MORRISON
FOERSTER

# PRODUCT LIABILITY

## 2014 YEAR IN REVIEW

**ATTORNEY ADVERTISING.** Endorsements and prior results do not guarantee a similar outcome, nor do they constitute a prediction concerning your legal matter.

# SOME ACCOLADES...

RANKED AS A LEADING FIRM IN PRODUCT LIABILITY AND MASS TORTS BY ***CHAMBERS USA.***

RANKED AS A LEADING NATIONAL FIRM IN PRODUCT LIABILITY AND MASS TORT DEFENSE: CONSUMER PRODUCTS AND TOXIC TORT BY ***LEGAL 500 US.***

***BEST LAWYERS*** RECOGNIZED 16 OF OUR PARTNERS: ERIN BOSMAN, MICHÈLE CORASH, GRANT ESPOSITO, ROBERT FALK, ARTURO GONZÁLEZ, PETER HSIAO, JAMES HUSTON, WILLIAM JANICKI, WILLIAM O'CONNOR, DENNIS ORR, CHARLES PATTERSON, PENELOPE PREOVOLOS, DON RUSHING, MICHAEL STEEL, WILLIAM STERN, AND MARK ZEBROWSKI.

"THEY'RE DEEPLY ENTRENCHED AND WELL VERSED IN OUR PRODUCT LIABILITY LITIGATION."
***– CHAMBERS USA***

"THE 'HIGHLY RESPONSIVE' TEAM AT MORRISON & FOERSTER LLP HAS 'GREAT INDUSTRY KNOWLEDGE' AND IS NOTED FOR ITS ABILITY TO HANDLE HIGH-RISK LITIGATION."
***– LEGAL 500 US***

***LEGAL 500 US*** RECOMMENDS ARTURO GONZÁLEZ, ERIN BOSMAN, AND JAMES HUSTON FOR THEIR EXPERTISE IN PRODUCT LIABILITY AND MASS TORT DEFENSE: PHARMACEUTICALS AND MEDICAL DEVICES.

***CHAMBERS USA*** RECOGNIZED DON RUSHING AND WILLIAM O'CONNOR AS LEADING LAWYERS IN AVIATION LITIGATION.

RANKED FOR PRODUCT LIABILITY AND MASS TORT DEFENSE: AEROSPACE/ AVIATION BY ***LEGAL 500 US***.

***LEGAL 500 US*** NAMED JAMES HUSTON AND DON RUSHING AS "LEADING LAWYERS" IN PRODUCT LIABILITY AND MASS TORT DEFENSE: AEROSPACE/AVIATION. ALSO RECOMMENDED WILLIAM JANICKI, WILLIAM O'CONNOR, CHARLES KERR, ERIN BOSMAN, AND KIMBERLY GOSLING.

***CHAMBERS USA*** LEADING NATIONWIDE AVIATION LITIGATION PRACTICE.

"I SEE THEM AS BEING EXTREMELY STRONG AND COMPETENT IN ANALYTICAL WRITING AND ADVOCACY SKILLS." – ***CHAMBERS USA*** 2014

"MORRISON & FOERSTER LLP 'HAS THE DEPTH NEEDED TO HANDLE LARGE COMPLEX CASES' AND 'GOES OUT OF ITS WAY TO MEET THE NEEDS AND EXPECTATIONS OF ITS CLIENTS'. THE FIRM IS NOTED FOR ITS 'STRONG DEFENSE COUNSEL' AND 'DEEP INDUSTRY KNOWLEDGE', AND ALSO COMES RECOMMENDED AS 'THE "GO TO" FIRM FOR COMPLEX LITIGATION FOR AVIATION MANUFACTURERS AND AIRLINES'." – ***LEGAL 500 US***

# INSIDE

# LETTER FROM THE CHAIR

As we look back on 2014, we want to thank you, our clients, for continuing to entrust us with your most important and complex product liability matters. We are honored to have helped you navigate this eventful year.

2014 was a year of major developments for clients in all aspects of our product liability practice. In the consumer products arena, our clients saw increased enforcement efforts and aggressive stances by CPSC against product manufacturers, with higher civil penalties and additional compliance-program requirements. In fact, the total penalties announced by CPSC for 2014 were more than double those of the previous year, continuing a trend that has established CPSC as a serious enforcement agency.

Meanwhile, our pharmaceutical clients endured the courts' continuing exploration of the limits of failure-to-update claims, while the door remained open to claims that a company failed to warn FDA. 2014 also saw the first state supreme court case (Alabama) holding that manufacturers of brand drugs can be liable for injuries caused by generic drugs.

Our aviation clients experienced a turbulent 2014—a year in which three major commercial airline crashes occurred overseas. These crashes likely will lead to significant litigation both in the United States and abroad, implicating interesting questions of forum selection and international law. In 2014, we also introduced our Drone/Unmanned Aircraft Systems (UAS) practice to help clients navigate the regulatory and legal issues in this new space. One of the many challenges facing drone operators was the FAA's failure to draft comprehensive rules to regulate drone operations, which left operators to decide whether to proceed in the regulatory void or ask the FAA for permission to operate.

Finally, 2014 saw the aggressive and fragmented enforcement of California's toxics regulations, including Proposition 65, by the state's attorney general's office and district attorneys. Our toxic tort clients were additionally challenged by California's embracing of citizen suit cases involving attorney fee awards, and the shifting of the burden of proof to defendant companies.

In our Annual Review, we will discuss these and other key legal and regulatory developments that impact consumer products, pharmaceutical and medical devices, aviation, and toxic torts, as well as our outlook for 2015.

We wish you all the best and look forward to continuing to represent your interests this year and beyond.

Sincerely,

Erin Bosman
Chair, Product Liability Group

RANKED AS A LEADING NATIONAL FIRM IN PRODUCT LIABILITY AND MASS TORT DEFENSE: PHARMACEUTICALS AND MEDICAL DEVICES BY ***LEGAL 500 US***.

"GREAT ATTENTION TO DETAIL – THEY LOOK INTO EVERY PROBLEM." – ***CHAMBERS USA***

***LEGAL 500 US*** RECOMMENDED MICHÈLE CORASH AS A LEADING LAWYER, AND DON RUSHING, MICHAEL STEEL, AND WILLIAM TARANTINO FOR THEIR EXPERTISE IN PRODUCT LIABILITY AND MASS TORT DEFENSE: TOXIC TORT.

***LEGAL 500 US*** RECOMMENDED ERIN BOSMAN, MICHÈLE CORASH, DON RUSHING, DAVID WALSH, ELLEN ADLER, WILLIAM STERN, AND WILLIAM TARANTINO FOR THEIR EXPERTISE IN PRODUCT LIABILITY AND MASS TORT DEFENSE: CONSUMER PRODUCTS.

MORRISON & FOERSTER IS VIEWED AS A 'HEAVY WEIGHT' FIRM IN THIS AREA BY ***LEGAL 500 US***.

"MORRISON & FOERSTER LLP IS A 'VALUED PARTNER IN LITIGATION MATTERS', OWING TO ITS 'EXTREMELY RESPONSIVE' NATURE AND ABILITY TO UNDERSTAND CLIENTS' BUSINESSES AND INDUSTRIES." – ***LEGAL 500 US***

# CONSUMER PRODUCTS

In 2014, we once again saw increased enforcement efforts as the U.S. Consumer Product Safety Commission (CPSC) continued to take aggressive stances against product manufacturers, with higher civil penalties and additional compliance program requirements. On the litigation side, key decisions interpreting the Class Action Fairness Act provided clarity with regard to whether federal courts can exercise jurisdiction over certain class action claims.

