence of other similar actions further reduces the United States' interest in this particular matter as they 'ensure [] that appropriate standards of care are applied,' and if the defendants are found liable, then they and others will be deterred from engaging in similarly inappropriate conduct in the future."[36]

In scores of other products liability cases involving pharmaceutical products or medical devices, courts across the country have dismissed claims brought by foreign nationals, finding that public interest and private considerations demonstrated that an alternative foreign forum was more suitable and convenient.[37] These cases offer defendants valuable precedent in procuring the dismissal of such claims. Most courts have agreed to dismiss such claims based on certain conditions, such as: (a) the defendant accepting service of process in the subsequent foreign suit; (b) the defendant not contesting that it is subject to jurisdiction in the foreign forum; and (c) tolling the applicable foreign statute of limitation during the time in which the matter was pending in the U.S.[38]

1 Smith Kline & French Lab. Ltd. v. Bloch, 1 W.L.R. 730 (1983).
2 Corporocion Tim, S.A. v. Schumacher, 418 F. Supp. 2d 529, 533 (S.D.N.Y. 2006).
3 330 U.S. 501, 508-09 (1947).
4 American Dredging Co. v. Miller, 510 U.S. 443, 448 (1994).
5 454 U.S. 235 (1981).
6 Id. at 255 n. 22.
7 Id.
8 Id. at 252.
9 Id. at 257.
10 Id. at 258-59.
11 Id. at 260.
12 Id. at 261.
13 Corporocion Tim, 418 F. Supp.2d at 533; see also Jhirad v. Ferrandina, 536 F.2d 478, 484-85 (2d Cir. 1976) ("It is not the business of our courts to assume the responsibility for supervising the integrity of the judicial system of another sovereign nation").
14 In re Vioxx Litig., 928 A.2d 935, 942 (N.J. Super. Ct. 2007); see also Ledingham v. Parke-Davis Div. of Warner-Lambert Co., 628 F. Supp. 1447 (E.D.N.Y. 1986); Ray v. Johnson & Johnson, 2011 U.S. Dist. LEXIS 143336, at *4 (N.D. Ohio Dec. 13, 2011); In re: Vioxx Products Liab. Litig., 2009 U.S. Dist. LEXIS 55973, at *20 (E.D. La. Feb. 11, 2009); In re: Rezulin Products Liab. Litig., 214 F. Supp.2d 396, 398 (S.D.N.Y. 2002).
15 See, e.g., Lueck v. Sundstrand Corp., 236 F.3d 1137, 1144-45 (9th Cir. 2000); Tang v. Synutra Int'l, Inc., 656 F.3d 242, 250-51 (4th Cir. 2011); In re: Silicone Gel Breast Implant Products Liability Litig., 887 F. Supp. 1469 (N.D. Ala. 1995); Stonnell v. Int'l Harvester Co., 132 Ill. App.3d 1043, 478 N.E.2d 518, 520 (1985).
16 See, e.g., Mercier v. Sheraton Int'l, Inc., 981 F.2d 1345, 1352-53 (1st Cir. 1992); In re Union Carbide Corp. Gas Plant Disaster at Bhopal, 809 F.2d 195, 205 (2d Cir. 1987); In re Vioxx Litig., 928 A.2d at 941.
17 Id.; Lockman Foundation v. Evangelical Alliance Museum, 930 F.2d 764, 768 (9th Cir. 1991); Union Carbide, 809 F.2d at 199.
18 928 A.2d 935, 943 (N.J. Super. Ct. 2007).
19 Douglas W. Dunham & Eric F. Gladbach, Forum Non Conveniens and Foreign Plaintiffs in the 1990s, 24 Brooklyn J. Int'l Law 665, 677 (1999).
20 See Piper Aircraft, 454 U.S. at 259; Doe v. Hyland Therapeutics Div., 807 F. Supp. 1117, 1126 (S.D.N.Y. 1992); Miller v. Boston Scientific Corp., 380 F. Supp.2d 443 (D.N.J. 2005); Ledingham, 628 F. Supp. at 1451.
21 Drug Product Liability, ch. 21 § 21.05[4][c] (2013).
22 Dowling v. Richardson-Merrell, Inc., 727 F.2d 608, 616 (6th Cir. 1984).
23 In re: Vioxx, 2009 U.S. Dist. LEXIS 55973, at *26-27.
24 Harrison v. Wyeth Lab. Div. of Am. Home Prod. Corp., 510 F. Supp. 1, 7-10 (E.D. Pa. 1980). See also Hyland, 807 F. Supp. at 1129-30 ("We are ill-equipped to enunciate the optimal standards of safety or care for products sold in distant markets, and thus choose to refrain from imposing our determination of what constitutes appropriate behavior to circumstances with which we are not familiar," and "[w]hile imposing our presumably more stringent standards to deter tortious conduct within our borders could afford a higher degree of protection to the world community, such an approach would also ignore the unique significance of the foreign forum's interest in implementing its own risk-benefit analysis, informed by its knowledge of its community's competing needs, values, and concerns.").
25 See Ledingham, 628 F. Supp. at 1452 ("[I]t would be manifestly unfair to the defendants, who claim to have complied with Canadian regulations, if this Court were to set a higher standard of care than is required by the Canadian government").
26 See Jones v. Searle Lab., 444 N.E.2d 157, 161 (Ill. 1982) ("The need to apply foreign law has frequently been deemed an important factor favoring dismissal of the suit") (citations omitted); Ray, 2011 U.S. Dist. LEXIS 143336 at *8 (finding that "the application of foreign law, namely the law of Canada, is a factor in favor, although not dispositive, of dismissal"); In re: Vioxx, 2009 U.S. Dist. LEXIS, at *30 n. 4 (finding that "the likelihood of having to apply foreign laws to a plaintiff's claims is a factor that weighs heavily in favor of dismissal"); Ledingham, 628 F. Supp. at 1452 ("This Court's unfamiliarity with Canadian law supports dismissal of the action on the basis of forum non conveniens").
27 2008 U.S. Dist. LEXIS 110831 (S.D.N.Y. Oct. 21, 2009).
28 Id. at *8.
29 Id. at *18-22.
30 Id. at *18, 21.
31 Id. at *20.
32 Id. at *12-13.
33 Id. at *13.
34 807 F. Supp. 1117, 1129 (S.D.N.Y. 1992).
35 Fosamax, 2008 U.S. Dist. LEXIS 110831, at *13-14.
36 Id. at *16 (quoting In re Rezulin, 214 F. Supp. 2d at 399).
37 See, e.g, Adams v. Merck & Co., 353 Fed. Appx. 960 (5th Cir. Nov. 30, 2009) (U.K. plaintiffs); de Melo v. Lederle Lab., 801 F.2d 1058 (8th Cir. 1986) (Brazilian plaintiff); Dowling v. Richardson-Merrell, Inc., 727 F.2d 608 (6th Cir. 1984) (U.K. plaintiffs); Ray, supra (Canadian plaintiff); In re: Vioxx Products Liab. Litig., 2009 U.S. Dist. LEXIS 55973 (E.D. La. Feb. 11, 2009) (plaintiffs from numerous foreign countries); In re: Vioxx Prod. Liab. Litig., 448 F. Supp. 2d 741 (E.D. La. 2006) (Italian and French plaintiffs); Miller, supra (Israeli plaintiffs); Silicone Gel Breast Implant, supra (Canadian, Australian, New Zealand, and U.K. plaintiffs); Hyland, supra (Irish plaintiffs); Ledingham, supra (Canadian plaintiff); Harrison, supra (U.K. plaintiffs); Stangvik v. Shiley Inc., 819 P.2d 14 (Cal. 1991) (Swedish and Norwegian plaintiffs); Jones, supra (U.K. plaintiffs); McCracken v. Eli Lilly & Co., 494 N.E.2d 1289 (Ind. Ct. App. 1986) (U.K. plaintiffs); In re Vioxx Litig., 928 A.2d 935 (N.J. App. Div. 2007) (U.K. plaintiffs); In re: N.Y. Bextra & Celebrex Prod. Liab. Litig., 2009 N.Y. Misc. LEXIS 3863 (N.Y. S.Ct. Feb. 11, 2009) (European plaintiffs).
38 See, e.g. Doe, 807 F. Supp. at 1133; Harrison v. Wyeth Lab. Div. of Am. Home Prod. Corp., 510 F. Supp. 1, 9 (E.D. Pa. 1980); Silicone Gel Breast Implant, 887 F. Supp. at 1478-79.

