

By Gail Rodgers

In the post *Riegel* and *Levine* legal landscape, mass tort attorneys must focus on the marketability and transferability of their valuable skills.

Evolving and Growing Your Mass Tort Practice

What if the *Wyeth v. Levine* ruling preempts pharmaceutical mass torts as we know them? What if the pharmaceutical mass tort on which I am spending the bulk of my time settles? What if a new wave of tort reform

affects my jurisdiction? What if my clients' litigation budgets are halved due to the current economy? What if I need a new game plan?

Mass tort practice as we know it is evolving, and pharmaceutical mass torts may verge on extinction during this Supreme Court term. The Supreme Court's decision in *Riegel v. Medtronic* significantly limited state law tort claims for injuries from medical devices by holding that those claims stemming from devices that receive FDA premarket approval are preempted by the 1976 Medical Device Amendments, as long as state requirements are "different from, or in addition" to federal requirements. 128 S. Ct. 999, 1011 (2008).

Following *Medtronic* comes *Wyeth v. Levine*, currently pending before the Supreme Court. It could result in much broader federal preemption of state law tort claims in prescription drug cases. Regardless of the outcome of *Wyeth v. Levine*, mass tort practice is susceptible to a vari-

ety of forces—a new administration, Congressional response to court preemption decisions, tort reform, reconsideration of previous tort reform and the backdrop of a poor economic environment.

As the playing field changes, the plaintiffs' bar will adopt more creative allegations and causes of action. In response to external environmental forces and the plaintiffs' bar's creativity, a mass tort defense lawyer must hone his or her skills to remain marketable amidst this shifting landscape. He or she must maximize skills that will satisfy clients' changing needs. This article explores avenues to transfer skills and knowledge obtained during traditional mass tort litigation into marketable and necessary attributes in related litigation. The article focuses on two primary areas for growth: (1) litigation that has developed as an off-shoot of pharmaceutical torts, and (2) the developing field of subcellular injuries and "injuries" from toxins.



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Related Litigation

Pharmaceutical mass torts in particular lend themselves to several different types of related and overlapping litigation. Frequently, the same facts at issue in a personal injury claim are key to related legal challenges faced by that same client. Attorneys familiar with pharmaceutical mass torts can provide service to clients in the related areas of third-party payer litigation, consumer fraud litigation, and governmental investigations. Each of the three areas requires familiarity with concepts and defenses common to personal injury mass torts centering on FDA regulations, clinical trials and epidemiological studies, sales and marketing of pharmaceuticals, pharmaceutical labeling and warnings, the learned intermediary doctrine, pharmaceutical branding, and off-label use and pharmaceutical promotion, among others. The mass tort lawyer's knowledge is ideal for defending pharmaceutical clients in related and overlapping legal challenges.

Consumer Actions

Along with personal injury litigation arising from pharmaceutical use, pharmaceutical companies commonly face accompanying third-party payer lawsuits and consumer fraud actions. In these cases, plaintiffs creatively avoid preemption, arguing that a drug was fraudulently marketed as "safe" or "effective" rather than that the drug actually injured an individual. Third-party payer suits are brought by entities such as health insurance companies, pension funds, and labor unions that pay for pharmaceuticals. Plaintiffs typically mount consumer fraud or RICO claims against pharmaceutical manufacturers to recoup what they believe to be excessive costs for drugs purchased through benefits programs. Third-party payer suits also may be brought by state and federal governments related to alleged overpayment for pharmaceuticals by Medicare and Medicaid programs. Some consumer fraud claims can potentially expose pharmaceutical companies to great liability, as the allegations of fraud may constitute violations of federal statutes that carry significant financial, and even criminal, penalties.

