crowell moring

CLIENT ALERT

Recent Happenings in Advertising & Product Risk Management - April 2013

Apr.19.2013

IMPORTANT HEADLINES YOU MAY HAVE MISSED

1) Supreme Court Hears Latest Preemption Arguments from Drug Manufacturers

On March 19, 2013, the Supreme Court of the United States heard oral argument in *Mutual Pharmaceutical Co. v. Bartlett*, Docket Number 12-142, to decide whether federal law preempts state law design defect claims against manufacturers of generic drugs. The *Bartlett* case is the latest battleground in the fight over whether and how both brand-name and generic pharmaceutical manufacturers may be held liable for injuries allegedly caused by their products.

In 2009, the Supreme Court ruled in *Wyeth v. Levine*, 555 U.S. 555 (2009), that federal law did not preempt state-based failure to warn claims brought against brand-name pharmaceutical manufacturers. Just two years later, however, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Court cabined its prior holding, ruling that federal law preempted the same failure to warn claims brought against *generic* drug makers. To justify this distinction, the Court reasoned that the Federal Food, Drug, and Cosmetic Act (FDCA) requires labeling for generic drugs to mirror the labels accompanying their brand-name counterparts, and thus that generic drug manufacturers could not be held liable for failing to add additional warnings.

While *Mensing* cut off most plaintiffs' attempts to hold generic pharmaceutical manufacturers liable under a failure to warn theory, the Court said nothing about cases proceeding under a design defect theory. It has the opportunity now to address that question in *Bartlett*.

In *Bartlett*, the defendant generic manufacturer argued that plaintiff's design defect claims are also preempted by federal law. Just as the FDCA precludes generic drug manufacturers from changing their products' labeling without FDA approval, the defendant reasoned that it also precludes manufacturers from changing the drug itself. Accordingly, any defect in the design of the drug is not the generic drug manufacturer's responsibility.

Both the federal district court and the U.S. Court of Appeals for the First Circuit rejected the manufacturer's argument. In particular, the First Circuit noted that the manufacturer did not need to change the drug to solve a defective design problem; rather, the manufacturer could just stop selling the drug.

The Solicitor General, arguing on behalf of the United States, sided with the manufacturers in *Bartlett*. This stands in contrast to the government's position in *Mensing*, when it supported the plaintiff's argument that federal law does not preempt state-based failure to warn claims against generic manufacturers. In *Mensing*, the United States had argued that while a generic drug label must mirror the label of its brand-name counterpart, generic drug manufacturers still had a duty to propose changes to the approved label to warn against serious hazards. Now the Solicitor General is arguing to extend *Mensing*'s holding, contending that design defect claims undercut FDA's evaluation of the safety risks and its conclusion that a drug was safe and effective for

its approved use. Notably, however, the government's argument would leave the door open to state-based design defect claims based on new and scientifically significant information that renders a drug misbranded under federal law.

The legal battles continue in fronts outside the Supreme Court as well. For instance, earlier this year in *Wyeth, Inc. v. Weeks*, No. 1101397 (Ala. Jan. 11, 2013), the Alabama Supreme Court held that plaintiffs taking generic versions of drugs can sue the brand-name drug manufacturer for failure to include adequate warnings in the drug's labeling. The Court concluded that the brand-name manufacturer should have foreseen that a doctor would rely on the brand-name manufacturer's warnings, even if the patient ultimately uses the generic counterpart. Because *Mensing* precluded plaintiffs from suing the generic manufacturers directly under the failure to warn theory, their only available recourse was to sue the brand-name manufacturer. Most courts to hear claims of "innovator liability" have rejected them, but courts in California and Vermont, like the Alabama Supreme Court, have sided with plaintiffs.

As the preemption battle continues against pharmaceutical manufacturers, Crowell & Moring will continue to monitor these fronts as well as any other new avenues for liability pursued by plaintiffs.

For more information, contact: John Fuson, Michael Kuppersmith

2) Chemistry Industry Files Suit to Prevent State from Placing BPA on Prop 65 List

The American Chemistry Council (ACC) recently filed a lawsuit against California's Office of Environmental Health Hazard Assessment (OEHHA) in an effort to block OEHHA from placing bisphenol A (BPA) on the Proposition 65 list of "known" reproductive toxins. ACC claims that the proposed addition of BPA to the Prop 65 list is scientifically "unjustified," and no governmental agency has ever found that BPA is a reproductive health concern.

