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CLIENT ALERT

Recent Happenings in Advertising & Product Risk Management – July 2017

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This news bulletin is provided by the Advertising & Product Risk Management Group of Crowell & Moring. If you have questions or need assistance, please contact Chris Cole, Cheryl Falvey, or any member of the APRM Group.

FEATURED ARTICLE

Adverse Event Reports for Cosmetics Products: Additional Litigation Risk?

According to a new Research Letter published in JAMA Internal Medicine, consumer complaints of adverse effects caused by cosmetic products are dramatically increasing. The Food and Drug Administration first began publishing data from its Center for Food Safety and Applied Nutrition's (CFSAN) Adverse Event Reporting System (AERS) in December 2016. Researchers at Northwestern University's Dermatology Department analyzed AERS cosmetic-related data collected between 2004 and 2016, and found a 78 percent increase in in 2015 and a 300 percent increase in 2016 compared with the mean across the entire time period (2004-2016). The three most implicated product classes were hair care products, skin care products, and tattoos.

This increase was largely driven by hair care products, which comprised 35 percent of all complaints logged over the twelve-year period. A large number of the recent adverse events came from one product. FDA received 127 adverse event reports about WEN by Chaz Dean Cleansing Conditioner products, according to a July 19, 2016 FDA Safety Alert. FDA characterized this as "the largest number of reports ever associated with any cosmetic hair cleansing product" and reported that facility inspections uncovered more than 21,000 complaints made directly to the manufacturer/distributor. The large jump in adverse events reported to CFSAN is likely skewed not only because of the increase in complaints as to this one product, but also because reporting is voluntary – there is no legal obligation to report for manufacturers, end users, or health care providers.

This analysis has significant limitations. There is no causality determination with regard to reports of health outcomes, many of which are unreliable given self-reporting by consumers and no ability to distinguish between reports provided by health care professionals vs. consumers. Indeed, the report reads more as an advocacy piece for (supposedly) better cosmetic surveillance and support for Senator Diane Feinstein's Personal Care Products Safety Act , which proposes FDA recall authority over cosmetics and mandatory adverse event reporting for cosmetics manufacturers.

This kind of advocacy, based on incident reporting and not causation, and the recent settlement of the WEN class action lawsuit, show the very real dangers faced by those in the cosmetics and personal care products industry. Not only is the industry subject to the common false advertising class action alleging misbranded labels or mischaracterized product descriptions, but it may now also face an increasing number of class actions involving personal injury claims.

As has come to be the norm, WEN's manufacturers were sued in a consumer class action in California. Plaintiffs invoked the usual claims of breach of warranty, false advertising, and unfair competition under California and Florida consumer protection laws, but went a step further and allege failure to warn and failure to test an inherently defective product. Plaintiffs alleged that the product was mislabeled not only because it claimed to be sulfate-free (but instead contains behentrimonium methosulfate), but also because it made the affirmative representation that it was "gentle enough to use every day" (but led to significant hair loss).

The parties recently filed a motion for final approval of a nationwide class settlement. The proposal consists of a $26.25 million fund for damages, an adverse event warning on the label, and allows for attorney's fees and costs up to $5.5 million.
This settlement highlights a big difference between the WEN case and the standard false advertising case. Although the WEN class complaint includes some standard labeling mischaracterizations, the driver of the settlement fund appears to be the personal injury claims of inherent design and manufacturing defects traditionally found in personal injury product liability cases.

This difference is reflected in the settlement structure: a Tier 1 claimant is eligible for $25 upon claiming a personal injury due to product use, while a Tier 2 claimant is eligible for up to $20,000 upon showing a bodily injury (including supporting documentation and determination by a Special Master). Likewise, the incentive award for the named plaintiffs with bodily injuries is $20,000, while the other named plaintiffs receive a more standard payment of $2,500.

Of course, defendants still have tools in their belt to defend cases like this. As the California Supreme Court has observed, class actions for personal injuries in mass tort litigation present a multitude of problems. "The major elements in tort actions for personal injury — liability, causation, and damages — may vary widely from claim to claim, creating a wide disparity in claimants' damages and issues of defendant liability, proximate cause, liability of skilled intermediaries, comparative fault, informed consent, assumption of the risk and periods of limitation." *Jolly v. Eli Lilly & Co*., 44 Cal.3d 1103, 1123 (1988).