By David L. Johnson

PRO TE SOLUTIO

PRODUCT DEFENSE AND FDA COMPLIANCE

In the world of pharmaceutical litigation, the jury typically considers FDA approval on issues such as the manufacturer's compliance with its duty of care, product defectiveness, and state of the art.[i] *The Restatement (Third) of Torts, Products Liability – adopted in many jurisdictions – states that "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective." By this standard, it is a significant, but not determining, factor. The state of Arkansas makes the distinction that compliance is "evidence" of non-defectiveness.*

However, in some states, FDA approval is the determining factor in a product liability case. In this article we'll study the extent to which FDA approval, clearance, or compliance with government regulations affects the availability of compensatory and punitive damages. Though each statute is unique in its specific language, they generally fall into four groups: (1) statutes containing a presumption against liability based on FDA approval; (2) statutes containing a presumption against liability based on compliance with governmental regulations; (3) statutes containing a bar to punitive damages based on FDA approval; and (4) statutes containing a bar to punitive damages based on compliance with governmental regulations.[ii]

PRESUMPTION AGAINST LIABILITY DUE TO FDA APPROVAL

Michigan: "In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States Food and Drug Administration, and the drug and its labeling were in compliance with the United States Food and Drug Administration's approval at the time the drug left the control of the manufacturer or seller."
MCL § 600.2946(5)

New Jersey: "If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the Federal Food and Drug Administration under the [FDCA] or [Public Health Service Act] a rebuttable presumption shall arise that the warning or instruction is adequate."
N.J.S.A. § 2A:58C-4.

PRESUMPTION AGAINST LIABILITY DUE TO COMPLIANCE WITH GOVERNMENT REGULATIONS

Federal: Applies to vaccine warnings only, providing that "a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the [FDCA and the Vaccine Act] applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought." 42 U.S.C. § 300aa-22(b)(2)

Colorado: "In any product liability action, it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product:
. . .
(b) Complied with, at the time of sale by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States or by this state, or by any agency of the United States or of this state."
C.R.S.A. § 13-21-403(1).

