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MoCRA-Required Recordkeeping, Reporting Now 'Fair Game' For Litigants – Crowell & Moring

by Eileen Francis

Cosmetic product manufacturers can expect the plaintiffs' bar to leverage new record-keeping, GMP and other provisions of the Modernization of Cosmetic Regulations Act to bring or advance litigation, Crowell & Moring attorneys say. They note some defensive tactics that could prove effective.

In July 2020 after four years of motions practice, Unilever United States, Inc. was granted summary judgment in a putative class action alleging that the company endangered consumers with its deceptively advertised St. Ives Apricot Scrub.

According to the plaintiff, the scrub contained walnut shell grit that caused "micro-tears" in skin, potentially leading to acne, infections, signs of aging and other unwanted effects. (Also see "*Unilever Seeks End To Litigation Over St. Ives Scrub, Plaintiffs' 'Fake Medical Condition'*" - HBW Insight, 24 Oct, 2018.)

California's Central District, and subsequently the Ninth Circuit, disagreed.

The lower court ruled that while consumer plaintiff Kaylee Browning offered some factual support that the St. Ives product disrupted the stratum corneum, they had not shown that the alleged micro-tears were a safety hazard in themselves or differed from the effects of standard exfoliation.

A panel of Ninth Circuit judges affirmed the decision on appeal, stating, "Plaintiffs provided no summary judgment evidence linking 'micro-tears' caused by Unilever's facial scrubs to any concrete injuries. … Moreover, Plaintiffs used the products for years and showed no symptoms of the 'dry irritated skin or infections' that [plaintiff expert] Dr. Nestor warned could be caused by

micro-tears."

While Unilever prevailed in that matter, it had a harder time with a class action complaint filed in August 2012 over alleged chemical burns, hair loss and hair damage linked to its Suave Professionals Keratin Infusion 30-Day Smoothing Kit. It failed to dismiss that case in May 2014 and went on to settle for $10m. (Also see "*Unilever To Create $10 Mil. Settlement Fund For Suave Hair-Smoother Ills*" - HBW Insight, 24 Feb, 2014.)

Unilever is just one of numerous beauty and personal-care companies to face such lawsuits. (Also see "*L'Oreal's Gunslinging Counsel On Killing Amla Hair-Relaxer Class Action: 'We Shot Every Bullet'*" - HBW Insight, 27 Mar, 2019.) These actions are certain to keep coming, and as of 2023 cosmetics companies are subject to new requirements under the Modernization of Cosmetic Regulations Act (MoCRA) that could bear on cases like the above and provide additional leverage for plaintiffs.

CROWELL & MORING PARTNER RACHEL RAPHAEL

Attorneys at international law firm Crowell & Moring LLP say cosmetic manufacturers can expect the plaintiffs' bar to exploit MoCRA's new registration, record-keeping and good manufacturing practices requirements in order to bring forward or advance litigation. In a *white paper* published on 16 August, the attorneys point to requirements for serious adverse event reporting, safety substantiation, and good manufacturing practices as potential toeholds for plaintiffs.

While plaintiffs are prohibited from relying on adverse event reports as evidence of an admission that a cosmetic product caused or contributed to the event, it does not prevent discovery of that information, attorneys Rachel Raphael, Helen Ogunyanwo, Julia Carbonetti, and Moriah Denton say.

"With access to this information, plaintiffs, potential plaintiffs, and their counsel may be better positioned to scrutinize (and criticize) a company's safety substantiation data and risk assessment process and allege with more specificity the potential risks posed by a company's products," say the attorneys, who advise personal care and consumer health companies on issues including consumer protection, advertising, unfair competition, tort, product liability and class action defense.

They add, "Companies should expect to see broad discovery requests seeking not only

information found in the adverse reports, but the company's testing and compliance practices, which, prior to MoCRA, a company might have had a better chance of shielding as privileged or proprietary."

Once the US Food and Drug Administration develops cosmetic GMPs through rulemaking, which must be finalized by 29 December 2025 per MoCRA, an FDA warning letter based on Form 483 findings, for example, could embolden plaintiffs "who can argue that the violation is sufficient evidence to show that the company was negligent," the Crowell & Moring attorneys say.

"Under the law, this would be described as negligence per se – the company is presumed to have breached the duty of care, and rather than plaintiff having the burden of proof, the company must demonstrate that it was not negligent in its conduct."

The concerns are consistent with those expressed by Greenberg Traurig, LLP attorneys in a "GT Alert" they posted on their website on 30 December, the day after President Biden signed the 2023 omnibus spending package that included MoCRA. (Also see "*Cosmetics Reform In, Dietary Supplements Out Of US Omnibus Spending Bill*" - HBW Insight, 20 Dec, 2022.)

Essentially, MoCRA's provisions give plaintiffs' attorneys new angles to explore in torts, product liability and consumer protection cases against cosmetic product manufacturers. (Also see "*Attorneys On Modernized Cosmetic Regulations And New Litigation Risks*" - HBW Insight, 11 Jan, 2023.)

Potential Defenses: Unclear Guidance, Prudential Mootness

However, stakeholders aren't without potential defenses, according to Raphael and her colleagues.