Under Prop 65's so-called "authoritative bodies" mechanism, a chemical may be listed as known to cause reproductive toxicity "if a body considered to be authoritative by [the state's qualified experts] has formally identified it as causing…reproductive toxicity." (California Health & Safety Code §25249.8, Subd. (b).) Here, OEHHA proposed listing BPA based on a 2008 report from the National Toxicology Program which found high levels of BPA exposure caused developmental toxicity in laboratory rats and mice. However, in 2009, OEHHA's Scientific Panel relied on the same NTP report to conclude that BPA did **not** meet the listing requirements for reproductive toxicants under Prop 65.

ACC contends that the 2008 NTP Report, based only on animal studies, expressly noted that the high doses of BPA used in the experiments were "far in excess of the highest estimated daily intake of bisphenol A in children, adults or workers," and that "to reach the excessive doses of BPA in those animal studies would have required the average human to consume over 170,000 twelve-ounce cans of food or beverages *per day, every day, for a lifetime.*" ACC further claims that the Report does not formally identify BPA as causing reproductive toxicity; since the studies were only conducted with laboratory animals, there is only "limited evidence" of adverse effects on human health. Thus, ACC asserts that OEHHA's proposed addition of BPA to the Prop 65 list directly contradicts the statutory requirements.

This lawsuit is of particular importance because the Court must decide the proper role that science should play in the determination to add chemicals to the Prop 65 list. Notably, this lawsuit follows on the heels of the Court of Appeal's decision in

Styrene Information & Research Center v. OEHHA, 210 Cal.App.4th 1082 (2012), holding that IARC 2B chemicals that are "possible human carcinogens" should not be included on the Prop 65 list.

Even if the ACC wins its suit, companies are still likely to continue to reformulate their products to eliminate BPA where practical or mandated. Effective July 1, 2013, California Assembly Bill 1319 will prevent the manufacture, sale or distribution in California of any bottle or cup that contains BPA at a detectable level above 0.1 ppb if the product is intended to used by children three and younger.

The comments received in response to OEHHA's proposed listing of BPA are posted on the OEHHA website.

For more information, contact: Lynn Levitan

3) FDA's Peanut Company of America Prosecution: Don't Mistake it as Setting the Bar

On February 21, the Department of Justice charged four former officials of the Peanut Corporation of America and a related company with numerous violations of the Federal Food, Drug, and Cosmetic Act as well as other federal statutes. The indictments alleged deliberate misconduct relating to salmonella-tainted peanuts and peanut products. In this article published last month, Crowell & Moring attorneys Ann Mason Rigby and John Fuson discuss the risk of criminal prosecution under the FDCA, even when the allegations are less spectacular or in the absence of criminal intent, and note how this case offers yet another reminder that the cover-up is often worse than the crime.

For more information, contact: Ann Rigby Mason, John Fuson

4) Rare Proposition 65 Trial Could Spark Robust Appellate Litigation

Trials in Proposition 65 cases are extremely rare—only 9 out of 3000 have actually gone to trial since the voter initiative went into effect in 1986. Currently, however, a private Prop 65 enforcer, The Environmental Law Foundation (ELF), is engaged in a bench trial against 16 baby food manufacturers, in the Alameda County Superior Court. ELF's claim is that the manufacturers failed to provide the required Prop 65 warnings for lead in their products, including carrots, peaches, pears and sweet potatoes, grape juice and fruit cocktail. Judge Steven Brick is being called upon to make potentially groundbreaking decisions concerning certain affirmative defenses raised by the companies. These will likely be taken up on appeal by the aggrieved parties, and could impact Prop 65 for years to come.

The principle issue advanced by defendants is federal preemption. The companies contend the Prop 65 warning requirement is preempted because the Food & Drug Administration (FDA) has determined that the products at issue do not pose unacceptable risks to consumers. Thus, they claim that to require Prop 65 warnings for these food products creates a conflict between state and federal law, making compliance with controlling federal law impossible.

Judge Brick is also being asked to decide, pursuant to the Prop 65 regulations, the most appropriate way to measure lead levels in the food products. ELF contends it is proper to use data from only a single day of exposure, while the manufacturers contend that a proper measurement must account for how often the product is consumed over time. The purported concentration of Prop 65-listed chemicals in a product, and hence the presumed level of consumer exposure, is often a hotly contested, and

costly, issue for parties in Prop 65 litigation because the current statutory scheme and case law provide little useful guidance. Accordingly, Judge Brick's decision, and the inevitable appeals, will likely influence the method and manner in which exposure data is generated, and interpreted, in future Prop 65 cases.

Lastly, the Court is expected to address the "naturally occurring substance" exception to Prop 65 application. This provides that food containing a purportedly excessive level of a Prop 65-listed chemical is exempted from the warning requirement if the chemical naturally occurs in that product. According to the manufacturers, virtually all of the lead present in their products is present in the soil from which the materials in their products are farmed, and is thus "naturally occurring." Further, they contend there are no agricultural or manufacturing mechanisms to ameliorate the presence of this lead.