Florida: The statute creates a rebuttable presumption that a product is not defective or unreasonably dangerous "if, at the time the specific unit of the product was sold . . .the aspect of the product that allegedly caused the harm:

a) complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury;
b) the codes, . . . are designed to prevent the type of harm that allegedly occurred; and
c) compliance with the codes, . . . is required as a condition for selling or distributing the product.
Fla. St. Ann. § 768.1256.

Texas: "[T]here is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
(1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the [FDCA] or [Public Health Service Act]; or
(2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application."
Tex. Civ. P. & Rem. § 82.007(a).

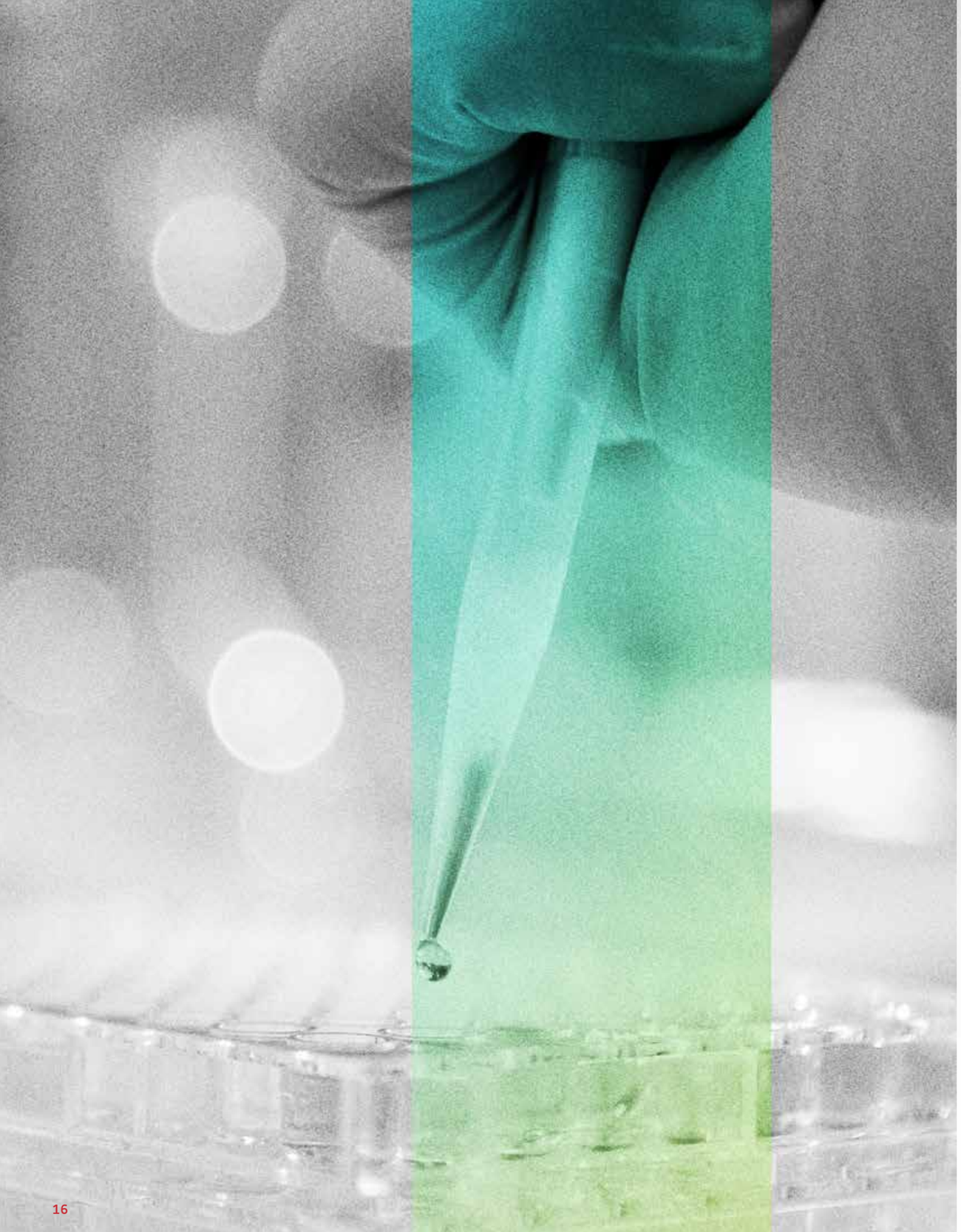
...in some states, FDA approval is the determining factor in a products liability case.

Indiana: "[T]here is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product:
. . .
(2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana."
IC § 34-20-5-1.

Kansas: "When the injury-causing aspect of the product was, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed not defective by reason of design or performance, or, if the standard addressed warnings or instructions, the product shall be deemed not defective by reason of warnings or instructions, unless the claimant proves by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions."
Kan. Stat. Ann. § 60-3304.