A class action cannot be maintained if each individual plaintiff's right to recovery depends on facts peculiar to that individual. Defendants could therefore assert that the common questions required for class certification are overshadowed by the unique factual and legal issues presented by each individual claimant and her specific personal injury. An obvious issue for class certification would be the enormous number of individual questions that would inevitably arise to determine causation. A plaintiff must prove that the accused product was the actual known cause of the injury, so medical comorbidities must be individually explored and a deep dive taken into medical records. Defendants could also explore any concomitant product use, as in the WEN matter, where the accused product was sold as part of a kit. Correspondingly, the JAMA study acknowledges that the AERS data is limited in this same way because it only contains demographic information consisting of sex and age, and has no information on comorbidities or concomitant product use. Damages would present another area where more individual than common questions would be likely, since a proposed class may include those who suffered minor injury as well as those who suffered life-threatening reactions. Individual issues will also arise on the defense of mitigation.

In short, although the cosmetics and personal care industry faces an ever-increasing risk of lawsuits, unfounded suits can be fought and defeated.

For more information, contact: Michelle Gillette

LITIGATION ROUNDUP

The litigation arena for the consumer products industry is as active as ever. Each newsletter we bring you a summary of the most important litigation developments from the past two months, from complaint filings and key court decisions to trial results and settlements. For more information about these and other developments, please visit our Food & Beverage Industry Tracking Report.

Filed

Grocery Manufacturers of America File Brief in Support of Supreme Court Petition Over Class Ascertainability

On May 12, 2017, the Grocery Manufacturers of America and other major business groups filed amicus briefs in support of Conagra Brand's April 10, 2017 petition for writ of certiorari asking the U.S. Supreme Court to reverse a decision certifying 11

statewide classes related to "natural" Wesson oil labels. The Ninth Circuit decision eliminates the "ascertainability" requirement for class certification by holding that class representatives do not have to show an "administratively feasible" way to identify class members (purchasers of Wesson oil) as a prerequisite to class certification. *Conagra Brands, Inc. v. Briseno, U.S.*, No. 16-1221, brief filed 5/12/17.

Kellogg Hit with False Advertising Suit Over "Natural" Pringles Flavoring

On May 11, 2017, California consumers filed a putative class action suit against Kellogg Co. alleging that the "natural" vinegar flavoring in Pringles' salt and vinegar chips is artificial flavoring. Plaintiffs claim the advertising led them to pay more for what they considered a premium product than they otherwise would have. The suit was removed to federal court on July 5, 2017. *Allred v. Kellogg Co.*, No. 3:17-cv-01354 (S.D. Cal).

Settled

Honest Co. Settling "Natural" Class Action Suits

On July 10, 2017, a New York federal judge granted preliminary approval of a $7.35 million class settlement agreement between Honest Co. customers comprising four class action suits against the company. The suits concerned Honest Co.'s allegedly misleading "all natural," "100% natural," and "no harsh chemicals, ever!" advertising statements. The proposed settlement would also require the company to stop using "all natural" and "100% natural" statements and to stop using its "no harsh chemicals, ever!" claim if specified chemicals are present. *In Re: Honest Marketing Litig.*, No. 1:16-cv-01125 (S.D.N.Y).

Dismissed/Stayed

Federal Judge Dismisses Data Breach Class Action Against VTech

On July 5, 2017, an Illinois federal judge dismissed a class action suit over a data breach of VTech's digital learning toys. Judge Manish Shah found that consumers failed to show how allegations of future harm of potential identity theft met the standing requirements. In November 2015, VTech's servers were compromised and names, e-mail addresses, passwords, and messages, amongst other things, were obtained. VTech suspended online services for approximately two months to investigate and change security protocols. Consumers alleged they would have paid less for the products or not purchased them if they had known about the inadequate security measures and long-term service suspension. The federal judge found that the complaint did not show how consumer's purchases included both the product and the online services nor how the stolen information, which did not include credit card or debit card information, would be used to commit identity theft. *In Re: VTech Data Breach Litig.*, 1:15-cv-10889 (N.D. Ill.).