While consumer fraud plaintiffs may have underlying claims for personal injury from use of a pharmaceutical, frequently the

claims only involve economic loss. Plaintiffs allege that they were defrauded when they purchased the drug at issue because an epidemiological study or studies allegedly indicated that the drug was not as effective as advertised or that it had risks or side effects that were not properly disclosed. Plaintiffs may seek economic damages for pharmaceutical expenditures because a pharmaceutical carried some allegedly undisclosed side effect, even if the individual consumer did not experience it. Plaintiffs also may allege that a drug was improperly marketed and promoted for an off-label indication without proof of medical benefit for that use. See Joseph J. Leghorn, Christopher Allen, Jr., and Tavares Brewington, *Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation*, 61 FOOD DRUG L.J. 519, 520 (2006).

These actions may be brought as class actions by putative classes of individual consumers, by individual health insurers or employee benefit funds, or by putative classes of third-party payers. These actions are particularly attractive to the plaintiffs' bar because many states have a consumer protection act that provide for enhanced damages—treble or compounded damages and attorneys' fees—and frequently, the burden of proof is less stringent than the burden required in a traditional common law product liability action. *Id.*

One leading example of a case illustrating the plaintiffs' bars attempts to bring third-party payer consumer fraud actions is *International Union of Operating Engineers v. Merck & Co.*, 929 A.2d 1076 (N.J. 2007). The plaintiff, a health care benefits plan, alleged that Merck engaged in a "wide-ranging fraudulent marketing scheme" in which it falsely marketed Vioxx as a safer and more effective alternative to less expensive pain medications. *Id.* at 1080. It claimed Merck's marketing sought to induce third-party payers to include Vioxx in their formularies or grant it preferred status. *Id.* at 1081–82. The plaintiff alleged that third-party payers would not have done so had the adverse information been disclosed, which also ultimately would have reduced reimbursement payments to plan members. *Id.*

The plaintiff attempted to rely on one witness' account of the marketing cam-

paign's effect on Vioxx's price, but the court said this was "the equivalent of fraud on the market, [which] we have not extended to [consumer fraud] claims." *Id.* at 1088. Fraud on the market is "essentially a creature of federal securities litigation" in which security purchasers are "permitted to demonstrate that they were damaged simply because defendant engaged in

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behavior otherwise prohibited and there was a change in price." *Id.* The trial court certified a nationwide class of similarly-situated third-party payers, but the New Jersey Supreme Court reversed, finding that common questions of law and fact did not predominate. *Id.* at 1089.

In another widely followed third-party payer action, in September 2008, Judge Weinstein of the Eastern District of New York certified a class of third-party payers who allegedly overpaid for the antipsychotic drug Zyprexa. Plaintiffs brought claims under RICO, 45 state consumer protection statutes, common law fraud, and unjust enrichment against Eli Lilly for mail fraud, all predicated on alleged overpricing. *In re Zyprexa Products Liability Litigation*, 04-MD-1596, slip op. (E.D.N.Y. Sept. 5, 2008).

The putative Zyprexa class included individual consumers, pension funds, labor unions and insurance companies, as well as several state attorneys general for reimbursement of state and federal funds. The plaintiffs claimed that Lilly promoted off-label uses, as well as misrepresented Zyprexa's safety and efficacy. *Id.* at 16. The plaintiffs also claimed that Lilly did not disclose Zyprexa's known side effects, which included weight gain and diabetes. *Id.* Although the court certified a class of third-party payers, it refused to certify a class of individuals who bought the drug.

As the court explained, finding reliable payment data for individuals would be difficult and the proposed class representatives were inadequate because they were also suing Merck for personal injury, which created a conflict of interest. Furthermore, ethical and proof issues would “unduly complicate the trial.” *Id.* at 11.

Both the Vioxx and Zyprexa litigation

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Plaintiffs have brought
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pharmaceutical companies
alleging violations of
the FDCA and FCA.

involved claims that hinged on the safety and efficacy of the pharmaceutical. Accordingly, plaintiffs’ third-party payer claims involve many of the same allegations and rely on much of the same information as the allegations and information involved in the personal injury litigation. These third-party actions turn on a company’s sales and marketing practices, which is also traditionally at issue in mass tort litigation.