North Dakota: "There is a rebuttable presumption that a product is free from any defect or defective condition if the plans, designs, warnings, or instructions for the product or the methods and techniques of manufacturing, inspecting, and testing the product were in conformity with government standards established for that industry or if no government standards exist then with applicable industry standards, which were in existence at the time the plans, designs, warnings, or instructions for the product or the methods and techniques of manufacturing, inspecting, and testing the product were adopted."
N.D. Cent. Code, § 28-01.3-09

Tennessee: "Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards."
Tenn. Code Ann. § 29-28-104(a)



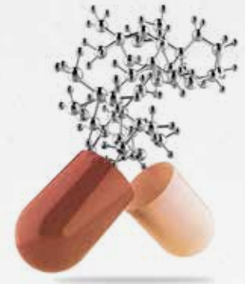
Texas: "There is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm . . . [or] if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency."
Tex. Civ. P. & Rem. § 82.008.

Utah: "There is a rebuttable presumption that a product is free from any defect or defective condition where the alleged defect in the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were in conformity with government standards established for that industry which were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were adopted."
Utah Code Ann. § 78B-6-703(2).

Wisconsin: "Evidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective."
Wis. Stat. § 895-.047(3)(b)

PUNITIVE DAMAGES BAR DUE TO FDA APPROVAL

Arizona: Drug-specific:
"The manufacturer or seller of a drug is not liable for exemplary or punitive damages if the drug alleged to cause the harm either:
1. Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the Federal Food and Drug Administration under the Food, Drug and Cosmetic Act (21 United States Code section 301, et seq.) or the Public Health Service Act (42 United States Code section 201, et seq.) or



2. Is generally recognized as safe and effective pursuant to conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations."
Ariz. Rev. Stat. § 12-701.

Generally:
"A manufacturer, service provider or seller is not liable for exemplary or punitive damages if any of the following applies:
1. The product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold or represented in relevant and material respects according to the terms of an approval, conditional approval, clearance, license or similar determination of a government agency.
2. The product, activity or service complied with all statutes of this state or the United States or standards, rules, regulations, orders or other actions of a government agency pursuant to statutory authority that are relevant and material to the event

or risk allegedly causing the harm and the product, activity or service complied at the time the product left the control of the manufacturer or seller."
Ariz. Rev. Stat. § 12-689.

New Jersey: "Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the Federal Food and Drug Administration under the [FDCA] or [Public Health Service Act] and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations."
N.J.S.A. § 2A:58C-5

Ohio: "[I]f a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug or device that allegedly caused the harm satisfies either of the following:
(a) It was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the Federal Food and Drug Administration under the [FDCA] or [Public Health Service Act].
(b) It was an over-the-counter drug marketed pursuant to federal regulations, was generally recognized as safe and effective and as not being misbranded pursuant to the applicable federal regulations, and satisfied in relevant and material respects each of the conditions contained in the applicable regulations and each of the conditions contained in an applicable monograph."
Ohio Rev. Code Ann. § 2307.80(c)(1).

Oregon: "[T]he manufacturer of the drug shall not be liable for punitive damages if the drug product alleged to have caused the harm:
(a) Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the Federal Food and Drug Administration under the [FDCA] or the Public Health Service Act; or
(b) Is generally recognized as safe and effective pursuant to conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations."
Or. R.S. § 30.927(a).

Utah: "Punitive damages may not be awarded if a drug causing the claimant's harm:
(a) received premarket approval or licensure by the Federal Food and Drug Administration under the [FDCA] or [Public Health Service Act];
(b) is generally recognized as safe and effective under conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations."
Utah Code Ann. § 78B-8-203

PUNITIVE DAMAGES BAR DUE TO COMPLIANCE WITH GOVERNMENT REGULATION

North Dakota: "Exemplary damages may not be awarded against a manufacturer or seller if the product's manufacture, design, formulation, inspection, testing, packaging, labeling, and warning complied with:
a. Federal statutes existing at the time the product was produced;

b. Administrative regulations existing at the time the product was produced that were adopted by an agency of the federal government which had responsibility to regulate the safety of the product or to establish safety standards for the product pursuant to a federal statute; or
c. Premarket approval or certification by an agency of the federal government."
N.D. Cent. Code, § 32-03.2-11(6)

Tennessee: "A manufacturer or seller, other than a manufacturer of a drug or device, shall not be liable for exemplary or punitive damages if:
(1) The product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented in relevant and material respects in accordance with the terms of approval, license or similar determination of a government agency; or
(2) The product was in compliance with a statute of the state or the United States, or a standard, rule, regulation, order, or other action of a government agency pursuant to statutory authority, when such statute or agency action is relevant to the event or risk allegedly causing the harm and the product was in compliance at the time the product left the control of the manufacturer or seller."
Tenn. Code Ann. § 29-28-104(b)

[i]As in, adhering to current industry standards.
[ii]This article does not address the various statutory exceptions to these compliance defenses. Some of these statutes contain exceptions if, for example, fraud has been committed by the FDA. In turn, some of those exceptions have been found preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). For instance, in *Lofton v. McNeil Consumer & Specialty Pharms.*, the Fifth Circuit held that a fraud on the FDA exception in the Texas statute was preempted by federal law. 672 F.3d 372, 381 (5th Cir. 2012); *see also Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) (same under Michigan statute); *McDarby v. Merck*, 401 N.J. Super. 10 (N.J. App. Div. 2008) (same under New Jersey statute).