Whichever side loses here (and, arguably, both sides could come away disappointed by the Court's multiple expected rulings) is expected to appeal, and it is conceivable the California Supreme Court could ultimately become involved, for the first time in many years, in deciding questions of law concerning Prop 65 matters.

For more information, contact: Lynn Levitan

5) Allegation of Data Breach Alone Insufficient to Sustain Claims Based on Inadequate Cybersecurity

On March 6, 2013, the United States District Court for the Northern District of California held that a putative class of LinkedIn premium users lacked standing to pursue state law unfair competition, breach of contract, and negligence claims resulting from a hacking incident. The court dismissed the complaint, concluding that the plaintiffs failed to establish any legally cognizable injury and any causation between the alleged incident and any alleged economic harm.

LinkedIn, the online community for professional networking, offers both free and premium paid accounts to consumers. The Privacy Policy applicable to both types of accounts provides that user information will be protected with "industry standard protocols and technology," but notes that it provides no guarantee that LinkedIn's security will be able to prevent all security breaches. On June 6, 2012, hackers infiltrated LinkedIn's computer systems and posted 6.5 million user passwords and email addresses. LinkedIn subsequently updated its password encryption method to prevent future breaches.

A putative class of premium LinkedIn users filed an amended complaint alleging unfair competition, breach of contract, and negligence claims. LinkedIn filed a motion to dismiss for lack of standing, which the court granted.

The plaintiffs claimed that they suffered "economic harm" because they were denied the full benefit of their bargain for the paid premium memberships. Specifically, the plaintiffs alleged that they would not have purchased the premium product absent the security guarantees, and that the 2012 hacking incident shows they did not receive the promised security. The court rejected the plaintiffs' "economic harm" argument for several reasons.

First, the plaintiffs failed to show that they paid consideration for LinkedIn's promise to safeguard their information because the same security policies applied equally to the free and paid accounts. Second, unlike situations involving food-labeling misrepresentations, the plaintiffs did not allege that they actually read the alleged misrepresentation—the Privacy Policy—and thus failed to show a causal relationship between the misrepresentation and any injury. Third, the plaintiffs failed to show that the alleged breach of contract (*i.e.*, failing to provide the security promised in the Privacy Policy) caused the economic loss (*i.e.*, not receiving the full benefit of the bargain). Instead, the court concluded that the injury could only have occurred before the

hacking incident at the time the parties entered into the contract. This particular aspect of the opinion addressing the timing of the alleged injury is likely to be the subject of debate. It was not, however, the sole basis for rejecting the plaintiffs' economic harm allegations. Indeed, the court also made clear that where plaintiffs allege harm from a defective product, plaintiffs must show "something more" than the economic harm of "overpaying for the defective product." Here, the plaintiffs alleged only that LinkedIn provided defective security, not that LinkedIn provided a product different than what the plaintiffs purchased. Consequently, the court concluded that the plaintiffs would need to allege "something more" resulted from the defective security, such as identity theft, which they did not do.

In addition to rejecting the plaintiffs' "economic harm" arguments, the court also held that the increased risk of future harm did not establish an injury sufficient to confer standing. The court concluded that the plaintiffs failed to state a legally cognizable injury by merely alleging that their passwords were publicly posted as opposed to alleging identity theft.

Based on the pleadings before it, this court concluded that the mere allegation of a security breach does not automatically confer Article III standing or provide the basis for cognizable state common law claims. Rather, the failure here to allege an injury beyond "overpaying" for a service, *e.g.*, identity theft, required dismissal of these claims. The court also rejected the plaintiffs' claimed injury stemming from an increased risk of future identity theft, deeming it speculative and thus insufficient to sustain the claims. This decision bolsters the "lack of standing" defense to claims premised on security breaches brought in federal court. The case is *In re LinkedIn User Privacy Litigation*, 2013 WL 844291 (N.D. Cal. Mar. 6, 2013).

For more information, contact: Jeff Poston

6) Federal Court Dismisses Class Action Complaint Based on NAD Decision

On February 11, 2013 a federal district court in New Jersey dismissed a putative class action false advertising complaint, holding that the complaint's core allegation that the advertising had been found "unsubstantiated" by the National Advertising Division of the Council of Better Business Bureaus (NAD) could not meet the required legal standard of showing the ad to be "false" under the New Jersey Consumer Fraud Act. The decision represents an important watershed for the NAD process, which had been under duress because of growing copycat class action fears, and is a reminder that class action complaints cannot be sustained solely on allegations that the advertiser lacks adequate substantiation for its claims.