In November 2008, the state of Nevada filed suit against Wyeth and Pfizer for misrepresenting the benefits and downplaying the risks of their hormone therapy medications, including Prempro and Provera. Jocelyn Allison, *Nevada Sues Wyeth, Pfizer Over Hormone Drugs*, Law360.com, (Nov. 19, 2008) available at <http://www.law360.com/>. The Nevada attorney general claimed that the companies violated state law by engaging in deceptive trade practices aimed at misleading consumers and physicians, leading doctors to overprescribe the drugs and resulting in increased instances of breast cancer in patients. *Id.* This case follows a similar suit that led to a \$57.8 million verdict for three Nevada women who claimed that hormone replacement therapy caused their breast cancer. *Id.*

Government Actions

In addition to consumer fraud litigation brought by individual consumers and

third-party payers, pharmaceutical companies may face governmental investigations and prosecutions based on consumer fraud allegations. These actions typically arise under the Food, Drug, and Cosmetic Act (FDCA) or the False Claims Act (FCA). They generally involve charges that a pharmaceutical company promoted a drug “off-label,” misbranded a drug, defrauded state or federal Medicare or Medicaid by obtaining payments for off-label use, and participated in financial schemes with doctors and pharmaceutical distributors to promote off-label use. The FDCA provides for both civil and criminal penalties, including imprisonment. *See* 21 U.S.C. §353 (2000). The FCA provides for substantial penalties, including fines of three times the amount of damages sustained by the government, and attorneys’ fees. 37 U.S.C. §3729 (2000).

The FDCA, 21 U.S.C. §301-97 (2000), requires manufacturers to demonstrate that new pharmaceuticals are safe and effective for their intended uses. The FDA does not prohibit doctors from prescribing approved drugs for “off-label” uses, although it does prohibit pharmaceutical companies from marketing or promoting drugs for off-label use. *Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001); 21 U.S.C. §§355(a), (d) (2000); 21 U.S.C. §331(d) (2000). A pharmaceutical company must resubmit an approved drug to the FDA to obtain approval for any previously unapproved use. 21 U.S.C. §360(aaa), *et seq.* (2000). FDA approval of a drug requires specific labeling for a product for its approved uses. If a pharmaceutical company promotes a drug for an unapproved use, under the FDCA, the drug is “misbranded,” because the labeling fails to contain “adequate directions for use.” 21 U.S.C. §352(f) (2000). *See Washington Legal Foundation v. Henney*, 202 F.3d 331, 332–33 (D.C. Cir. 2000); *see also*, Mark A. Ford, *Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing*, 83 B.U. L. REV. 429, 438 (2003).

Plaintiffs have brought assorted actions against pharmaceutical companies alleging violations of the FDCA and FCA. Purdue Pharma recently was accused of misbranding and violating several FDCA regulations for off-label promotion of the pain medication OxyContin. Richard C. Ausness,

“There’s Danger Here, Cherie!”: Liability For The Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses, 73 BROOK. L. REV. 1253, 1262 (2008). The company settled a civil suit, agreeing to pay \$19.5 million to 26 states and the District of Columbia. *Id.*

The civil litigation was just the beginning of Purdue Pharma’s challenges over OxyContin. The U.S. Department of Justice next brought criminal charges against the company and three top executives, charging them with involvement in a fraudulent and deceptive marketing campaign that “falsely claimed that OxyContin, because of its timed-release formula, was more resistant to abuse and less likely to cause addiction than competing products such as Percocet.” *See id.* Ultimately, the company and officers pled guilty to the criminal charges and admitted that the company made false statements. *Id.* Purdue Pharma paid \$470 million in fines and payments to federal and state agencies, in addition to \$130 million to individual tort plaintiffs. *Id.* The executives also pled guilty to misdemeanor FDCA violations involving misbranding. *Id.* The executives avoided prison time because the federal prosecutors did not produce evidence that the officers were aware of the company’s wrongdoing. *Id.* at 1264.