## "FAILURE TO REPORT" CASES RESULT IN RECORD CIVIL PENALTIES

Continuing 2013's trend, 2014 was another year of record-high penalties. The total penalties announced in 2014 were more than double the $6 million in total penalties assessed in 2013, which was up from $4.3 million in 2012. At the top of 2014's list was the largest fine ever imposed by CPSC—a $4.3 million civil penalty agreed to by Baja, Inc., and One World Technologies, Inc., involving minibikes and go-carts.

The significant increase in penalties levied against companies over the past few years shows that CPSC is intent on staking its claim as a serious enforcement agency. Not only is the number of companies facing fines increasing, but the average penalty has been steadily increasing as well, as evidenced by the $4.3 million fine against Baja. This upward

trend reflects a tough stance on enforcement that CPSC has been seeking to build ever since Congress passed the Consumer Product Safety Improvement Act in 2008 in response to heightened consumer awareness and concerns over consumer product safety.

CPSC also continued its trend of mandating comprehensive safety compliance procedures in "failure-to-report" cases. Many companies that were fined by CPSC were also required to implement a compliance program designed to ensure compliance with the safety statutes and regulations enforced by CPSC. These compliance programs impose additional reporting and record-keeping requirements on the settling companies. The companies are also forced to make available to CPSC all information, materials, and personnel deemed necessary by CPSC to evaluate the companies' compliance with the terms of the agreement.

## NEW EMPHASIS ON SOCIAL MEDIA

In 2014, CPSC continued to emphasize the importance of companies using social media to increase consumer awareness of safety issues, including recalls. As part of this emphasis, CPSC rolled out a new monthly reporting template for recalling companies, which includes new metrics for monitoring social media activity. CPSC's heightened focus on social media is also reflected in its "Social Media Guide for Recalling Companies,"[1] which encourages companies to post on Facebook, tweet about the recall, and conduct other social media notifications through sites such as Pinterest, Google+, and Instagram. CPSC notes that while tweets can be up to 140 characters, its own "recall tweets are 97 characters so that we can include a link to a document and a photo of the product." CPSC makes substantial efforts to use the very forums it encourages recalling companies to use and posts recall information on Twitter, Flickr, and Google+ (although it has yet to set up a Facebook presence). However, CPSC has not yet made any formal requirements for social media notifications, and it remains to be seen what, if anything, would be required in this regard for small businesses that do not maintain an online social media presence.

## OBLIGATION TO MONITOR ONLINE AUCTION SITES

Another attempt to keep up with the times was evident in the new monthly reporting template's question regarding online auction sites. Specifically, the form asks whether the recalling company found the recalled product on online auction sites and what, if any, action was taken. This question suggests an obligation—where there previously was none—for recalling companies to monitor online auction sites for the sale of recalled products. While it is widely known that selling a recalled product is illegal, companies have traditionally taken the position that policing online auction websites for recalled products is CPSC's obligation.

## REPORTS OF HARM

In 2014, the Fourth Circuit decided a case that provides some guidance on how to handle potential material inaccuracies in a report of harm. *Doe v. Pub. Citizen*, 749 F.3d 246 (4th Cir. 2014). The case arose from a report of harm that CPSC received in 2011, attributing the choking death of an infant to an Ergobaby carrier. In response, Ergobaby filed a claim with CPSC that the report contained materially inaccurate information. Despite four requests by Ergobaby to have the report corrected, CPSC refused to halt publication of the original report. Ergobaby successfully brought suit in the District of Maryland to enjoin CPSC from including the report of harm in CPSC's SaferProducts database.

The entire proceeding was litigated under seal and a group of consumer advocates seeking greater public access to court documents appealed the district court's denial of their motion to intervene, as well as the district court's orders sealing the docket. The Fourth Circuit reversed the district court's sealing orders and ordered the docket unsealed, including the actual name of "Company Doe."

The result in *Company Doe* presents product manufacturers with a dilemma in cases where CPSC disagrees with the manufacturers' claims of material inaccuracy in a report of harm. The good news for manufacturers is that courts can provide relief, as in *Company Doe*. But at what cost? Such a suit is likely to draw increased attention to the report and to the company. Even if the court ultimately finds the report inaccurate, relief may come too late, especially with the rapid dissemination of information in today's electronic media. At the very least, companies should take care to publish comments in response to the report on the CPSC website, should CPSC reject

# CONSUMER PRODUCTS

claims that a particular report is materially inaccurate.

## LOWER BARRIERS TO FEDERAL JURISDICTION UNDER CAFA

2014 also saw several key decisions regarding federal jurisdiction over class action claims under the Class Action Fairness Act (CAFA). CAFA was designed to lower the barrier for diversity jurisdiction over class action claims, recognizing that certain class action cases could be of national importance and should be heard in federal court. Two opinions underscore this purpose of providing access to federal courts and should provide encouragement to consumer product manufacturers that seek to remove consumer class action cases.

First, the U.S. Supreme Court held that a defendant seeking to remove a class action under CAFA need not provide evidence of the amount in controversy. *Dart Cherokee Basin Operating Co., LLC v. Owens*, 135 S. Ct. 547 (2014). In *Dart*, the defendant removed the case, alleging that the three requirements for diversity jurisdiction under CAFA—more than 100 class members, minimal diversity, and amount in controversy greater than $5 million. The plaintiff moved to remand on the grounds that defendant provided no evidence of the alleged $8.2 million amount in controversy. The Supreme Court held that "a defendant's notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold."

The Ninth Circuit also weighed in as CAFA, holding that cases with fewer than 100 plaintiffs could still be removed to federal court under CAFA's "mass action" provision if multiple cases were coordinated for trial and therefore met the 100-plaintiff requirement. *Corber v. Xanodyne Pharms., Inc.*, 771 F.3d 1218 (9th Cir. 2014). No doubt plaintiffs will continue to seek ways to circumvent federal jurisdiction under CAFA, but these cases make clear that plaintiffs must do more than make simple assertions to take advantage of certain exceptions to federal jurisdiction.

## CONSUMER PRODUCTS REGULATORY OUTLOOK FOR 2015

As CPSC continues to emphasize enforcement, consumer products manufacturers should expect increased scrutiny with regard to reporting requirements and recall compliance. CPSC has also announced that in 2015 it plans to pilot its new "single window" electronic information portal, which was required by Executive Order 13659 ("Streamlining the Export/Import Process for America's Businesses"). The program is expected to be live by December 2016. The Executive Order requires that businesses transmit all data required for import or export of goods through a single International Trade Data System.

With the ever-increasing emphasis on enforcement, consumer products companies should evaluate their internal compliance programs and ensure that they have mechanisms in place for the appropriate personnel to evaluate product incidents and determine whether they are reportable to CPSC. Companies conducting recalls should evaluate their social media presence and ensure that they get the word out through multiple forms of media. Expect to see more of the same in 2015, along with steeper penalties for companies. As publicity about CPSC's tough enforcement stance increases, CPSC undoubtedly will have higher expectations that companies are aware of their compliance obligations.

1. http://www.cpsc.gov/en/Business--Manufacturing/Recall-Guidance/Social-Media-Guide-for-Recalling-Companies/.

## KEY PRACTICE HIGHLIGHTS

### FORCE RECALL & LITIGATION

Serve as national coordinating counsel for Fitbit in five class action lawsuits and over 30 personal injury lawsuits arising from the widely publicized recall of Fitbit's Force activity tracker. We successfully conducted the recall in a short timeframe and negotiated a quick and favorable settlement of the class action litigation.