By Susanna M. Moldovean

HEALTH CARE STRIKE FORCE:

UNCOVERING FRAUD IN THE **HEALTHCARE INDUSTRY**

Names such as "Strike Force" and "HEAT" conjure up images of Special Forces or SWAT teams, but they are actually the names of dedicated teams of federal and state agents – dedicated to finding fraud in the health care industry. The federal government's fraud prevention tools include a joint Department of Justice (DOJ) and Department of Health and Human Services (HHS) Medicare Fraud Strike Force which is a multi-agency team of federal, state, and local investigators designed to fight Medicare fraud.[1] The Federal Bureau of Investigation is the primary investigative agency when it comes to health care fraud and has jurisdiction over both the federal and private insurance programs. The FBI has partnered with agencies such as the HHS Office of Inspector General (OIG) and state and local agencies before, but their efforts were more specific to the needs of a particular investigation. According to HHS, the Strike Force uses Medicare data analysis techniques and an increased focus on community policing to combat fraud.[2]

Background

The Medicare Fraud Strike Force was originally established in 2007 in Miami – an area referred to as ground zero for health care fraud. The Miami model was so successful that the strike force expanded to more cities which include:[3]

- Baton Rouge, LA
- Brooklyn, NY
- Chicago, IL
- Dallas, TX
- Detroit, MI
- Houston, TX
- Los Angeles, CA
- Tampa Bay, FL

Data analysis has been the driver of these investigations. The first task force was formed in Miami after computers detected an abnormally large number of claims for medical equipment, such as scooters.[4] The Miami strike force targeted "home health care services" after the computer analysis showed one of every 15 Medicare dollars for home care nationwide was being spent in the Miami area.[5] According to a DOJ spokeswoman, the federal government is prioritizing cities with higher numbers of billing anomalies, showing a potential for illegal activity.[6]

Just a couple of months after the establishment of this first strike force, DOJ announced 38 people had been arrested.[7] In this first wave, teams identified two primary schemes to defraud Medicare – infusion therapy[8] and durable medical equipment suppliers. Arrests and indictments were accompanied by seizures of assets. With the announcement of these arrests and the formation of the first strike force, DOJ stated the force is able to identify potential fraud cases for investigation and prosecution quickly through real-time analysis of billing data from Medicare Program Safeguard Contractors and claims data extracted from the Health Care Information System.[9]

In this first wave, teams identified two primary schemes to defraud Medicare – infusion therapy[8] and durable medical equipment suppliers.

Medicare Program Safeguard Contractors have responsibility for detecting and deterring fraud and abuse in Medicare. The Centers for Medicare & Medicaid Services (CMS) completed transfer of these responsibilities in 2006.[10] Program Safeguard Contractors are tasked with identifying potentially fraudulent providers and conducting investigations to determine the facts and magnitude of alleged fraud and abuse.[11] According to the government, one of the reasons for delegating this responsibility to the private sector is to harness innovative and proactive data analysis. Program Safeguard Contractors are expected to cooperate with HHS-OIG and other law enforcement agencies. The incentive to proactively find anomalies in billings is great considering a Program Safeguard Contractor will receive more work from the government if it initiates successful investigations.

Along with the formation of strike forces, the government is continuously improving upon its tools to analyze data more efficiently and rapidly. In November 2007, for example, the FBI, IRS, and DOJ began to use a subpoena attachment that allowed for the production of financial information sought in electronic format to allow for quicker and easier analysis.[12] Using more technology, the strike force can identify Medicare irregularities faster – completing in days what used to take months.

With the formation of the first strike force, DOJ reported that the strike force teams are led by a federal prosecutor supervised by both the Criminal Division's Fraud Section in Washington and the local office of the United States Attorney.[13] Each team has four to six agents, at least one

agent from the FBI and HHS Office of Inspector General, as well as representatives of local law enforcement.[14]

In addition to the formation of strike forces, in May 2009, HHS and DOJ created the Health Care Fraud Prevention and Enforcement Action Team (HEAT).[15] HEAT's mission according to the HHS website includes cracking down on people who abuse the system and highlighting best practices to be used by providers and organizations. According to HHS, HEAT actions have led to a 75% increase in individuals charged with criminal health care fraud.

Results

The strike force has produced results with the targets and prosecutions all having similarities. In recent years, the Medicare Fraud Strike Force charged close to 100 individuals each year nationwide according to the various news releases issued by DOJ. These individuals include doctors, nurses, and health care company owners and executives who are charged for their alleged participation in Medicare fraud schemes involving hundreds of millions of dollars in false billing. The charges typically include conspiracy to defraud Medicare, criminal false claims, violations of the anti-kickback statutes, money laundering, and aggravated identity theft. The charges are based on a variety of alleged fraud schemes involving various medical treatments and services such as home health care, mental health services, psychotherapy, physical and occupational therapy, durable medical equipment, and ambulance services. Most often, the services billed were not medically necessary and/or were not provided.