In addition to misbranding charges, companies may face allegations of Medicare and Medicaid fraud. Drugs are only eligible for Medicaid reimbursement for use “approved under the Federal Food Drug and Cosmetic Act,” or in other words, “on-label” uses. *Franklin*, 147 F. Supp. 2d at 44; 42 U.S.C. §§1396b(i)(10), 1396r-8(k) (3) (2000). The False Claims Act, 37 U.S.C. 3729, prohibits “false or fraudulent claim[s] for payment or approval” or knowing false records or statements to secure payments. The FCA has been implemented to police government reimbursements for off-label use. The Department of Justice has been very successful in prosecuting such claims, including obtaining a much publicized \$430 million settlement and guilty plea regarding promotion of Neurontin. Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 101–02 (2008).

Parke-Davis’ drug Neurontin was FDA-approved to treat epilepsy, but it was also

used off-label to control pain and to treat bipolar disease and attention deficit disorder. *Franklin*, 147 F. Supp. 2d at 45. In 1996, a Parke-Davis medical liaison, Dr. David Franklin, filed a qui tam “whistleblower” action against Parke-Davis under the False Claims Act for allegedly engaging “in a fraudulent scheme to promote the sale of the drug Neurontin for ‘off-label’ uses... and that this illegal marketing campaign caused the submission of false claims to the Veterans Administration and to the federal government for Medicaid reimbursement.” *Id.* at 43–44. Franklin alleged that Parke-Davis hired medical liaisons, including himself, to serve as sales and promotion personnel for off-label uses, and these liaisons were instructed to exaggerate the drug’s safety and efficacy. Franklin also accused Parke-Davis of paying doctors for prescribing large quantities of its drugs and giving the company information about the patients taking its drugs. In response to Parke-Davis’ motion to dismiss, the court held that the FCA could be used to enforce the FDCA’s restrictions of off-label promotion because it essentially provided “tools not available to the FDA, including civil money damages and private enforcement, for the enforcement of its restrictions on promotion of off-label uses.” Johnson, *supra* at 106.

After the defendant’s motion to dismiss was denied, the Department of Justice became actively involved in the case. *Id.* at 111. Ultimately, Parke-Davis settled with both the federal and state governments, paying \$152 million plus interest in reimbursement for off-label prescriptions that state and federal Medicaid programs had paid to consumers. *Id.* at 113. Parke-Davis also paid some \$38 million for state consumer protection claims and a criminal fine of \$240 million for post-approval communications with physicians that violated FDCA restrictions, and accordingly, violated the FCA. *Id.* This flurry of litigation spawned even more litigation; Parke-Davis next faced lawsuits from private insurers due to payments for off-label Neurotonin prescriptions. *Id.*

Commonalities between Pharmaceutical Mass Torts and Related Litigation

Many of the statutes, allegations and defenses discussed above will be familiar

to the personal injury mass tort lawyer. The medical, regulatory and marketing facts from the underlying products liability litigation often will be contested during consumer fraud lawsuits or governmental investigations.

For example, as an overriding concept, pharmaceutical products liability cases typically consider a drug’s efficacy, whether it causes injuries, and whether manufacturers properly warned consumers about potential injuries. Pharmaceutical consumer fraud cases turn on whether the product fulfilled consumers’ expectations, whether manufacturers promised consumers more than they delivered, and whether manufacturers warned consumers of potential risks. In practice, these issues are nearly identical. Both negative scientific findings and harmful testimony about sales or marketing practices may negatively impact an individual products liability lawsuit, but may have greater implications for concurrent or future governmental investigations.

Involvement in both areas of litigation provides lawyers the opportunity to appreciate the interplay of the related litigations and assist the client to safeguard against potential additional exposure.