### CAMERA DEFECT

Defended client with class actions alleging that the camera had a shutter mechanism defect that caused oil and dust to settle on the camera's image sensor. Through active early case investigation

and assessment, we were able to resolve the matter for the client without ever having to respond to the complaints. The approach demonstrated the benefit of frank and collaborative discussions with opposing counsel at the outset.

## PRODUCT DEFECT SETTLEMENT

Defended a well-known consumer products manufacturer in two class action/product liability matters alleging a defect in the product. The facts were strong, and by arranging an early face-to-face meeting with class counsel, we convinced them their case had no merit. Both cases were dismissed at a cost of $20,000 in benefits to the class, plus a payment of attorneys' fees—100% of which was paid by the client's carrier.

## PRODUCT RECALL

Advising client on one of the largest product recalls in the United States in recent years concerning multiple brands of a consumer product recalled due to potential fire and overheating hazards. We are representing the client before the CPSC and defending related litigation and claims arising from the recall brought by distributors and a joint venture partner.

## HOME ENVIRONMENTAL MONITOR

Advising client on the launch of a home environmental monitor/sensor that can be programmed with a smartphone by evaluating its product liability exposure, as well as advice on certifications and compliance issues.

## TAINTED GRAIN CLASS ACTION

Defended U.S. grain processor against claims that it sold a tainted and downgraded product. We held an early mediation and demonstrated, by a compelling presentation, why plaintiffs would lose. The matter was resolved a month later at a fraction of the client's GAAP reserve.

# PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

In 2014, failure-to-warn liability for generic pharmaceutical companies continued to hold the industry's attention. Theories of liability explored in 2014 included failure to update label claims, with the door remaining open to claims that a company failed to warn FDA. 2014 saw the first state supreme court case (Alabama) hold that a brand manufacturer can be liable for injuries to consumers of generic drugs. Although several key cases touching on generic pharmaceutical liability in this area have been appealed to the U.S. Supreme Court, we think it is unlikely the Court will grant certiorari in any of these cases. Therefore, we anticipate little clarity in the coming year until FDA publishes its final rule on labeling obligations for generic drug companies.

## INNOVATOR LIABILITY

A surprising development in 2014 was the Supreme Court of Alabama's adoption of "innovator liability," the notion that manufacturers of brand drugs can be liable for injuries caused by generic drugs. *Weeks v. Wyeth, Inc.*, No. 1101397, -- So. 3d --, 2014 WL 4055813 (Ala. Aug. 15, 2014).

The 2014 opinion affirmed, after reargument, the court's 2013 holding in the same case. *See Wyeth, Inc. v. Weeks*, No. 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013). The Supreme Court of Alabama held that it was foreseeable that a generic drug user's doctor would rely on representations by a brand drug manufacturer. In reaching this conclusion, the court relied on *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which interpreted federal statutes and regulations as requiring generic drug manufacturers to copy

brand drug manufacturers' labels. Unlike most other courts that have examined this issue, the *Weeks* court found that the foreseeability deriving from the federal regulatory scheme was sufficient to establish that the brand drug manufacturer could be liable for fraud or misrepresentation because it owed the generic drug user a duty of care.

In reaching this decision once again (*Weeks II*), the court highlighted Alabama law regarding misrepresentation and held that the absence of a "contractual relationship or other dealings" between two parties "does not preclude the finding of a legal duty not to make a material misrepresentation or to suppress a material fact." The majority concluded by reiterating that the fraud or misrepresentation claim at issue sought liability not based on "a defect in the product itself but as a result of statements made by the brand-name manufacturer that Congress, through FDA, has mandated be the same on the generic version of the brand-name drug."

While "innovator liability" remains the minority viewpoint in courts across the country, one federal district court did adopt this position early in 2014. *Dolin v. SmithKline Beecham Corp.*, No. 12 C 6403, -- F. Supp. 2d --, 2014 WL 804458 (N.D. Ill. Feb. 28, 2014).

## DUTY TO WARN FDA

In 2014, the United States Supreme Court denied Medtronic's petition for *certiorari* in the case of *Medtronic, Inc. v. Stengel*, No. 12-1351, an appeal from the Ninth Circuit's 2013 *en banc* decision in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013). The question presented in *Stengel* was "[w]hether the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act preempt a state-law claim alleging that a medical device manufacturer violated a duty under federal law to report adverse-event information to the Food and Drug Administration."

The denial of Medtronic's petition means that "failure to warn FDA" remains a viable cause of action in the Ninth Circuit. But the Solicitor General planted a seed of doubt in its amicus brief recommending that the Court deny the petition for a writ of certiorari. Specifically, the Solicitor General noted that plaintiffs relied on the wrong theory and incorrectly argued that defendant failed to warn FDA. Instead, plaintiffs should have argued that the device manufacturer was liable for failure to warn based on a duty to update its label and warn doctors directly via a Changes Being Effected (CBE) supplement.

Of note, the Solicitor General made no mention of the "parallel claim" requirement for medical device liability under *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (express preemption clause for medical devices does not preempt "state duties" that "'parallel,' rather than add to, federal requirements"). Nor did he distinguish the cases since *Riegel*, holding that failure-to-warn claims against manufacturers of Class III medical devices are preempted. *See, e.g., Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1302 (11th Cir. 2011); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010).

Under the Ninth Circuit's holding in *Stengel*, liability will still be difficult to prove given the problems inherent in proving a causal link between failure to warn FDA and the plaintiff's injury. Due to this lack of a clear path to liability and the lack of guidance provided by the Solicitor General's amicus brief, we expect both sides will continue to vigorously litigate claims that defendants failed to warn FDA as they seek the appropriate case that would warrant review by the Supreme Court on this issue.

## FAILURE TO UPDATE

Of all the theories of liability invoked by plaintiffs seeking recovery for injuries due to generic drugs, "failure-to-update" claims once again continued to see the most success. These claims allege that a failure-to-warn claim could proceed against a generic manufacturer for failing to timely follow the brand-name label. *See Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 364 (Iowa 2014). While courts have generally continued to find such claims legally viable, they have imposed strict pleading requirements on plaintiffs. *See, e.g., In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 932 (6th Cir. 2014) (plaintiffs' complaint failed to state a cause of action for failure to update because it did "not identify whose failure to implement the warnings caused the injuries.").

Not all courts agree such claims are viable. Most notably, the Fifth Circuit affirmed its previous decision holding that failure-to-update claims were preempted by federal law. *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014) ("a claim

# PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

that [the generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted." (quoting *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013)); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014) (same).

Petitions for writs of *certiorari* have been filed for both *Huck* and the California Court of Appeal's 2013 decision in *Teva Pharms. USA, Inc. v. Superior Court*, 217 Cal. App. 4th 96, 100 (2013), review denied (Sept. 25, 2013). Both petitions present the same question: whether federal law preempts "state tort claims predicated on allegations that a generic drug manufacturer violated the FDCA by failing to immediately implement or otherwise disseminate notice of labeling changes that the United States Food and Drug Administration approved for use on the generic drug product's brand-name equivalent."

In December 2014, the Solicitor General filed an amicus brief in *Teva*, recommending that the Supreme Court deny the petition for a variety of reasons. Most notably, the Solicitor General asserted that Dear Healthcare Provider (DHCP) letters could be sent by "a generic manufacturer to communicate warnings *already present* in the relevant brand-name labeling . . . . Such letters would not imply any difference between the generic and brand-name drugs or otherwise run afoul of FDA's regulatory requirements."[1]

We anticipate both the *Huck* and *Teva* petitions will be denied, leaving generic manufacturers susceptible to failure-to-update claims until and unless FDA's proposed rule for generic drug labeling goes into effect.

