



## **Innovation, Consumer Products, and Legal Risk: Points to Consider**

**By**

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Products that embody tried, true, and especially cutting-edge technologies are generally embraced by retailers as sure-fire pathways to marketing success. What's not to like about best sellers and newer, faster, cleaner, or otherwise improved products? Sometimes overlooked is what is hidden behind the technology curtain -- what is the secret sauce that makes the product faster, cleaner, or better? In marketing products with new modes of action and spiffy new attributes, retailers are part of a product liability chain of which they need to be aware. This paper provides an overview of emerging legal and practical issues pertinent to the inclusion of technologies supporting products marketed to the public.

### **Innovation**

The intersection of product liability and innovation is not new.<sup>2</sup> With innovation comes the promise of improvement, but not without tradeoffs. The law demands safety, but zero risk, particularly for revolutionary or “disruptive” technologies, is impractical, and entrusting juries to make these judgments is dicey. Historically, the lure of commercial success has incentivized innovation despite the inherent risks of the unknown. These risks have also greatly elevated the need for enhanced product stewardship and precautionary design principles since the floor of regulatory compliance is not a reliable defense. While the evolution of stewardship and other voluntary codes of higher performance are welcome byproducts of an increasingly proactive corporate community and of the ever-present awareness of product litigation, the high cost of that litigation, the accompanying reputational injury, and related business harms all have tempered the zeal for investing in innovation, despite its rewards.

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<sup>2</sup> See National Academy of Engineering. 1994. *Product Liability and Innovation: Managing Risk in an Uncertain Environment*. Washington, DC: The National Academies Press.

This ratio of product complexity to risk avoidance/management is expected to increase with the growing sophistication of consumer products. Manufacturing at the nanoscale vividly reflects this axiom. The evolutionary trend to manufacture at ever smaller units and optimize (and monetize) the unique attributes of chemicals and structures at the nanoscale range of 1-100 nanometers have highlighted the “unknowns” of products of nanotechnology. These circumstances also have invited relentless debate and public discourse about the ability of traditional legal and regulatory governance systems to identify and manage potential risks from engineered nanoscale materials, given that these systems are premised on conventionally-sized materials manufactured at the bulk-scale range.<sup>3</sup> The commercialization of nanotechnology has posed challenges for regulators, policymakers, product innovators, and product marketers struggling to find the correct balance between commercializing “novel” and/or “unique” product functionalities and providing the assurance that the health and environmental implications of all such novel product features have been thoroughly vetted and found to be safe. The nano revolution has involved creating a new lexicon including new naming conventions, defining new terms like “nanoparticles” and “nanomaterials,” developing new standards and instruments calibrated to detect and measure matter at the nanoscale range, and a host of other “firsts.” All of this “nano-ness” has caused significant consternation and no small amount of disruption in commercial markets, especially in investment and insurance circles. Unsurprisingly, the lack of certainty regarding the suitability of traditional governance approaches to product innovation has invited investor anxiety and significant commercial caution.

The products of applied synthetic biology raise perhaps even greater cautionary issues for business. The potential to create new DNA sequences that do not exist in nature, to create new genetic code by synthesizing novel DNA bases and base pairs, and the potential to create new life forms are among the most controversial aspects of synthetic biology, the next big wave of product innovation hitting our commercial shores. From the technical and regulatory perspectives, looking beyond the ethical and societal implications that such developments would create, these applications share with the more conventional applications a series of questions that must be addressed in balancing the potential risks and benefits of any new genetically modified organism and its gene products. These questions are not new -- how to balance the potential benefits of new organisms and/or their gene products with their potential to harm humans or the environment. Businesses will nonetheless be challenged mightily given the complexity of the ethical precedents that will be set in their resolution.