Blistex Packaging Deemed Not Deceptive

On July 5, 2017, Illinois District Judge Elaine Bucklo dismissed a proposed class action alleging that the Blistex applicator design is "deceptive." The plaintiff alleged that the design prevented customers from accessing all of the lip balm in the container as some would become trapped in the tip of the applicator. Judge Bucklo determined that the design of the applicator was apparent from the packaging and that consumers are aware that they may not extract every bit of common products from their packaging. *Hillen v. Blistex, Inc.*, 1:17-cv-02074 (N.D. Ill.).

REGULATORY ROUNDUP

With a new executive administration getting its bearings in Washington, the regulatory landscape is in a state of flux—with important changes on the horizon. Each newsletter we bring you a rundown of key developments for the consumer products industry from each of the three main regulatory agencies, as well as the NAD.

CPSC

- CPSC announced a request for information on potentially reducing regulatory burdens without increasing risk to consumers. Written submissions are due September 30, 2017.
- CPSC released a report showing that the number of reported fatal drownings of young children in swimming pools has decreased 17 percent nationwide since 2010. Notwithstanding the decrease, Acting Chairman Ann Marie Buerkle has urged vigilance when children are in and around water this summer. Relatedly, the CPSC released an updated report on suction entrapment incidents in swimming pools, spas and whirlpool bathtubs.
- On July 25, CPSC is holding a workshop on improving the effectiveness of consumer product recalls. The goal of the workshop is to identify proactive measures for effective implementation of recalls, from initial public announcement through product correction. There will be breakout sessions focusing on communicating the hazard, consumer motivation, in-store notification, and social media. The workshop will be held at the CPSC headquarters in Bethesda, MD. Click here for more information on the workshop.

FDA

- On July 6, 2017, the FDA announced the entry of a consent decree of permanent injunction between the United States and Medistat RX LLC, the company's co-owners, and its quality manager and pharmacist-in-charge. According to the FDA, Medistat manufactured and distributed drug products made under unsanitary conditions and in violation of requirements under the Federal Food, Drug and Cosmetic Act, and manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. The consent decree prohibits Medistat, its owners, and its pharmacist-in-charge from manufacturing, holding or distributing drugs until they comply with the Act and its regulations, in addition to other requirements.
- FDA has approved a new treatment for sickle cell disease, the first approval for this blood disorder in nearly 20 years.
- FDA has unveiled a strategic plan to eliminate its existing backlog of requests for orphan drug designation and ensure its timely responses to new requests.

FTC

- FTC Acting Chairman Maureen Ohlhausen announced the departure of Abbott (Tad) Lipsky, Acting Director of the FTC's Bureau of Competition, who retired earlier this month. Markus H. Meier, who has served as Acting Deputy Director of the Bureau of Competition since November 2015, replaces Mr. Lipsky as Acting Director of the Bureau of Competition.

As part of these changes, Acting Chairman Ohlhausen appointed Haidee L. Schwartz as an Acting Deputy Director of the Bureau of Competition.

- In June 2017, the FTC released updated guidance on the Children's Online Privacy Protection Act (COPPA) which will be of particular interest to manufacturers of IoT products for children capable of data collection. As part of its business education and enforcement efforts to protect children's privacy and safety online, the FTC's guidance sets forth a "step-by-step" plan for determining if a company is covered by COPPA and how to comply.
- The FTC submitted public comments to the U.S. Commerce Department's National Telecommunications and Information Administration (NTIA) working group responsible for developing guidance about ways for Internet of Things (IoT) device manufacturers to better inform consumers about security updates. The comments build on the FTC's enforcement and business education efforts on security for Internet-connected products, including Start with Security guidance and consent agreements with companies such as TrendNet and Asus.
- As part of ongoing enforcement in the lead generation business, on July 5, 2017, the FTC announced a settlement of charges that a company misled consumer into filling out loan applications and unlawfully sold those applications, including consumers' sensitive data, through websites offering to connect applicants with a network of lenders. As part of the settlement, the company has promised to protect and secure the sensitive information consumers provided, such as Social Security numbers and bank account numbers.
- The FTC announced the agenda for its first Economic Liberty roundtable event to be held July 27. The event will explore options for enhancing portability of occupational licenses across state lines.