## FDA'S PROPOSED RULE

In 2013, FDA proposed a new rule to allow generic manufacturers to revise warnings without having to maintain the same label as the reference listed drug. 78 Fed. Reg. 67985 (proposed Nov. 13, 2013). The industry had hoped for clarity from this new rule, which was originally anticipated to go into effect in late 2014.

The proposed rule would eliminate the requirement that generic labels be the "same" as brand labels. The proposed rule could also clarify the scope of the failure-to-update claims discussed above, as it allows generic manufacturers only 30 days to conform their labels once FDA approves another company's CBE submission. A company that fails to update its labels within this tight window could face claims for negligence per se for violating federal standards.

In its recent amicus brief, the Solicitor General noted the clarity that this new rule might bring:

> As FDA has explained, these changes, if adopted, "may eliminate the preemption of certain failure-to-warn claims with respect to generic drugs." 78 Fed. Reg. at 67,989. Although FDA's proposal is not retroactive and would not apply to pending failure-to-warn claims, it would circumscribe the number of cases affected by the outcome of this litigation and limit the significance of a ruling by this Court in this case.[2]

Originally it was anticipated that the rule would be finalized in late 2014. But the proposed rule had vocal opponents. According to *The Wall Street Journal*, FDA acknowledged that the heated debate on the rule led to a delay in publication of the final rule, as FDA is "committed to reviewing and considering all of the comments received as we develop the final rule."[3] These comments include the Generic Pharmaceuticals Association's commissioned study concluding that the proposed rule will increase annual healthcare costs by $4 billion; a letter from 19 Senate and House Republicans concerned about the increased costs the rule could impose; and numerous others opposing the rule in its current form. Thus, despite expectations that the rule would be finalized in late 2014, FDA now indicates the rule will likely be published in fall 2015. While many are hopeful that the rule will shed light on the labeling obligations of generic pharmaceutical companies, there still remains much doubt that the rule will provide the clarity and finality that drug manufacturers seek with regard to both regulatory compliance and product liability concerns.

---

1. *See Brief for the United States as Amicus Curiae at 21-22, Teva Pharms. USA, Inc. v. Super. Ct., No. 13-956 (U.S. Dec. 16, 2014).*
2. *See Brief for the United States as Amicus Curiae at 24, Teva Pharms. USA, Inc. v. Super. Ct., No. 13-956 (U.S. Dec. 16, 2014).*

3. Ed Silverman, *FDA Delays Final Rule on Allowing Generic Drug Makers to Update Labels,* Wall St. J., Nov. 18, 2014, http://blogs.wsj.com/pharmalot/2014/11/18/fda-delays-final-rule-on-allowing-generic-drug-makers-to-update-labels.

## KEY PRACTICE HIGHLIGHTS

### IN RE REGLAN/METOCLOPRAMIDE LITIGATION

Defending a client in hundreds of lawsuits (comprising more than 2,000 individual claims) that have been filed in numerous jurisdictions around the United States, alleging that Reglan/metoclopramide (when prescribed off-label for psychiatric purposes) causes significant side effects and damages health. The cases are pending in mass tort proceedings in Pennsylvania, New Jersey, and California.

### NEW DRUG CLINICAL TRIAL

Assisting a biopharmaceutical company with analysis of documents for the clinical trial of its new drug for Crohn's disease, a chronic inflammatory condition of the gastrointestinal tract affecting as many as 700,000 Americans.

### WRONGFUL DEATH CLAIM

Advised a medical device manufacturer on a potential wrongful death claim related to its device. We evaluated the potential claim exposure and conducted a risk assessment.

### HEPARIN PRODUCTS LIABILITY LITIGATION

Serve as national coordinating counsel in numerous cases filed around the United States alleging injuries from heparin-induced thrombocytopenia (HIT). Our client is the largest manufacturer of heparin, a prescription injectable anticoagulant (blood thinner) often used in hemodialysis and cardiac-invasive procedures.

### ORAL ANTIBIOTIC LITIGATION

Represent client in several cases filed in California alleging that numerous plaintiffs developed peripheral neuropathy from taking the antibiotics Cipro and Avelox. These are the first of what will likely be many cases alleging injury from these oral antibiotics. Cipro received national attention in the 2000s as an approved treatment for the inhaled form of anthrax.

# AVIATION

2014 was a year of turbulence in the field of aviation, with three major, fatal commercial airline crashes happening overseas. These crashes will likely prompt significant aviation litigation both in the United States and abroad, implicating interesting questions of forum selection and international law. The international aviation insurance market took correspondingly large losses, necessitating significantly raised premiums for aviation insureds in 2015.

Incredible advances in technology led to the significant proliferation of unmanned aircraft systems (UAS) and industries desiring to use them. But the rapid advances also made it difficult for the FAA to draft comprehensive rules to regulate UAS operations, instead prompting the FAA to enforce a purported all-out ban on commercial operations. This left operators with hard choices to make: operate in the regulatory void or ask the FAA for permission that, before 2014, had never been granted.

## INTERNATIONAL TREATY UPDATE

The year 2014 brought with it some significant developments in aviation treaty law. First, in March, the Ninth Circuit decided *Narayanan v. British Airways*, holding that the two-year limitations period set forth in Article 35(1) of the Montreal Convention begins to run when an aircraft arrives at its destination, even if the claim has not yet accrued at that time. The ruling—which decided an issue of first impression in the Ninth Circuit—provided greater certainty for air carriers and effectuated the Montreal Convention's purpose of uniformity.

The plaintiff, Narayanan, had boarded a British Airways flight from Los Angeles, California, to Bangalore, India, with an intermediate stop in London, England, in December 2008. Narayanan, who suffered from terminal lung disease, was assured before boarding that supplemental oxygen would be provided to

him during the flight. Thereafter, however, he was denied access to supplemental oxygen. Although he received medical treatment in both London and Bangalore, and received further treatment upon his return to the United States in January 2009, his health continued to deteriorate and, on June 11, 2009, he passed away.

In March 2011, Narayanan's widow filed a claim against British Airways under Article 17(1) of the Montreal Convention, alleging that the airline's denial of supplemental oxygen hastened Narayanan's death. British Airways moved to dismiss, arguing that the Complaint was time-barred under the two-year limitations period established by Article 35(1) of the Convention. The district court agreed.

Article 17(1) provides that a carrier is "liable for damage sustained in case of death or bodily injury of a passenger upon condition only that the accident which caused the death or injury took place on board the aircraft[.]" As used in Article 17(1), an "accident" means a happening that is external to the passenger. *Air France v. Saks*, 470 U.S. 392, 405 (1985).

Article 29 of the Convention limits such claims, providing that "any action for damages . . . can only be brought subject to the conditions and such limits of liability as are set out in this Convention[.]" Article 35(1) sets forth one such limit, stating that the "right to damages shall be extinguished if an action is not brought within a period of two years, reckoned from the date of arrival at the destination[.]"

The Ninth Circuit considered "whether Article 35(1) applies irrespective of when a claim actually accrues, or whether local law governs the timeliness of any claims which were not in existence when the aircraft arrived at its destination." After carefully considering the Montreal Convention's text, drafting history, and relevant case law, the court found the former: Article 35(1)'s limitation applied regardless of when the plaintiffs' claim accrued. The court held that "Article 35(1) leaves no room for flexibility as to the commencement of the limitations period[,]" noting that 103 signatory nations agreed to the text and to the Convention's "cardinal purpose" of "achieving uniformity of rules governing claims arising from international air transportation."

