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ONE-ON-ONE INTERVIEW

# MANAGING AND RESOLVING COSMETICS & PERSONAL CARE PRODUCT DISPUTES



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**Laurie Henry** has more than 15 years of experience focusing on complex litigation, with an emphasis on pharmaceutical and medical device product liability defence and cosmetics and personal care products litigation. She has defended significant lawsuits in multidistrict litigation, mass torts and consolidated proceedings, and class actions, as well as individual cases pending in state and federal courts across the country. Ms Henry has significant experience handling wrongful death and catastrophic injury litigation, and has worked with and against many experts across the life sciences realm, and in a broad range of sciences, industries and technologies.



**CD: Could you provide an overview of the extent to which the cosmetics and personal care sector is subject to regulatory initiatives, consumer activism and emerging litigation threats? What factors are driving the uptick in scrutiny?**

**Henry:** The proposed bipartisan bill currently under consideration in congress would reform the US approach to cosmetics regulation, potentially in significant ways. It is important to understand, however, that even under the existing framework, cosmetics and personal care products are regulated in a number of ways, even if they are not subject to pre-market approval from the US Food and Drug Administration (FDA). There are federal, state and local regulations that apply to these products. Further, consumer activism can and does drive change. Consumers are more concerned than ever before about what they are putting on their bodies, are increasingly engaged digitally and socially, and are looking to brands to join them in their quest to make the world better.

**CD: What types of dispute are typically made against the manufacturers, sellers and transporters of cosmetics and personal care products?**

**Henry:** We continue to see a marked emphasis from consumers on the ingredients in cosmetics

and personal care products. Consumers can locate this information more easily than ever before, and it has led to increased scrutiny of what ingredients are present in a product and what risks and downstream effects those ingredients may have. Labelling claims continue to be an important area of litigation. In the absence of FDA definitions for 'organic' and 'natural' in the personal care products arena, plaintiffs continue to file lawsuits related to alleged mislabelling of products based on how companies are using these terms. Companies should be diligent to ensure proper substantiation for their labelling claims and particularly cautious about labelling claims that suggest a cosmetic product can cure, treat or mitigate disease. When labelling claims go too far, it can pose a litigation threat.

**CD: Once a dispute has occurred, what strategies should companies deploy to preserve, collect, process, review and produce data for discovery and compliance purposes? How important are expert witnesses in this regard?**

**Henry:** There are three simple steps companies should follow. First, identify the individual custodians and shared sources likely to have relevant documents and electronically stored information. Do not hesitate to reach out to the central players for their help in making sure the list is complete. Second, distribute the necessary hold notices, making sure

the IT department is in the loop on what is needed. Third, focus first on collecting and producing material from the central players and sources. Ask your opponent to review their documents first before talking about widening the circle. In most instances, expert witnesses are not required.

**CD: Are there any cases of note which highlight the key issues likely to arise during a dispute, such as product labelling, contamination and injury allegations, pathogen prevention, facility inspections, product recalls and crisis management?**

**Henry:** Litigation against the cosmetics and personal care products industry continues to borrow causes of action and themes from those previously asserted against other industries: negligence, personal injury and even wrongful death claims. Those claims can be levied against almost anyone involved in the process of manufacturing or supplying the product. Class action litigation against personal care companies continues to increase, and complaints have been particularly focused on labelling claims. The FDA's enforcement powers can feature prominently in these lawsuits, as an FDA warning letter can trigger litigation.

**CD: With the sector increasingly subject to regulatory scrutiny, what measures should companies be taking to ensure compliance with US Food and Drug Administration (FDA) regulations, for example? How can risk best be managed across the supply chain?**

*“Class action litigation against personal care companies continues to increase, and complaints have been particularly focused on labelling claims.”*

*Laurie A. Henry,  
Shook, Hardy & Bacon LLP*

**Henry:** The first step is to become familiar with relevant regulations. Begin with FDA regulations and FDA guidance documents, which provide an excellent source of intelligence about best practices for companies. But familiarity with the FDA's pronouncements are really just the first step. Companies need to consider what other regulations apply to them – whether that be state or local regulations – and how to comply with

those regulations in addition to the federal rules. For instance, should a company participate in the FDA's voluntary reporting? Have they considered how to properly dispose of unsold products? What are the relevant regulations if they are importing from a foreign country? Questions like these can be answered by regulatory or other outside counsel, and having counsel weigh in frequently ensures that companies are compliant with the myriad regulatory frameworks that could impact their businesses.

**CD: What additional advice would you give to companies in the sector in terms of the steps they can take to protect their business interests against predatory lawsuits?**

**Henry:** Cosmetics and personal care products companies should be certain of their substantiation of claims. Without proper substantiation, companies are vulnerable to lawsuits. Companies should ensure that they have robust substantiation so that, if they are named in a predatory lawsuit, they are in the best possible position to defend against such claims. Another key consideration is a company's social media presence. Today, companies can engage with consumers through social media in a way that was not possible even 10 years ago. But be aware of what statements can be attributed to your company

as labelling claims, even when the statement is on a social media account, not a label. Social media platforms are growing daily, and with it so are the rules of engagement. Finally, companies should remain informed about litigation trends as well as actions by the FDA, the Federal Trade Commission (FTC) and the National Advertising Division (NAD). Staying informed can help companies anticipate and address issues before they become problems.

**CD: What scientific, regulatory and litigation developments do you expect to impact the cosmetics and personal care products space in the years ahead?**

**Henry:** Should the cosmetics regulatory reform bill be passed, it could have a substantial impact on the cosmetics and personal care products industry. Consumers' focus on ingredients and labelling, particularly 'natural' and 'organic', will continue to be a source of litigation for some time. Further, we expect to see increased pressure from consumers about corporate social responsibility, ranging from the sourcing of products to responsible supply chains and beyond. Smart cosmetics and personalised personal care products will only continue to grow, as will gender-neutral personal care products and personal care products geared specifically toward men. **CD**