"Although MoCRA's requirements provide guidance to cosmetics companies, much of this guidance is relatively vague and open-ended. Given the ambiguity, companies might consider arguing that MoCRA and its requirements are not specific enough to put companies on notice as to what is prohibited and what is acceptable," the Crowell & Moring attorneys say.

Asserting primary jurisdiction also could be an effective defense strategy. "Under the primary jurisdiction doctrine, a court may dismiss or stay a case pending agency review when the case presents a novel or complex issue that implicates the specialized or technical expertise of a regulatory agency," they explain.

A landmark case in the cosmetics industry involving primary jurisdiction was filed against Hain Celestial in 2011 over "natural" claims on JASON products. A California Northern District Court dismissed the suit in 2012, declining to pass judgment on a labeling issue it deemed squarely within FDA's purview. On appeal, the Ninth Circuit overturned and remanded the case back to

the district court, holding that the lower court erred in not staying the case to let FDA weigh in on the subject matter. Ultimately, a settlement was reached and the case was dismissed with prejudice. (Also see "*Waiting For FDA: Federal Courts Debate Stays Of 'Natural' Class Actions*" - HBW Insight, 14 Aug, 2017.)

In a putative class action alleging that Nivea Skin Firming Hydration Body Lotion was an unapproved drug being marketed illegally, Beiersdorf Inc. argued effectively in 2015 that questions of cosmetic-versus-drug regulatory status fell under the primary jurisdiction of the FDA.

But that only stayed the lawsuit until the FDA could be consulted. It was not until April 2020 – after five and a half years, three dismissal motions and one appeal – that Beiersdorf convinced California's Southern District that the US Food, Drug and Cosmetic Act impliedly preempted the plaintiff's allegations. (Also see "*Plaintiff Claims Against Beiersdorf For 'Unlawfully Marketed Drug' Are Preempted By FDCA, Court Rules*" - HBW Insight, 24 Apr, 2020.)

MoCRA will be implemented through rules and reports still to come from the FDA on such issues as disclosure of fragrance allergens and use and safety of per- and polyfluoroalkyl substances (PFAS), and that should help to support defendants' primary jurisdiction arguments, according to the white paper authors.

The paper reads, "Once the FDA issues this guidance, cosmetics companies will be in a position to potentially defeat lawsuits early or in the proceedings on the grounds that the FDA has made pronouncements on the same issues."

Prudential mootness is another viable defense. "Under that doctrine, courts may dismiss a case as moot where the alleged product defect has been properly remedied by the defendant while the litigation is pending (or even before it has started)," the attorneys say.

They note that in recent months federal courts have increasingly exercised that discretionary doctrine to dismiss cases where they determine a government agency is already overseeing remedial actions related to an alleged injury, such as a product recall.

"As a result of the FDA's newfound ability to mandate recalls of cosmetic products and suspect facility registration (and therefore operation) of companies that manufacture and process those products, cosmetics companies who recall products or carry out other remedial actions in coordination with the FDA, may have a strong defense against certain lawsuits involving their products," the attorneys say.

Best Defense? Compliance

In the view of the Crowell & Moring attorneys, MoCRA provides cosmetic manufacturers,

packers and distributors a "better road map" for substantiating safety, responding to adverse events and guaranteeing the quality of their products.

"Cosmetic companies that invest in educating their employees and creating internal systems aimed at achieving compliance with MoCRA's new requirements will be in the most defensible position in the event of a lawsuit involving one of their products," they say. "Evidence of compliance may lead to inferences that the company acts diligently or even that its products are safe and effective."

To prepare for the proposed rulemaking on GMPs which FDA must publish by 29 December 2024, the attorneys advise stakeholders to consider the FDA's 2022 *GMP Guidelines and Inspection Checklist for Cosmetics*, which may inform the rulemaking.

"Companies might want to consider which aspects of the 2022 GMP Guidelines and Inspection Checklist for Cosmetics might create unforeseen costs or other problems, or whether any critical exemptions are needed to MoCRA's mandatory reporting requirements." Such considerations should be factored into stakeholders' or trade groups' feedback to the agency as rulemaking develops.

The attorneys also encourage companies to conduct gap analyses to determine the systems, records and processes they already have in place and how they measure against MoCRA requirements; to create a system for tracking, reporting and maintaining records of adverse events; prepare for inspections; and put together plans for facility registration and product listing, due on 29 December of this year, when provisions for cosmetic product safety substantiation also enter into effect.

The FDA has not provided guidance on what constitutes adequate substantiation of safety, but MoCRA requires a responsible person to ensure and maintain safety records for marketed cosmetic products. According to the FDA's website, "Manufacturers can use relevant safety data that is already available to support the safety of their products. Animal testing is not a requirement for marketing a cosmetic product. It's important, however, that all data used to support the safety are derived from scientifically robust methods."

In a June webinar, Locke Lord urged companies to line up toxicologists right away to do the necessary work for safety substantiation, noting those experts are getting "bombarded" with work as the effective date draws closer. (Also see "*FDA Will Be Motivated To Bring Enforcement Action Under MoCRA; 'Get Your Ducks In a Row'*" - HBW Insight, 6 Jun, 2023.)

Meanwhile the plaintiffs' bar is arming up, the Crowell & Moring attorneys warn, and "[t]he recordkeeping, reporting, and testing now required by MoCRA are now fair game."