A month later, in April 2014, the International Civil Aviation Organization (ICAO) officially adopted a protocol to amend the Tokyo Convention on offenses committed on aircraft. The culmination of a four-year effort to modernize the Tokyo Convention, the Montreal Protocol 2014 makes key changes to improve airlines' ability to deal with unruly passenger incidents and enhance aviation security.

The Tokyo Convention, which came into effect in 1969, governs the actions an airline may take to address offenses and other acts that occur on board an aircraft during flight. The Convention allows the aircraft commander to take reasonable measures against an unruly passenger, including restraint, to (1) protect the safety of the aircraft, passengers, and crew, (2) maintain good order and discipline on board, and (3) enable the aircraft commander to deliver the passenger to law enforcement. Article 10 of the Convention provides immunity from liability in any proceedings for actions taken in accordance with its provisions.

It is generally thought that this 50-year-old Convention has served the aviation industry well. Nonetheless, the past five years have seen a dramatic increase in unruly passenger in-flight incidents. To address the rising tide of unruly passenger incidents, a Diplomatic Conference was held between March 26 and April 4, 2014. The Conference considered proposed revisions to the Tokyo Convention, aimed at ensuring that the Convention continues to work as an effective deterrent to unruly in-flight behavior.

And so, the Montreal Protocol 2014 was born. The Protocol makes three key improvements to the Tokyo Convention, including the clarification of the definition of "unruly behavior," the extension of jurisdiction over in-flight incidents, and the recovery of costs stemming from unruly passenger behavior. These changes, along with the measures already being taken by airlines, ensure greater liability protection for airlines dealing with unruly passenger incidents.

## HERE COME THE DRONES

In 2014, the uses for and users of drones increased dramatically. These operations, however, have consistently occurred within an uncertain legal framework. The cause of this uncertainty was two-fold.

First, FAA rulemaking for drones has been significantly delayed. Congress mandated rulemaking as part of the FAA Modernization and Reform Act of 2012 (the "Act"), which requires the FAA to "provide

# AVIATION

for the safe integration of civil unmanned aircraft systems into the national airspace system as soon as practicable, but not later than September 30, 2015." The Notice of Proposed Rulemaking (NPRM) for small UAS (meaning UAS that weigh less than 55 pounds) was expected sooner—with Congress requiring the FAA to issue a final rule by August 2014. But the first in what's expected to be a series of NPRMs wasn't issued until February 15, 2015. And, there's no telling when the proposed rules may be finalized.

Second, in March 2014 an administrative law judge (ALJ) issued an order vacating a $10,000 civil penalty assessed by the FAA against a UAS operator, Raphael Pirker. The FAA alleged that Pirker carelessly or recklessly operated a Ritewing Zephyr unmanned aircraft in violation of 14 C.F.R. § 91.13(a), which provides that "[n]o person may operate an aircraft in a careless or reckless manner so as to endanger the life or property of another." The ALJ found that Pirker's unmanned aircraft did not qualify as an "aircraft" subject to FAA regulation under the statute. Many UAS operators saw the ALJ's decision as permission to freely fly.

That "permission," however, did not last long. In an order issued on November 18, 2014, the NTSB reversed the ALJ's decision in its entirety. The NTSB addressed two questions: (1) whether Pirker's drone qualifies as an "aircraft" that falls within the FAA's enabling statute and (2) whether Pirker's drone is subject to 14 C.F.R. § 91.13(a). The NTSB answered both questions in the affirmative. Thus, it became clear that both the FAA and the NTSB believe the existing Federal Aviation Regulations (FARs) apply to UAS operations. The extent to which the FARs apply and the likelihood of sanction thereunder, however, remained unclear. Importantly, the NTSB decision did not say that flying a drone, as such, is prohibited.

This lack of certainty regarding the use and regulation of UAS prompted companies to seek creative ways to get their drones off the ground. For example, in June 2014, seven aerial photo and video production companies asked the FAA for regulatory exemptions under Section 333 of the Act that would permit them to use UAS in the film and television industry. Companies from other industries (including precision agriculture, power line and pipeline inspection, and oil and gas flare stack inspection) soon followed suit.

Under Section 333, the Secretary of Transportation can grant regulatory exemptions for UAS that can operate safely in the national airspace system, before the FAA completes the rulemaking process. Exemption can be granted only if the UAS will not create a hazard to existing national airspace users or the public considering the "size, weight, speed, and operational capacity of the UAS; its proximity to airports and populated areas; and operation of the UAS within the visual line of sight of the operator.

By the end of September 2014, the FAA granted its first exemptions under Section 333. The exemptions, which were granted to six aerial film companies, were highly restrictive. They permit the use only of certain models of drones that must fly at speeds below 50 knots. The flights must be conducted below 400 feet above ground level and within the visual line of sight of the pilot in command, who must possess at least a private pilot's certificate. The exemptions also incorporate the various UAS operators' manuals that were submitted to the FAA in support of the exemption requests. Flight plans of activities are required to be submitted to the local Flight Standards District Offices, and the operators must obtain waivers from the relevant Air Traffic Organizations. A handful of additional exemptions were also granted in 2014, all with similarly restrictive operating parameters. By the end of 2014, the FAA had a docket of over 200 exemption requests to consider. That docket, along with the task of finalizing the first set of proposed regulations for small UAS, should keep the FAA extremely busy into 2015.

## LOOKING AHEAD TO 2015

All signs indicate that 2015 will be an eventful year for aviation litigation. The courts will be occupied with handling the massive litigation related to the 2014 accidents, and the FAA will be tasked with analyzing comments on and finalizing regulations for UAS. Stay tuned.

## KEY PRACTICE HIGHLIGHTS

### *IN RE CESSNA 208 SERIES AIRCRAFT PRODUCTS LIABILITY LITIGATION*

Secured a complete defense victory on behalf of Cessna in a product liability personal injury case in Omaha, Nebraska. Following a three-and-a-half-week trial, the jury concluded that the crash of a Cessna Caravan 208B aircraft was not caused by any defect in the airplane.

### MAJOR AIR CRASH LITIGATION

Advising a significant aerospace manufacturer regarding the investigation and possible litigation arising out of two major commercial air crash disasters.

### FAA REGULATORY ADVICE REGARDING DRONES

Assisting several clients in obtaining FAA approval for significant confidential UAS application projects.

### *CITY OF SANTA MONICA V. FEDERAL AVIATION ADMINISTRATION*

Advising City of Santa Monica on issues arising from its future plans for the Santa Monica Airport, including the high-profile litigation against the FAA. The City of Santa Monica initiated a process regarding the future of the airport since its agreement with the FAA regarding airport operations and current noise restrictions is set to expire in 2015.

### *WILLIAMS V. MD HELICOPTERS, INC., ET AL.*

Represent MDHI in a lawsuit arising from the crash of an MD369E helicopter near Glastonbury, England. Plaintiff claims that the helicopter crashed due to the failure of two tail rotor components—a pitch horn and a pitch link—caused by corrosion. This case raises issues regarding the exercise of general personal jurisdiction over an out-of-state aircraft manufacturer and forum non conveniens as the accident occurred in the UK.

# TOXICS REGULATION AND TOXIC TORT


In 2014, California continued to lead the nation in toxics regulation and litigation, exposing any company that sought access to the state's consumer marketplace, including those that merely have a website, to a confusing array of requirements and burdensome reporting obligations. In addition to a large docket of traditional toxic tort litigation, the enforcement of these laws by the state's attorney general's office and district attorneys was aggressive and fragmented. This created new challenges for companies faced with conflicting interpretations by various state agencies and enforcers. Navigating this gauntlet is no simple task, and new developments in the law promise to make it even more difficult in 2015 and beyond.