In addition to arrests and prosecutions following strike force action, HHS has suspended or taken other administrative action against more providers following a data-driven analysis leading to credible allegations of fraud. Under the Affordable Care Act, HHS has the authority to suspend payments to a provider when there is a "credible allegation of fraud" until the resolution of an investigation.[16]

In October 2012, $430 million worth of false billing charges were brought, which was comprised of more than $230 million in home health care fraud; more than $100 million in mental health care fraud, and more than $49 million in ambulance transportation fraud; and millions more in other frauds.[17] According to DOJ, more than 500 law enforcement agents from the FBI, HHS-OIG, multiple Medicaid Fraud Control Units, and other state and local law enforcement agencies participated in the takedown.[18]

According to a press release issued in December 2013, the Medicare Fraud Strike Force has charged more than 1,700 defendants who have collectively billed the Medicare program for more than $5.5 billion.[19] The federal government is also using tools authorized by the Affordable Care Act to fight fraud, as noted above, including increased data sharing across the government and expanded recovery efforts for overpayments and greater oversight of private insurance abuses.[20]

The largest case brought against a single physician to date is the case against Dr. Jacques Roy in Texas.[21] He, along with his office manager and five owners of home health agencies, is accused of bilking Medicare and Medicaid of nearly $375 million from 2006 through November 2011.[22] In addition to the indictments, CMS suspended an additional 78 home health agencies associated with Roy based on credible allegations of fraud against them.[23] The alleged fraud was discovered by data analysis – specifically, the fact that the association owned by Dr. Roy certified more Medicare beneficiaries for home health services and had more purported patients than any other medical practice in the United States during the above time period. "Using sophisticated data analysis we can now target suspicious billing spikes," said HHS Inspector General Daniel R. Levinson. "In this case, our analysts discovered that in 2010, while 99 percent of physicians who certified patients for home health signed off on 104 or fewer people – Dr. Roy certified more than 5,000."[24] Trial is currently set for June 23, 2014.[25]

According to the FBI's report on Financial Crimes for 2010-2011, Medicare and Medicaid are the most visible health care programs subject to fraud.[26] The fact that people are now living longer will produce a greater demand for Medicare benefits. As a result, utilization of long and short term care facilities such as skilled nursing, assisted living, and hospice services will expand in the future.[27] Recently, the owner of a Miami health care company was sentenced to 235 months in prison for her participation in a $7 million health care fraud scheme following investigation by the FBI and HHS-OIG as part of the Medicare Fraud Strike Force.[28] Dora Moreira was convicted by a jury of one count of conspiracy to commit health care fraud, one count of conspiracy to defraud the

Using more technology, the strike force can identify Medicare irregularities faster – completing in days what used to take months.

HEAT actions have led to a 75% increase in individuals charged with criminal health care fraud.

United States and receive and pay health care kickbacks, one count of payment of kickbacks in connection with a federal health care program, one count of conspiracy to commit money laundering, and five counts of money laundering.[29]

According to the government, Moreira billed Medicare for services not medically necessary and/or not provided.[30] She paid kickbacks and bribes to patients, interacted with patient recruiters, and oversaw the submission of fraudulent claims.[31]

The FBI continues to identify and analyze industry fraud trends through input from private and public health care program experts. Present areas of concern include DME, hospital fraud, physician fraud, home health agencies, beneficiary-sharing, chiropractic, pain management, associated drug diversion, physical therapists, prescription drugs, multidisciplinary fraud, and identity theft which involves physician identifiers used to fraudulently bill government and private insurance programs.[32]

Emphasis is placed on recovering the illegal proceeds of these schemes through seizure and forfeiture proceedings as well as substantial civil settlements.[35] Upon successful conviction, the FBI provides information to various regulatory and state agencies to assist them in seeking to exclude convicted medical providers from further participation in the Medicare and Medicaid health care systems.[36]

As part of their national strategy, and not just the work of the strike force, the FBI cooperates with DOJ and various United States Attorneys' Offices throughout the country to pursue offenders through parallel criminal and civil remedies.[33] According to the FBI, these cases typically target large-scale medical providers, such as hospitals and corporations, which engage in criminal activity and commit fraud against the government.[34] Emphasis is placed on recovering the illegal proceeds of these schemes through seizure and forfeiture proceedings as well as substantial civil settlements.[35] Upon successful conviction, the FBI provides information to various regulatory and state agencies to assist them in seeking to exclude convicted medical providers from further participation in the Medicare and Medicaid health care systems.[36]

The FBI states that it has more than 500 agents and analysts using intelligence and data to uncover health care fraud schemes and collecting evidence through undercover operations

and wiretaps.[37] Following more strike force arrests, HHS-OIG Deputy Inspector General Cantrell stated: "the Office of Inspector General is committed to the strike force model and will continue to use advanced data analytics along with traditional investigative methods to root out those who steal from our Medicare program."[38]