As with any emerging technology, applications of synthetic biology are diverse. That synthetic biology is capable of delivering on its promise of clean energy, personalized medicine, pollution remediation, and other benefits is clear. What is less clear, and what innovators and regulators alike are addressing, is how the potential for harm through the inadvertent release of organisms into the environment will be prevented. An October 2015 report prepared by Bergeson & Campbell, P.C. (B&C<sup>®</sup>), under the auspices of The Synthetic

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<sup>3</sup> See Bergeson, L., Hester, T. 2008. *Nanotechnology Deskbook*. Environmental Law Institute; Davies, J. Clarence. 2008. *Nanotechnology Oversight: An Agenda for the New Administration*. Wilson Center/Project of Emerging Technologies.

Biology Project of the Woodrow Wilson International Center for Scholars (Wilson Center/Synthetic Biology Project)<sup>4</sup> outlines in granular detail how innovators can be flummoxed in obtaining the necessary signoffs from government agencies in commercializing their products, and the steps needed to diminish these challenges.

### **Product Liability Issues**

The shift in the 1960s from fault-based standards to strict liability has lowered the bar in holding product manufacturers and others in the commercial value chain liable for alleged injury in the absence of a showing of negligence. A product can be determined to be defective even if it meets regulatory standards and even if the manufacturer comported its operations to the requisite standard of care believed to be controlling at the time of manufacture. Damages could include recovery for personal injury, medical monitoring, fear of future injury, deceptive trade practices (inviting treble damages), and punitive damages.

Well before the products of today’s cutting-edge technologies brought their own promise, and their own challenges to modern commerce, the legal doctrine of “strict liability” itself began to expand and has become the litigation avenue of first resort for plaintiffs seeking recovery for damages from what they characterize as defective products. The realm of tort law known as strict liability, liability without having to establish fault, became an increasingly attractive litigation pathway beginning in the 1960s, in the wake of an influential decision by the California State Supreme Court that other courts increasingly adopted. Before that, litigants more typically pressed their claims based on theories of negligence, which involves proof of fault or breach of warranty, grounded on promises made and the presence of a specified relationship between buyer and seller. Even after negligence and breach of warranty theories for the recovery of damages that became less restrictive over time, the strict liability doctrine streamlined product liability litigation, beginning with the California Supreme Court’s edict that “[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”<sup>5</sup>

Soon, with court-made law expanding, the basic rule for a seller’s strict liability for harm to the consumer or user of a product could be summarized as follows:

The seller of any product in a defective condition that is unreasonably dangerous to a user or consumer, or to the property of either, is subject to liability for physical harm caused by the product if:

- (a) The seller is in the business of selling that product; and

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<sup>4</sup> Bergeson, L., *et al.* 2015. *The DNA of the U.S. Regulatory System: Are We Getting It Right For Synthetic Biology?* Wilson Center/Synthetic Biology Project.

<sup>5</sup> *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897, 900 (Cal. 1963).

- (b) The product is expected to, and does, reach the user or consumer without substantial change in the condition in which it is sold.

The basic rule would apply even if:

- (a) The seller has exercised all possible care in the preparation and sale of his product; and
- (b) The user or consumer has not bought the product from or entered into any contractual relation with the seller.<sup>6</sup>

The rule set out above, referred to as the “Restatement Second” approach, based on the authoritative treatise that set it out, expanded the categories of injured parties who could seek money damages and the chain-of-distribution defendants who might be held liable. Manufacturers, distributors, retail sellers, and others in the distribution system all are open to liability if the necessary tests, such as causation, are met.

The Restatement Second does not specifically define what is meant by “defective condition,” separate from the “any product in a defective condition unreasonably dangerous” notion, but the commentary relies significantly on whether a reasonable consumer without special knowledge would consider the product safe to use. Tort law from the leading jurisdiction of California soon focused on the “defect” aspect rather than the “unreasonable danger,” proving that if the defect existed before the product reached the consumer, there was sufficient evidence for recovery in tort without a separate showing of unreasonable danger.

Within the past twenty years, legal scholars surveyed the fast-developing law and issued a Restatement Third of Torts, referred to as the “Restatement Third,” which focused entirely on products liability. These principles largely coexist with, rather than supersede, the above-quoted Restatement Second provisions, but they reflect more recent legal developments. The two most fundamental sections of the Restatement Third address (1) liability of sellers and distributors of defective products; and (2) categories of defective products, as follows:

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.<sup>7</sup>

A product is defective when, at the time of sale or distribution, it (a) contains a manufacturing defect (b) is defective in design; or (c) is defective because of inadequate instructions or warnings, as follows:

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<sup>6</sup> See Restatement (Second) of Torts: Strict Liability § 402A.