## CALIFORNIA EARTHQUAKE: PROPOSITION 65 ABOUT TO BE ROCKED?

California's "Proposition 65" warning requirements (Health & Safety Code Sections 25249.6 *et seq*.) are a magnet for litigation against consumer product manufacturers, importers, and retailers. Businesses whose products contain even a detectable amount of any one of more than 900 chemicals often face enforcement lawsuits brought by for-profit plaintiffs, unless their products contain a "clear and reasonable" Proposition 65 warning. Companies seeking to immunize themselves from such "bounty hunter" claims must either meet certain "safe harbor" levels for the chemicals, or label or display their products with a warning that "This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm."

California has considered changes to Proposition 65, but not always to the benefit of business. In 2013, the Governor's Office proposed changes to the law that did not make it through the legislature. On January 12, 2015, the California Office of Environmental Health Hazard Assessment (OEHHA) formally proposed an extensive set of new rules concerning the requirements for Proposition 65 warnings to be deemed "clear and reasonable"

(or which, in other words, fall within a "safe harbor"). While Proposition 65's current regulations allow for safe harbor compliance with its warning requirements through a generic, one-sentence, simple black-on-white statement appearing in English, the proposed regulations will require:

- use of a yellow triangle pictogram containing an exclamation point;
- a more unequivocal warning statement indicating that the product "can expose" a user to chemicals known to the state to cause cancer and birth defects or other reproductive harm;
- listing particular chemicals if they are among a group of twelve that OEHHA has identified and which are the most frequent targets of Proposition 65 litigation (already being referred to as the "dirty dozen");
- adding a URL to all warnings linking a public website that OEHHA will operate to provide information supplementing the warning for those so interested, including potential plaintiffs' lawyers (see more about this below); and
- presentation of the warning in additional languages if the product label otherwise displays them for any other purpose (in French for Canadian products and often in other languages for free trade purposes).

The proposed regulations also specify alternative and additional requirements for certain types of products or facilities, including food and restaurants; among these are several that have previously been the subject of enforcement litigation. In addition, the proposed legislation revise and impose more onerous requirements for warnings for "environmental exposures," such as for air emissions from the operation of facilities or equipment within the state.

OEHHA's regulatory proposal also seeks to alter the allocation of responsibility for giving Proposition 65 warnings as between retailers and their supply chains. The regulation would impose the warning obligation on a retailer only when *any* of the following applies:

- the product is a house brand;
- the retailer caused the listed chemical to be added to the product;
- the retailer has altered a warning label;
- the supplier has provided warning materials that the retailer has failed to pass on to the consumer;
- the retailer has "actual knowledge" of the potential exposure to a listed chemical; and *either*
    - there is no supplier subject to Prop 65., or
    - the supplier is not subject to U.S. jurisdiction.

For purposes of this last criterion, "actual knowledge" is defined as: "specific knowledge of the product exposure that the retailer receives from any reliable source. If the source of this knowledge is a notice [of intent to sue], the retailer shall not be deemed to have actual knowledge of any product exposure that is alleged in the notice until two business days after the retailer receives the notice."

The net effect of the retailer provision appears to be that retailers will not be responsible for warnings for products supplied by persons subject to Proposition 65 and U.S. jurisdiction, unless the products are house brands or the retailer interferes with the warning. For products provided by other suppliers, the plaintiff must be able to prove that the retailer had actual knowledge of the exposure, with the two-day grace period if the first knowledge was gained from the notice of intent to sue.

If adopted without further corrective changes, the proposed regulations will make the law less predictable and more difficult to comply with, and will significantly increase the potential for and the cost of Proposition 65 litigation.

## LITIGATION TO REMOVE SAFE HARBOR FOR LEAD IN CONSUMER PRODUCTS

Responding in part to favorable court decisions obtained by Morrison & Foerster in 2014 to further define the lead standard, and one day after the state announced its new proposed regulations, one of the most active Proposition 65 bounty hunter groups, the Mateel Environmental Justice Foundation ("Mateel"), filed a superior court lawsuit in Oakland, California seeking to invalidate Proposition 65's

# TOXICS REGULATION AND TOXIC TORT

longstanding "safe harbor" warning threshold for lead. The lawsuit contends that the 0.5 microgram/day regulatory warning threshold for lead, already the most stringent in the world, was not set consistent with Proposition 65's 1,000-fold safety factor requirement for reproductive toxicants. It therefore argues that the 0.5 microgram/day warning threshold for lead should be declared illegal and inoperative despite its having been published as a final rule more than 25 years ago. If this were to occur, prior compliance determinations or even court-approved settlements based on the existing lead warning threshold could be called into question. Mateel further argues that OEHHA should be ordered to promptly establish a dramatically more stringent safe harbor level for lead based on controversial scientific views that have evolved over the past two decades.

It is currently unknown whether the California Attorney General will vigorously defend the longstanding regulatory safe harbor level or instead attempt to settle this lawsuit with some sort of compromise. The risk is that businesses can ill-afford the revision to the lead warning threshold that Mateel contends the statute demands. Such a result would likely mean that any product that presents an exposure to *any* detectable amount of lead, no matter how small, will require a Proposition 65 reproductive harm and birth defects warning. If this were to occur, reformulation standards that have established thresholds for such warnings based on the concentration of lead in a product would likely become meaningless, as most have been justified on the basis of the 0.5 microgram/day safe harbor level that is the subject of Mateel's attack.

In sum, this is no time for businesses subject to Proposition 65 to rest comfortably, regardless of whether they have been giving warnings or relying on widely used reformulation standards/warning thresholds, including those often employed by international third-party testing laboratories to "pass" products for Proposition 65 compliance. Business should consider actively participating in OEHHA's current rulemaking process by providing feedback on the agency's warning and website proposals before its announced public comment deadline of April 8, 2015. Further steps include active support for the Attorney General's potential defense of the Mateel lawsuit—or possibly joining other businesses and trade associations in intervening in the case.

## TOXICS OUTLOOK FOR 2015

Toxic tort lawsuits rely upon the availability of information, including studies and data regarding the potential injuries and exposure pathways, from the use of chemicals. California is poised for a massive expansion of the collection and availability of such information. In its Green Chemistry Initiative, adopted in 2013, the state proposed to create a web-based collection of such data collected from other authoritative health agencies and non-government organizations. It has further adopted Safer Consumer Product Regulations that will allow the state's Department of Toxic Substances Control to require consumer product companies to perform detailed studies of potential safer substitutes for chemicals in their products, and to disclose detailed information about their manufacture, composition, and end-of-life effects. More information about these new regulations can be found on our web portal at *www.mofo.com/generalcontent/resources/greenchemistry*.

In addition, OEHHA is also proposing that it operate a website to provide information to the public to supplement and explain the basis for the Proposition 65 warnings given by businesses. Information to be provided on this website may include the routes or pathways by which exposure to a chemical from a product may occur, OEHHA's quantification of the level of exposure to a chemical presented by a product, and other information that may be of interest to bounty hunter plaintiffs as well as to sensitive consumers and other members of the public.

Significantly, in addition to its potential public education function, the proposed website regulations also empower OEHHA to demand that manufacturers, importers, and distributors of products bearing a Proposition 65 warning provide the agency with information. Such information may include the identities of the chemicals in the product for which a warning is being given, the location or components of a product in which such chemicals


are present, the concentration of those chemicals, and "any other information the lead agency deems necessary." While trade secret protection may be asserted in some circumstances, the requirement to provide information upon request will be enforceable by public prosecutors, including the California Attorney General and District Attorneys. We are carefully monitoring these developments and the new burdens they will place on consumer product companies.