1 *See e.g.*www.stopmedicarefraud.gov, sponsored by the U.S Department of Health & Human Services and the U.S. Department of Justice.
2 *Id.*
3 *Id.*
4 Horswell, Cindy, "Feds Strike at Medicare Fraud in Houston Area," *Houston Chronicle*, July 11, 2009. *Available at* http://www.chron.com/news/houston-texas/article/Feds-strike-at-Medicare-fraud-in-Houston-area-1728261.php. *Last accessed* February 7, 2014.
5 *Id.*
6 *Id.*
7 U.S. Department of Justice, "Strike Force Formed to Target Fraudulent Billing of Medicare Program by Health Care Companies", May 9, 2007, *Available at* http://www.justice.gov/opa/pr/2007/May/07_ag_339.html. *Last accessed* February 7, 2014.
8 Typically, "infusion therapy" means that a drug is administered intravenously, but the term may also refer to situations where drugs are provided through other non-oral routes.
9 U.S. Department of Justice, "Strike Force Formed to Target Fraudulent Billing of Medicare Program by Health Care Companies", May 9, 2007, *Available at* http://www.justice.gov/opa/pr/2007/May/07_ag_339.html. *Last accessed* February 7, 2014.
10 Department of HHS, Office of Inspector General. (July 2007). Medicare's Program Safeguard Contractors: Activities to Detect and Deter Fraud and Abuse.
11 *Id.*
12 DOJ, FBI Financial Crimes Section, Criminal Investigative Division. Financial Crimes Report to the Public, Fiscal Years 2010-2011.
13 U.S. Department of Justice, "Strike Force Formed to Target Fraudulent Billing of Medicare Program by Health Care Companies", May 9, 2007, *Available at* http://www.justice.gov/opa/pr/2007/May/07_ag_339.html. *Last accessed* February 7, 2014.
14 *Id.*
15 *See* U.S. Department of Health and Human Services, "HEAT Task Force", *Available at* http://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/. *Last accessed* February 7, 2014.
16 Patient Protection and Affordable Care Act, Section 6402(h).
17 U.S. Department of Justice, "Medicare Fraud Strike Force Charges 91 Individuals for Approximately $430 Million in False Billing", October 4, 2012, *Available at* http://www.justice.gov/opa/pr/2012/October/12-ag-1205.html. *Last accessed* February 7, 2014.
18 *Id.*
19 U.S. Department of Justice, "Health Care Clinic Owner Sentenced for Role in $7 Million Medicare Fraud Scheme", December 19, 2013, *Available at* http://www.justice.gov/opa/pr/2013/December/13-crm-1337.html. *Last accessed* February 7, 2014.
20 U.S. Department of Justice, "Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud", February 11, 2013, *Available at* http://www.justice.gov/opa/pr/2013/February/13-ag-180.html. *Last accessed* February 7, 2014.
21 *See United States v. Roy, et al.*, No. 3:12-cr-54 (ND TX).
22 U.S. Department of Justice, "Dallas Doctor Arrested For Alleged Role in Nearly $375 Million Health Care Fraud Scheme", February 28, 2012, *Available at* http://www.justice.gov/opa/pr/2012/February/12-crm-260.html. *Last accessed* February 7, 2014.
23 *Id.*
24 *Id.*
25 *See United States v. Roy, et al.*, No. 3:12-cr-54 (ND TX).
26 DOJ, FBI Financial Crimes Section, Criminal Investigative Division. Financial Crimes Report to the Public, Fiscal Years 2010-2011.
27 *Id.*
28 *See United States v. Moreira et al.*, 1:13-cr-20298 (SD FL).
29 *Id.*
30 U.S. Department of Justice, "Health Care Clinic Owner Sentenced for Role in $7 Million Medicare Fraud Scheme", December 19, 2013, *Available at* http://www.justice.gov/opa/pr/2013/December/13-crm-1337.html. *Last accessed* February 7, 2014.
31 *Id.*
32 DOJ, FBI Financial Crimes Section, Criminal Investigative Division. Financial Crimes Report to the Public, Fiscal Years 2010-2011.
33 *Id.*
34 *Id.*
35 *Id.*
36 *Id.*
37 Federal Bureau of Investigation, "Historic Medicare Fraud Strike Force Takedown", May 2, 2012, *Available at* http://www.fbi.gov/news/news_blog/strike-force-takedown-050212. *Last accessed* February 7, 2014.
38 U.S. Department of Justice, "Medicare Fraud Strike Force Charges 107 Individuals for Approximately $452 Million in False Billing", May 2, 2012, *Available at* http://www.justice.gov/opa/pr/2012/May/12-ag-568.html. *Last accessed* February 7, 2014.

By Amanda B. Barbour

DIVERSITY
IN CLINICAL TRIALS:
BARRIERS PERSIST,
BUT SO DOES PROGRESS

In August 2012, Pro Te: Solutio reported on the issue of diversity in clinical trials.[1] That report focused on five key points:

(1) Because ethnic differences may be one factor in determining the risk-benefit ratio of a drug therapy in a specific patient, these differences should be considered during drug development and, more specifically during clinical trials;

(2) Failing to ensure diversity and the proper reporting of demographics in clinical trials may result in an inability to secure study funding from such sources as the National Institutes of Health (NIH) and may also result in the FDA's refusal to accept the sponsor's application for approval;

(3) The FDA has taken action, primarily through Guidances, to provide standardized methods of defining, collecting, and reporting race and ethnicity information in clinical trials in order to ensure consistency in demographic subset analyses, to compare results across studies, and to assess potential subgroup differences in safety and effectiveness;

(4) Despite a near consensus that diversity in clinical trials is important, barriers to achieving adequate representation persist, despite the best efforts of sponsors; and

(5) Although barriers persist, there are opportunities to improve diversity in clinical trials.

The August 2012 *Pro Te: Solutio* report detailed a number of recommendations to increase diversity in clinical trials, including, but not limited to:

- Design clinical trials that include healthcare needs specific to ethnically-diverse populations.
- Work with ethnically diverse physicians to recruit patients;
- Ensure clinical trials involve ethnically diverse investigators; and
- Develop and support community outreach programs.[2]

This update focuses on important developments that have begun to break down these barriers.