Emerging Developments in Personal Injury Mass Torts

Another growth area for mass tort lawyers is arising from emerging technology and science. While some personal injuries are evident—a heart attack, cancer, prescription drug addiction—others are less evident and harder to diagnose and quantify. Some such difficult to diagnose and quantify injuries if, in fact, they can be characterized as injuries, lead to genetic damages or “body burden” claims. While many of these claims have found little success in the courts historically, the advent of new technology and increasing publicity regarding toxic or contaminated products may result in burgeoning nontraditional injury claims.

Genetic Claims: DNA or Subcellular Damage

Genetic data have implications in a wide variety of contexts in the toxic tort arena. Genetic data may prove or disprove causation of a particular injury or evaluate the value of a plaintiff’s suffering to determine

damages. Gary E. Marchant, *Genetics in the Courtroom: Genetics and Toxic Torts*, 31 SETON HALL L. REV. 949, 949 (2001). It also can provide objective and quantifiable proof of exposure to a toxin, as well as determine individual susceptibility of exposed persons. *Id.* In addition, genetic data can be implicated in less apparent damages claims; for example, alleged damages at the sub-cellular level or to the plaintiff’s DNA.

Historic Failed Claims

For almost 20 years, plaintiffs have brought largely unsuccessful claims for DNA or subcellular damage, due to an inability to link toxic exposure to definitive DNA damage and medical conditions. Courts have been reluctant to hold that DNA or subcellular damage is a compensable bodily injury. Recent advances in genetic research have enabled scientists to link specific chemical and radiation exposures to specific DNA mutations and, in some instances, to link these specific mutations to diseases. As a result, plaintiffs may soon have reliable evidence to support claims and preclude summary dismissals.

The Sixth Circuit examined subcellular damage allegations in *Rainer v. Union Carbide Corp.*, 402 F.3d 608 (6th Cir. 2005). The plaintiffs, uranium-enrichment plant workers, sought damages for “certain subcellular damage to their DNA and chromosomes.” *Id.* at 613. They showed that 8 percent of the plaintiffs’ cells had “various structural chromosome abnormalities” compared to a background average of 1.3 percent, as reported in scientific literature. *Id.* In holding that the workers’ alleged cellular damages were not “bodily injur[ies],” the court focused on policy concerns, including the potential for the floodgate to burst if claims were allowed for “even the most benign sub-cellular damage.” *Id.* at 621–22. Further, the court realized allowing recovery for a nominal DNA injury under Kentucky’s “one claim rule” would prevent plaintiffs from recovery should they later develop a debilitating injury. *Id.* The court also struggled with calculating damages for injuries that were not quantifiable—no medical costs, lost wages and current pain or suffering. *Id.* The court noted that “DNA damage is harmful only insofar as it is predictive of future disease,”

and the plaintiffs' evidence of subcellular damage was insufficient to be considered "bodily injury." *Id.* at 614, 622. The court affirmed summary judgment for the defendants. *Id.* at 625.

In September 2008, the Ninth Circuit held that subcellular DNA damage was not a bodily injury for purposes of recovery under the Price-Anderson Act, which

In addition to misbranding charges, companies may face allegations of Medicare and Medicaid fraud.

provides compensation for nuclear injuries. *Dumontier v. Schlumberger Technology Corp.*, 543 F.3d 567 (9th Cir. 2008). The plaintiffs were exposed to radioactive cesium while working on a drilling rig but had not developed cancer or other illnesses. Nevertheless, they argued that the slightest exposure to radiation could denature proteins and modify DNA. *Id.* at 570. The court responded that "not every alteration of the body" is injurious, and the presence of DNA or subcellular damage does not "establish that there is or will be pain or interference with bodily functions." *Id.* at 570-71. Even if the plaintiffs had established risk of a disease, they had not established a compensable disease as defined by the Price-Anderson Act, so the court affirmed summary judgment for the defendants. *Id.* at 567, 570-71.