In recent years, there has been an explosion of consumer class actions premised on allegations of false and unsubstantiated advertising. Plaintiffs in such cases often pattern their complaints on published Federal Trade Commission (FTC) consent orders or on NAD's written decisions. These kinds of complaints often do little more than rehash the FTC or NAD decisions, which most often are premised on a finding that advertiser lacked adequate prior substantiation for the claims, and not on proof that the advertising is actually false.

As recently decided by the United States Court for the District of New Jersey, however, private plaintiffs must meet a higher burden than simply alleging the advertising is unsubstantiated. In *John Gaul, et al. v. Bayer Healthcare LLC*,2013 U.S. Dist. LEXIS 22637 (D.N.J 2013), Plaintiffs had filed a complaint on the heels of a report issued by NAD in which NAD found that Bayer, the makers of Citracal® SR calcium supplement, did not have sufficient support for the claim that the calcium supplement was twice as potent as the leading product. Plaintiffs, on behalf of a putative class, claimed Bayer had violated the New Jersey Consumer

Fraud Act based entirely on the allegation that NAD had ruled that Bayer lacked adequate substantiation for its claims and that, as a result, the claims should be considered false.

The court dismissed the complaint, explaining that the Third Circuit distinguishes false advertising from inadequate substantiation and that the complaint only alleged inadequate substantiation, not false advertising. The court noted that the plaintiffs "appear not to recognize one of the distinctions fundamental to scientific research, the distinction between reliability and validity." *Id*. at n.4. The NAD report had found that Bayer's testing, which was offered as sole support for its claims, was unreliable in that it "shows signs that, if repeated, it would not produce the same results." *Id*. at *4. The NAD report had not, however, concluded that the claims were necessarily false. The court explained that a finding of unreliable testing does not lead to the logical conclusion that the marketing claims were actually false; indeed "[i]t is a very big leap from this assert [of unreliable testing] to the conclusion that Bayer's labeling claims are false." *Id*. In other words, simply because the NAD had found the claims to be unsubstantiated does not mean that the claims are necessarily false. To carry its burden, the plaintiff would have had to make a plausible allegation tending to show that the potency of the product had been overstated.

NAD itself, which has voiced concerns that the growing number of plaintiffs attempting to copy NAD decisions in their class action complaints will discourage advertisers from participating in the NAD process, immediately touted the decision in a release to law firm members of the BBB: "As we have reinforced through a recent amendment to our Procedures, self-regulation is about holding advertisers to high standards set by the industry, not about whether the law has been violated." In September 2012, NAD issued an amendment to its Procedures stating that "an advertiser's voluntary modification of advertising, in cooperation with NAD/CARU/ NARB self-regulatory efforts, is not to be construed as an admission of any impropriety."

For more information, contact: Dina Epstein, Chris Cole

CROWELL AND MORING SPEAKS

The Crowell & Moring Advertising & Product Risk Management Group hosted a seminar on March 19, 2013, titled "Staying Afloat When Your Brand is Under Pressure: How to Avoid, Mitigate and Manage Product Crises." In conjunction with the seminar, the group published a *Crisis Management Handbook*, which can be found here. To request a hard copy of the Handbook, please contact Gabrielle Ballantine.

Lynn R. Levitan spoke on "Assessing and Managing Human Health Risks in the U.S.: Striking a Balance Between Costs, Benefits, Efficacy and Unintended Consequences" at The Association for Environmental Health and Sciences Foundation's 23rd Annual International Conference on Soil, Water, Energy, and Air, in San Diego, March 20, 2013.

John B. Brew and **John Fuson** spoke at the Grocery Manufacturer's Association Science Forum on April 3, 2013, at Marriott Wardman Park in Washington, D.C. Their panel included a discussion of Understanding the Food Safety Modernization Act's Impact on your International Supply Chain.

Cheryl A. Falvey and **Scott L. Winkelman** will be speaking at "The National Law Journal Presents 'Crisis Litigation: Navigating Fallout from Catastrophic Events'" on May 1, 2013 in New York. Their panel is titled "Strategic Legal Planning: Best Practices for 2013 & Beyond."

* * *

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Christopher A. Cole
Partner – Washington, D.C.
Phone: +1 202.624.2701
Email: ccole@crowell.com

Cheryl A. Falvey
Partner – Washington, D.C.
Phone: +1 202.624.2675
Email: cfalvey@crowell.com

John Fuson
Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

Jeffrey L. Poston
Partner – Washington, D.C.
Phone: +1 202.624.2775
Email: jposton@crowell.com