Barriers Persist, But So Does Progress

Since the August 2012, report there have been a number of steps taken by both private entities and the FDA to improve diversity in clinical trials. For example, in June 2013, Pharmaceutical Research and Manufacturers of America (PhRMA) announced that it would partner with the National Minority Quality Forum (NMQF)[3] and Microsoft to increase diversity in clinical trials.[4] Noting the importance of achieving this goal, the Vice President of Scientific Affairs for PhRMA noted that "[p]romoting awareness and creating connectivity that can translate into enhanced participation in clinical trials by a diverse patient population is a priority for PhRMA and our member companies[.]"[5] He further noted that "[t]his collaboration brings clinical research and healthcare closer to each other to prevent disparities in the evaluation and access to innovative medicines."[6]

Although barriers persist, there are opportunities to improve diversity in clinical trials.

The partnership immediately created a process which could seize opportunities. It included joint outreach efforts, such as those listed in the August 2012, report and agreed to create by Q4 2013 the National Clinical Trial Network (NCTN) online portal, which is "an interactive portal linking communities of patients, practicing physicians and researchers to increase participation and diversity in clinical trials[.]"[7] The goal of the NCTN portal is "to provide a permanent IT infrastructure enabling research investigators to quickly identify minority populations who share a medical need and, when appropriate facilitate their recruitment into clinical trials in a timely and cost-efficient manner."[8] This national database allows "clinical trial sponsors [to] locate patients by geographical and demographic characteristics who meet a unique study protocol while simultaneously identifying points of care and community resources that can assist with site locations, investigator and patient recruitment."[9] To say the least, a partnership comprised of such influential medical and technology organizations as PhRMA and Microsoft is a significant step taken by private entities to increase diversity in clinical trials.

There are other beacons of hope as well. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 required the FDA to study the availability of data on the participation of demographic subgroups (sex, age, race, and ethnicity) in the clinical trial data used to support applications for new drugs, biologics, and medical devices.[10] In particular, the FDASIA required the FDA to report on:

(1) The extent to which subgroups participate in clinical trials.

(2) Whether reports of subgroup safety and effectiveness

To say the least, a partnership comprised of such influential medical and technology organizations as PhRMA and Microsoft is a significant step taken by private entities to increase diversity in clinical trials.

are reported to the FDA in a manner consistent with the FDA requirements and guidance.

(3) Whether and how safety and effectiveness data by subgroup is made public.[11]

In August 2013, the FDA issued its report, and concluded that "the statutes, regulations, and polices currently in place generally give product sponsors a solid framework for providing data in their applications on the inclusion and analysis of demographic subgroups."[12] The FDA also concluded that

sponsors were, in fact, describing demographic profiles of clinical trial participants and that FDA was sharing this information with the public in various ways.[13]

Despite the FDA's conclusion that the current framework is "solid," it did note areas of improvement.[14] Perhaps the most important area needing improvement was stated as follows: "Whites represented a high percentage of clinical trial study participants for biologic, drug, and medical device applications. In many cases, other racial subgroups were underrepresented."[15] Fortunately, FDASIA also tasked the FDA with publishing and implementing an "action plan" within one year after the publication of its Report.[16] The FDA established a docket in the Federal Register to allow for submission of comments to the FDA, which will be used to help develop the action plan.

Conclusion

The combination of private partnerships and public/government efforts to increase diversity in clinical trials represents a near universal recognition that this is a worthy goal and that there are still barriers to achieving the goal. But, it also demonstrates a significant commitment to achieving the diversity needed to ensure the highest level of care for all patients. The forthcoming action plan should shed light on how the FDA believes these goals can be accomplished.

1 Spicer, Adam J., No Missing Pieces: The Importance of Diversity in Clinical Trials, Pro Te: Solutio, Vol: 5, Number: 3 (August 2012) at 3.
2 Id. at 4 – 5.
3 NMQF is a Washington, DC–based not-for-profit, non-partisan, independent research and education organization dedicated to improving the quality of health care that is available for and provided to all populations.
4 National Minority Quality Forum (2013). PhRMA Joins with National Minority Quality Forum and Microsoft to Address Diversity in Clinical Trials [Press Release]. Retrieved from http://www.nmqf.org/phrma-joins-with-national-minority-quality-forum-and-microsoft-to-address-diversity-in-clinical-trials.

The combination of private partnerships and public/government efforts to increase diversity in clinical trials represents a near universal recognition that this is a worthy goal and that there are still barriers to achieving the goal. But, it also demonstrates a significant commitment to achieving the diversity needed to ensure the highest level of care for all patients.

5 Id.
6 Id.
7 Id.
8 Id.
9 PRNewswire (2013). National Minority Quality Forum Announces Addition of PhRMA to Collaboration to Increase Diversity in Clinical Trials [Press Release]. Retrieved from http://www.prnewswire.com/news-releases/national-minority-quality-forum-announces-addition-of-phrma-to-collaboration-to-increase-diversity-in-clinical-trials-214644401.html.
10 Pub. L. 112-144, 126 Stat. 993 (2012).
11 Id. at § 907.
12 10 FDA Report: Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products, August 2013, at 2.
13 11 Id.
14 12 FDA Report at 58.
15 13 Id. at 59.
16 14 Pub. L. 112-144, 126 Stat. 993 (2012) at § 907.

By Adam J. Spicer