## KEY PRACTICE HIGHLIGHTS

### COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS COFFEE LITIGATION

Represent every major producer of packaged or brewed coffee sold in California, including Folgers, Green Mountain Coffee Roasters, illy, and Maxwell House, in litigation brought by the Council for Education and Research on Toxics regarding the presence of acrylamide in coffee. We recently went to trial on the merits of the case and are awaiting the judge's decision.

### *PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE V. KFC CORP.*

Secured a victory on behalf of KFC and YUM! in Proposition 65 enforcement action brought by a vegan group seeking to use Prop. 65 warnings to stigmatize the consumption of grilled chicken. The trial court sustained defendants' demurrer on a number of grounds, including that the plaintiff's failure to obtain evidence of an actual violation of Proposition 65 before serving its mandatory pre-suit notice rendered its notice inadequate and its complaint invalid. The California Court of Appeal agreed, affirming the judgment in February 2014.

### CALIFORNIA RETAILER WORKING GROUP

Working with California's largest retailers to address ambiguities and contradictions in the state's hazardous waste regulations. Retailers have been fined hundreds of millions of dollars for violation of California's hazardous waste regulations. These regulations were designed for industrial facilities producing toxic wastes rather than "expired" or other unsaleable consumer products such as vitamins, cosmetics, and shampoo.

### FIRE RETARDANT CHEMICALS LITIGATION

Led an industry joint defense group in sidelining litigation alleging that products containing foam cushioning had been treated with fire retardants containing toxic chemicals like TDCPP and TCEP. We negotiated a master consent judgment allowing companies to avoid the continued use of certain chemicals, deploy non-chemical fire retardant barrier systems for certain products, and sell off their existing inventories. By employing this strategy, we minimized litigation and discovery expenses and protected the upholstered furniture's and juvenile product's industries images.

### FOOTWEAR DEFENSE

Defend client against a lawsuit in which the Center for Environmental Health (CEH) alleges that client manufactures, distributes, and/or sells footwear without providing a clear and reasonable warning that its footwear contains lead, a chemical listed under Proposition 65.

# PUBLICATIONS

## CONSUMER PRODUCTS/ TOXIC REGULATIONS

**"Coming Christmas 2014: California Adds Another Phthalate Chemical to Its Proposition 65 List,"** Client Alert, 1/8/14, Robert Falk and William Tarantino.

**"Lead Paint Companies Hit With Billion Dollar Judgment in California Public Nuisance Case,"** Client Alert, 1/13/14, Peter Hsiao and Andrew Stanley. Republished in *Product Liability Law360*, 2/5/14 and *International Law Office*, 2/6/14.

**"California's Green Chemistry Initiative – The Safer Consumer Product Regulations,"** *Environmental Law*, 2/5-7/14, Peter Hsiao, Sv027 Ali-Cle 173.

**"Toxics In Consumer Products: California Implements Safer Consumer Product Regulations,"** *Environmental Law*, 2/5–7/14, Peter Hsiao, SV027 ALI-CLE 169.

**"Safer Consumer Products Program Focus For California Chemical Regulators in 2014,"** *Environmental Law*, Peter Hsiao, 2/5–7/14, Sv027 Ali-Cle 153.

**"Proposed Changes to CPSA Section 6(b) Reduce Protections Currently Available to Manufacturers and Private Labelers,"** *Bloomberg BNA Product Safety & Liability Reporter*, 2/24/14, Erin Bosman, Ellen Adler, and Sara Bradley.

**"Like a Zombie, Mandatory Genetically Engineered Food Labeling Proposal Resuscitated in California,"** Client Alert, 2/27/14, Michael Steel and Alejandro Bras.

**"Crusade For Genetically Engineered Food Labeling Continues,"** *Consumer Protection Law360*, 3/14/14, Michael Steel and Alejandro Bras.

**"California Announces First Consumer Products Subjected to New Green Chemistry Rules,"** Client Alert, 3/13/14, Peter Hsiao and William Tarantino. Republished in *International Law Office*, 4/3/14.

**"New Prop 65 Warning Requirements on the Horizon?"** Client Alert, 3/18/14, Michael Steel and Dan Gershwin.

**"New Calif. Chemistry Product Rules: A National Template?"** *Environmental Law360*, 3/21/14, Peter Hsiao, William Tarantino, and Robert Falk.

**"California setting the pace for toxic chemical protections,"** *San Francisco Daily Journal*, 3/24/14, Peter Hsiao, William Tarantino, and Robert Falk.

**"Genetically engineered food labelling bill moves through legislature,"** *International Law Office*, 5/15/14, Michael Steel and Alejandro Bras.

**"Looking to Litigate in Secret? Fourth Circuit Creates Hurdles for Product Manufacturers,"** Client Alert, 5/20/14, Erin Bosman, Julie Park, and Chika Arakawa. Republished in *International Law Office*, 5/29/14.

**"The Epic Buckyballs® Saga Settles,"** Client Alert, 5/30/14, Erin Bosman, Julie Park, and Jeffrey David. Republished in *International Law Office*, 6/5/14.

**"GMO Bill Fails in California Senate,"** Client Alert, 6/2/14, Michael Steel and Alejandro Bras. Republished in *International Law Office*, 6/19/14.

**"The 'Discovery' Rule Is No Longer Supreme: The Supreme Court Holds That State Statutes of Repose Are Not Preempted by CERCLA,"** Client Alert, 6/11/14, Peter Hsiao, William Tarantino, Robert Falk, and Andrew Stanley.

**"CPSC Emphasizes Internet Presence with New Monthly Progress Reporting Template,"** Client Alert, 6/18/14, Erin Bosman, Ellen Adler, and Julie Park.

**"Nanotechnology And The Environment: Big Things In Small Packages,"** *Practical Real Estate Lawyer*, 9/14, Peter Hsiao and Andrew Stanley.

**"Seller Beware: California Announces Draft Plan for New Consumer Product Categories Under Its Green Chemistry Initiative,"** Client Alert, 9/15/14, Peter Hsiao, and William Tarantino. Republished in *International Law Office*, 9/25/14.

**"For Better or Worse: California Solicits Input on Further Revisions to Its Proposition 65 Regulations,"** Client Alert, 9/17/14, Robert Falk, Michèle Corash, and Michael Steel. Republished in *International Law Office*, 10/23/14.

**"Get Ready Now for the Upcoming Proposition 65 Warning Requirements for DINP and Other Chemicals,"** Client Alert, 10/7/14, Michael Steel.

**"CPSC Imposes Record-High Penalties in 2014,"** Client Alert, 11/11/14, Erin Bosman and Julie Park. Republished in *International Law Office*, 12/4/14.

## PHARMACEUTICALS AND MEDICAL DEVICES

**"Comment Period Extended for Proposed Rule on Changes-being-effected Supplements,"** *International Law Office*, 1/16/14, Erin Bosman, James Huston, and Julie Park.

**"New Jersey punitive damages analysis ignores established precedent,"** *International Law Office*, 1/23/14, Erin Bosman, Julie Park, and Chris Dalton.

**"*Lance v. Wyeth*: A New Cause of Action in Pennsylvania?"** Client Alert, 1/28/14, James Huston, Erin Bosman, and Jessica Roberts. Republished in *AIG Legal Insights*, Spring 2014.