Some of the most compelling reasons courts have given for denying latent damage claims in the past are the lack of a genetic baseline against which to measure alleged damage and uncertainty about the medical consequences of such exposure. See *Brafford v. Susquehanna Corp.*, 586 F. Supp. 14, 18 (D. Col. 1984) ("[T]he inability to precisely quantify the extent of present damage to the chromosomes is a function of medical technology's inability to make such a measure."). Courts also struggle with quantifying damages that are uncertain. *Temple-Inland Forest Products Corp. v. Carter*, 993 S.W.2d 88, 93 (Tex. 1999) (Case

for recovery is weak where "bodily injury is at most latent and any eventual consequences uncertain").

In the *Rezulin* litigation, the court found no evidence of observable injury. The plaintiffs alleged that the diabetes drug Rezulin caused compensable subcellular injuries. *In re Rezulin Products Liability Litigation*, 361 F. Supp. 2d 268, 278 (S.D.N.Y. 2005). The court found "no evidence that plaintiffs' alleged injuries have manifested any clinically observable detriment. Indeed, there is no evidence that plaintiffs' alleged mitochondrial damage was permanent or irreversible." *Id.* at 278.

Historically it has been virtually impossible to distinguish mutations allegedly caused by toxic exposure from those present in an individual's DNA from birth, those due to another cause, and those that developed spontaneously. As mentioned above, until recently, there have been few established links between specific acquired gene mutations and medical conditions. It has been similarly unclear whether having a certain gene mutation means an individual will develop a specific disease or condition or whether that mutation merely puts the individual at a higher propensity for developing the disease.

Scientific Developments

Recent scientific developments have made human DNA available so that eventually litigants may overcome the scientific obstacles that precluded success with these claims in the past. For example, Harvard University's Personal Genome Project aspires to create an on-line database containing 100,000 volunteers' genomes. Personal Genome Project Home Page, <http://www.personalgenomes.org/> (accessed January 8, 2009). The genomes will be freely accessible, along with information about the volunteers' medical conditions and physical characteristics, to researchers attempting to link particular gene sequences to medical conditions and physical characteristics. Recording and publishing a substantial database of DNA will provide a baseline against which to compare those individuals' genetic codes later, to evaluate changes in their DNA and to track exposures to agents believed to cause such changes. While hurdles remain, banking DNA may signal the beginning of the development

of sufficient scientific evidence to support causation of specific genetic damage from products such as pharmaceuticals.

Recent advances also have linked genes to specific diseases. *Nature* reported in November 2008 that Washington University researchers decoded a cancer patient's genome and linked ten genes to the acute myelogenous leukemia (AML) that proved fatal for the patient. Press Release by Caroline Arbanas, Washington University in St. Louis School of Medicine, Washington University scientists first to sequence genome of cancer patient (November 5, 2008), available at <http://mednews.wustl.edu/news/page/normal/12873.html/>. The scientists identified relevant genes by comparing the patient's cancer tissue DNA to the same patient's healthy DNA. Although the research was undertaken to develop more effective cancer treatment, genetic links to AML could potentially impact toxic tort and product liability litigation. Toxins are frequently implicated in cancer development, and AML has been linked to benzene exposure. See *Wells v. Shell Oil Co.* (E.D. Texas March 2, 1998) (jury verdict); *Lavender v. Bayer Corp.* (W. Va. Cir. Ct. May 29, 1998) (No. 93-C-226-K); *Cord v. City of Los Angeles*, 2004 WL 2189182, at *9 (Cal. App. Sept. 30, 2004).

Other projects are underway, such as the Diseasome, which maps diseases that scientists believe are genetically related and tracks the necessary number of genes theorized to need to change to produce a disease. Andrew Pollack, *Redefining Disease, Genes and All*, N.Y. TIMES, May 6, 2008, at F1. Researchers are trying to identify molecular pathways that are common among diseases once thought to be unrelated and map their findings. *Id.* As these developments progress, they may help link toxins to specific diseases and disease patterns.