NAD

- NAD has referred advertising claims by Verizon Communications Inc. for the Internet speed of Verizon FiOS to the FTC and FCC for further review, after the company declined to participate in NAD proceedings based on Comcast's challenge of claims, including "Fastest Internet Available" and "Fastest Most Reliable Internet Available."
- In a separate matter, NAD has recommended that Verizon Communications, Inc. modify or discontinue certain advertising claims for the Google Pixel, including the claim "Exclusively at Verizon." T-Mobile USA challenged claims regarding where Google Pixel, the first mobile phone made by Google is available, and Verizon modified or permanently discontinued some of those claims.
- On July 12, 2017, NAD referred advertising claims by Lab Door, LLC to the FTC for further review, after the company declined to participate in NAD proceedings. Jarrow Formulas, Inc., a maker of dietary supplements, has challenged the Internet claims of Lab Door concerning its dietary supplement ratings and rankings, including statements concerning safety, efficacy, and quality of advertised products.
- Also on July 12, 2017, the Children's Advertising Review Unit referred to the FTC for further review the company Genesis Toys, maker of "My Friend Cayla Party Time" doll and operator of an accompanying app and website, based on the company's response to an initial privacy inquiry.
- NAD has recommended that JustFab, Inc., modify "VIP offers" advertising for its "Fabletics" activewear to clearly and conspicuously disclose material terms and limitations of the membership program.

Crowell & Moring's Retail & Consumer Products Law Observer

Each week, Crowell & Moring's Advertising & Product Risk Management Group brings you the top stories in retail and consumer products law.

CPSC Hears Rare Oral Argument in Zen Magnets Recall Litigation

Scott Winkelman, Cheryl Falvey, Matthew Cohen, and Carolyn Wagner discuss the CPSC's fascinating hearing on Zen Magnets and small rare earth magnets. This article details the background of this controversial case and predicts the Commission will overturn ALJ Dean Metry's opinion and return Zen to the proverbial penalty box.

Who "Wood" Have Thought? Plaintiffs Challenge Longstanding Lumber Labeling Practices

Chalana Williams talks about two recent class action lawsuits against Menard and Home Depot regarding lumber labelling practices, raising an interesting question about "common knowledge" and the "average consumer."

U.S. Supreme Court: Shaping the Personal Jurisdiction Landscape in Product Liability Cases

Rebecca Chaney explains the impact of the Supreme Court's decision in *Bristol-Myers Squibb Co. v. Superior Court* on personal jurisdiction in product liability lawsuits, particularly mass litigation faced by pharmaceutical and medical device manufacturers.

Trampoline Manufacturer Can't Bounce Away From FTC Trouble

Danielle Rowan and Lauren Aronson analyze the FTC's recent complaint against two brothers who relied on deceptive endorsements and misleading review websites to sell trampolines. They offer guidance on how best to make material connection disclosures and describe self-sponsored reviews.

This Week in Digital Advertising: Fake News, Bots, and Implications for Digital Trust

Chris Cole discusses the influence of bot campaigns, the Interactive Advertising Bureau's inventory of Authorized Digital Sellers, and the duopoly that exists in the digital ad market.

CROWELL & MORING SPEAKS

Upcoming Engagements

On July 27, Preetha Chakrabarti and Anne Li will be presenting a webinar hosted by the U.S. Fashion Industry Association titled "Printer Cartridges & Cheerleading Uniforms: What the Key 2017 IP Supreme Court Decisions Mean for Apparel Companies." Read more about this webinar here.

Turf Wars: Science vs Fear, A Field of Dreams or a Real Nightmare
On July 27, Cheri Falvey will be presenting as part of a webinar on crumb rubber hosted by the Sports & Fitness Industry

Association. For more information and to register for the webinar, please click here. Please use the promo code CR2017 to attend free of charge.

Previous Engagements

On May 24, John Fuson spoke on a panel about "GMO Labeling: Analysis of the New Law and Strategies for Practical Implementation" at the American Conference Institute's Food Law and Regulation Forum.

On June 13, Michelle Gillette co-chaired the ABA Food & Supplements Workshop in Hershey, PA. John Fuson presented an update on the Food Safety Modernization Act.

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