**"$4 Billion Price Tag for Pleasing Plaintiffs' Bar? New Study Estimates Costs of FDA's Proposed Rule on Generic Drug Labeling,"** Client Alert, 2/26/14, Erin Bosman, James Huston, Jessica Roberts, Julie Park, and Sara Bradley. Republished in *International Law Office*, 3/13/14, and *Westlaw Journal Pharmaceutical*, 4/15/14.

**"'Brand' New Law: Illinois Court Holds Brand Manufacturers Owe Duty of Care to Generic Users,"** Client Alert, 3/6/14, James Huston, Erin Bosman, and Julie Park. Republished in *Product Liability Law360*, 3/14/14.

**"Launch of openFDA Increases Accessibility to Adverse Drug Event Reports,"** Client Alert, 6/17/14, James Huston, Erin Bosman, and Julie Park. Republished in *International Law Office*, 7/3/14.

**"Drugs and the Internet: FDA Distributes New Draft Guidance Regarding Social Media Platforms and Prescription Drugs,"** Client Alert, 6/25/14, Erin Bosman and Joanna Simon. Republished in *International Law Office*, 7/17/14.

**"The Ghosts of Litigation Holds Past,"** Client Alert, 7/24/14, James Huston, Erin Bosman, and Kimberly Gosling. Republished in *International Law Office*, 8/14/14.

**"Weeks II: Innovator Liability Finds a Sweet Home in Alabama,"** Client Alert, 8/20/14, James Huston, Erin Bosman, and Julie Park. Republished in *Law360*, 9/4/14.

**"Engle: A Mass Tort Run Amok,"** *International Law Office*, 10/30/14, James Huston, Erin Bosman, Julie Park, and Sara Bradley.

**"Ninth Circuit Offers Guidance to Defendants Seeking to Establish Removal Jurisdiction,"** Client Alert, 11/6/14, Chris Dalton, Kim Gosling, and Don Rushing.

**"'Generic' Logic Helps Branded Drug Achieve Dismissal,"** Client Alert, 11/6/14, James Huston, Erin Bosman, and Julie Park.

## AVIATION

**"Airlines Are Entitled to Immunity under the ATSA Unless Statements Are Materially False,"** Client Alert, 1/28/14, Joanna Simon, Ellen Adler, William O'Connor, and Brian Matsui.

**"Narayanan v. British Airways: Ninth Circuit Says the Montreal Convention's Statute of Limitations May Begin to Run Before Claim Accrues,"** Client Alert, 3/24/14, Joanna Simon and William O'Connor.

**"Ventress III Provides Another Tool for Airlines: Ninth Circuit Says Federal Aviation Act Preempts Pilot's State Law Employment Claims,"** Client Alert, 3/31/14, Joanna Simon, Ellen Adler, and William O'Connor. Republished in *Law360*, 4/10/14.

**"Unruly Passengers Beware: ICAO Delivers Montreal Protocol 2014 to Enhance Enforcement Measures Against Unruly Passengers,"** Client Alert, 4/29/14, William O'Connor, Ellen Adler, and Joanna Simon.

**"Drones: A Bird's-Eye View of the (Non-Privacy) Legal Landscape for UAS,"** Client Alert, 5/20/14, William O'Connor, Joanna Simon, and Sara Bradley.

**"Drones: Hollywood's Requests for Regulatory Exemptions from the FAA Could Get UAS for Commercial Use Off the Ground,"** Client Alert, 6/4/14, William O'Connor, Joanna Simon, and Sara Bradley.

**"Drones: When, Why, and How Will the FAA Investigate Unauthorized UAS Use?"** Client Alert, 7/29/14, William O'Connor, Joanna Simon, and Sara Bradley.

**"Drones: The FAA Grants Hollywood the First Regulatory Exemptions Permitting the Commercial Use of UAS,"** Client Alert, 9/26/14, William O'Connor, Chris Carr, and Joanna Simon. Republished in *Law360*, 9/30/14.

**"Drones: Why You Should Start Thinking Now About the Anticipated UAS Regulations,"** Client Alert, 10/23/14, William O'Connor, Chris Carr, and Joanna Simon. Republished in *Law360*, 10/23/14.

**"*Huerta v. Pirker*—NTSB Says No More 'Gray Area' for Drone Operations,"** Client Alert, 11/20/14, William O'Connor, Christopher Carr, Joseph Palmore, and Joanna Simon.

**"May State and Local Governments Control Low-Flying Drones?"** Client Alert, 12/3/14, William O'Connor, Christopher Carr, Zane Gresham, Joseph Palmore, and Joanna Simon.

# KEY CONTACTS


**JAMES BERGIN**
Senior Counsel, New York
(212) 468-8033
jbergin@mofo.com

**ERIN BOSMAN (CHAIR)**
Partner, San Diego
(858) 720-5178
ebosman@mofo.com

**TIFFANY CHEUNG**
Partner, San Francisco
(415) 268-6848
tcheung@mofo.com

**MICHÈLE CORASH**
Partner, San Francisco
(415) 268-7124
mcorash@mofo.com

**GRANT ESPOSITO**
Partner, New York
(212) 468-8166
gesposito@mofo.com

**ROBERT FALK**
Partner, San Francisco
(415) 268-6294
rfalk@mofo.com

**DAVID FIOCCOLA**
Partner, New York
(212) 336-4069
dfioccola@mofo.com

**ARTURO GONZÁLEZ**
Partner, San Francisco
(415) 268-7020
agonzalez@mofo.com

**PETER HSIAO**
Partner, Los Angeles
(213) 892-5731
phsiao@mofo.com

**JAMES HUSTON**
Partner, San Diego
(858) 720-5154
jhuston@mofo.com

**WILLIAM JANICKI**
Of Counsel, San Diego
(858) 720-5195
wjanicki@mofo.com

**REBEKAH KAUFMAN**
Partner, San Francisco
(415) 268-6148
rkaufman@mofo.com

**CHARLES KERR**
Partner, New York
(212) 468-8043
ckerr@mofo.com

**DANIEL LEVISON**
Partner, Singapore
+65 6922 2041
dlevison@mofo.com

**DAVID MCDOWELL**
Partner, Los Angeles
(213) 892-5383
dmcdowell@mofo.com

**WILLIAM O'CONNOR**
Partner, San Diego
(858) 720-7932
woconnor@mofo.com

**JULIE O'NEILL**
Of Counsel, Washington D.C.
(202) 887-8764
joneill@mofo.com

**DENNIS ORR**
Partner, New York
(212) 468-8161
dorr@mofo.com

**CHARLES PATTERSON**
Senior Counsel, Los Angeles
(213) 892-5553
cpatterson@mofo.com

**PENELOPE PREOVOLOS**
Partner, San Francisco
(415) 268-7187
ppreovolos@mofo.com

**DON RUSHING**
Partner, San Diego
(858) 720-5145
drushing@mofo.com

**JAMES SCHURZ**
Partner, San Francisco
(415) 268-6449
jschurz@mofo.com

**ROBIN STAFFORD**
Of Counsel, San Francisco
(415) 268-6674
rstafford@mofo.com

**MICHAEL STEEL**
Partner, San Francisco
(415) 268-7350
msteel@mofo.com

**WILLIAM STERN**
Partner, San Francisco
(415) 268-7637
wstern@mofo.com

**WILLIAM TARANTINO**
Partner, San Francisco
(415) 268-6358
wtarantino@mofo.com

**DAVID WALSH**
Partner Los Angeles
(213) 892-5262
dwalsh@mofo.com

MORRISON
FOERSTER

© 2015 MORRISON & FOERSTER LLP