Future Considerations

Despite recent scientific developments, DNA and subcellular claims face obstacles. Even as genetic mutations are linked with toxins or environmental insults, unless a plaintiff has a "baseline" genetic map, it is challenging to prove that the mutation was not preexisting. A distinct mutation may be identifiable and linked to a toxin, but it still may be difficult to determine the picture of a "normal" genome. Additionally,

even when a subcellular injury is linked to a toxin, the chromosome involved is often affected by more than just that particular toxin.

One way that plaintiffs may advance claims is to identify a hallmark or signature mutation that is associated with a toxin. In the Three Mile Island litigation, the Third Circuit advocated using a particular type of DNA damage known as “dicentric chromosomes” to measure exposure to harmful radiation, stating, “counting the number of dicentrics is an accepted method, not simply for determining if the subject of the analysis was irradiated, but also for estimating radiation dose.” *In re TMI Litig.*, 193 F.3d 613, 622–23 (3d. Cir. 1999), *cert. denied*, 120 S. Ct. 2238 (2000) at 690. While the court found that using dicentric chromosomes in the Three Mile Island case itself was misplaced, it recognized dicentric chromosomes as a hallmark of radiation exposure.

Another hurdle plaintiffs face is alleging some type of compensable injury. If plaintiffs develop a disease, they may be able to associate the injury with a toxin. However, if plaintiffs only establish a genetic mutation, they may not have a traditional compensable injury. Plaintiffs may be able to circumvent the need for a compensable injury by bringing claims for medical monitoring of a disease. In addition to medical monitoring, depending on the disease or injury at issue, plaintiffs may allege emotional damages based on fear of developing that disease. The plaintiffs’ bar already promotes such allegations, and even advertises on websites for DNA damage claims due to toxins.

Toxic Trespass and Biomonitoring

Another developing legal theory is that of “toxic trespass,” or claims for unwanted chemicals’ presence in an individual’s body. Erin Marie Daly, “*Toxic Trespass Could Be the Next Big Toxic Tort*,” *PRODUCT LIABILITY LAW* 360, Nov. 15, 2007, <http://productliability.law360.com/public/default.aspx>. Plaintiffs have been largely unsuccessful with toxic trespass claims, but “body burden” and “biomonitoring” research could improve success. “Body burden” and “biomonitoring” refer to the monitoring of chemical levels in body fluids and tissues. Several biomonitoring or body bur-

den initiatives have started to track the accumulation of environmental toxins in human body tissue over time. Researchers use these levels to determine the chemicals to which people have been exposed, the amount in the body, and the chemical concentrations that cause adverse health effects. Department of Health and Human Services: Centers for Disease Control and Prevention: Division of Laboratory Sciences, National Biomonitoring Program, <http://www.cdc.gov/biomonitoring/about.htm> (accessed January 8, 2009). The National Biomonitoring Program monitors more than 100 toxins. The origin of some of these chemicals can be traced to specific products or types of products, including benzophenone-3, (a sunscreen agent used in various consumer products), phthalates (used in plastics such as food storage containers and plastic bags), pesticides, polychlorinated biphenyls, and flame retardants.

Researchers correlate toxin levels to participants’ characteristics and choices, including residence, diet, and occupation, to identify the source of each particular chemical. In some cases, they can identify a specific product or source by measuring the chemical or its metabolites in the blood or urine of the subject. Centers for Disease Control and Prevention, Third National Report on Human Exposure to Environmental Chemicals. Atlanta (GA): CDC, 2005.

California started a similar effort in 2006, the California Environmental Contaminant Biomonitoring Program. Program participants submit body measurements, demographic, medical, diet, and occupational information and have their blood and urine tested for metals and organic compounds. California Environmental Contaminant Biomonitoring Program (CECBP), http://www.cdph.ca.gov/programs/Biomonitoring/Documents/CECBP_Overview_11_07.pdf (accessed January 8, 2009). The California program focuses on pesticides and heavy metals that farm workers and their families, fishermen, and consumers will likely absorb, such as phthalates, used in plastic toys and food packaging, and mercury. California Department of Health Services: California Biomonitoring Plan (2003), available at http://www.cdph.ca.gov/programs/Biomonitoring/Documents/CDHS_Biomonitoring_Plan.pdf (accessed January 8, 2009).

In addition to monitoring toxic chemicals, online databases have been established to correlate chemical toxins to health effects. The Human Toxome Project maintains an online listing of health effects and reference material by chemical. Human Toxome Project: Health Effects, <http://www.ewg.org/sites/humantoxome/healtheffects/>, (accessed January 8, 2009). For example,

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the website’s information for bisphenol A, a chemical found in certain plastics, includes a summary of the chemical’s history and current uses in baby bottles, food can linings, and dental sealants, among others. The website also lists known or suspected health effects, such as cancer and endocrine diseases, and posts the results of biomonitoring tests. *Id.* The plaintiffs’ bar has taken note of these developments, offering online guidance to clients explaining how absorption, elimination, and accumulation of chemicals can be useful for proving toxic torts. Richard Alexander, *Personal Injury Attorney: Proving Toxic Torts: A Primer on Pharmacokinetics*, <http://www.consumerlawpage.com/article/toxic.shtml>, (accessed January 8, 2009); Robert M. Fellheimer, P.C., *Proving Medical Causation and Damages in a Toxic Tort Case*, <http://www.toxictort.com/index.html>, (accessed January 8, 2009). Other plaintiffs’ firm websites offer lists of known and suspected carcinogens vaguely resembling those created by biomonitoring initiatives. See Metzger Law Group: Chemical Carcinogens, <http://www.toxictorts.com/chemical-carcinogens.shtml>, (accessed January 8, 2009).

Courts have started to recognize the value of tracking and testing for toxins. The **Mass Tort**, continued on page 66

Mass Tort, from page 33

California Court of Appeal recognized the importance of these tests in an unreported 2004 case, stating this type of research “can test for 180,000 different chemicals, including the chemicals to the plaintiffs claim [the plaintiff] was exposed resulting in his cancer... [B]ecause no such tests were performed on [the plaintiff], ‘it is impossible to determine to a medical certainty’ whether [his] exposure, absorption or toxicity to benzene or other chemicals exceeded normal and expected levels. In other words, existing tests were available to measure whether [he] in fact had excessive exposure to benzene and other chemicals, but plaintiffs’ experts did not use them.” *Cord v. City of Los Angeles*, 2004 WL 2189182, at *9 (Cal. App. Sept. 30, 2004).

In recent weeks and months, hardly a news cycle passes without word of toxins contaminating a food product, household product, children’s toy or other commonly

used consumer item. As testing and monitoring for toxin levels becomes more widely used, plaintiffs are sure to increasingly attempt to link measurable toxins to both diseases and to specific products, which they will attempt to hold liable.

Conclusion

In today’s changing legal and economic market, the mass tort attorney must focus on the “employability” or marketability of his or her skills. Fortunately, many skills possessed by a mass tort attorney are valuable assets, transferrable to related litigation or defense of new theories of mass tort liability.

For the traditional pharmaceutical mass tort client, the defense attorney possesses institutional knowledge of both the client and the pharmaceutical vital to related litigation, such as consumer fraud actions and governmental investigations. While consumer fraud and governmental actions

tend to differ in form from the form of traditional pharmaceutical mass torts—a class action or criminal prosecution—they involve litigation of the same facts and issues. They also involve dealing with representative plaintiffs, either as class representatives or bellwether plaintiffs.

The mass tort defense attorney also has experience dealing with complex problems, detailed fact patterns, high case volume and complicated scientific and medical data. All of the skills developed through experience defending mass torts are also necessary in defense of “toxic” torts, such as genetic damages or toxin-induced injuries.

By becoming knowledgeable about related litigation and remaining abreast of scientific developments, an attorney can exercise a preemptive strike and develop his or her mass tort practice, even in the current environment. 