<sup>7</sup> Restatement (Third) of Torts: Products Liability § 1.

- (a) A product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.
- (b) A product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omissions of the alternative design renders the product not reasonably safe.
- (c) A product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.<sup>8</sup>

The broad language in Section 1 of the Restatement Third subjects a seller or other distributor to liability for harm caused by a defective product; no mention is made of proving unreasonable danger. There is no mention of fault or of the likelihood that the product was rendered “defective” by an action or omission of the manufacturer rather than the seller. The manufacturer may well be on the hook for liability, but this does not necessarily mean that a retailer or distributor is not. Section 2 gives content to the term “defective product,” which may be comprised of a manufacturing defect, a design defect, or defective instructions or warnings.

A manufacturing defect occurs when a product departs from its intended design, even where all possible care was taken in its preparation and marketing. Thus, a plaintiff need not establish “unreasonable danger” as a basis for recovery for a manufacturing defect. The notion of “unreasonable danger,” however, is part of the equation when it comes to design defects or defects in instructions or warnings. A design defect alone is not enough to establish strict liability unless it could have been avoided by adopting “a reasonable alternative design.” Similarly, the omission of adequate warnings or instructions will render a product “not reasonably safe” only if foreseeable risks could have been avoided had the warnings or instructions been provided. The approaches to design defects and instruction/warning defects insert negligence-related concepts such as avoidable risk into strict liability law. Also discernible are policy judgments about which party is best positioned to take steps to avoid the problem in the first place, or to bear the costs of failing to take those steps.

Products liability law continues to evolve. Although many liability issues treated as difficult conundrums fifty or more years ago now are largely settled law, thorny questions remain. Litigants and courts still wrestle with “unavoidably unsafe” products, some of which, such as prescription drugs, arguably are useful to society despite their unavoidable risks, or cigarettes, which more obviously are not.

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<sup>8</sup> Restatement (Third) of Torts: Products Liability § 2.

Another difficult area relates to dangers considered unknowable at the time a product is designed and produced. “Reasonable foreseeability” often guides the courts in these kinds of cases. Manufacturers are not often expected to design around, or warn of, dangers they could not reasonably anticipate, given the state of knowledge at the time. Future outcomes in litigation based on defects alleged in the products of new technologies, such as nanotechnology and synthetic biology, where many products are marketed, allowably, despite necessarily incomplete databases, will remain to be seen. Retailers may find themselves in the position of making their own judgments about whether or not it makes sense from a commercial perspective to sell some of these products.<sup>9</sup>

The duty to warn can be something of a curve ball within products liability law. As noted above, the Restatement Third identifies a failure to provide adequate instructions or warnings to address potential dangers as one type of a product defect. The absence of a sufficient warning often serves as the basis for a product liability action. On the other hand, if a product already is considered defective by another standard -- in its manufacture or its design -- even a clearly-stated warning will not save the defendant’s bacon. That is, a defect cannot be reversed by a warning.

When a product is correctly designed and manufactured, however, users’ instructions and/or a warning still are essential if there is a non-obvious risk associated with its use. As described above, this is an aspect of product liability law in which negligence concepts also play a role. The manufacturer especially, but also the seller of the product, typically are considered better-positioned than the user, whether a consumer or an employee, to understand the foreseeable risks of harm from using the product and also to counter these risks by way of appropriate instructions and/or warning language. The manufacturer or seller, however, is not generally required to warn of unknowable risks if those risks are unforeseeable. This does not mean that the manufacturer can shield itself from knowing about such risks by omitting to test the product, or test properly, where such testing would be reasonable, or that a seller should intentionally omit to ask questions. But where risks are truly unknowable, courts generally are disinclined to place liability with the manufacturer or seller.

Duty-to-warn suits may be compromised by the existence of government-prescribed labeling standards. In general, compliance with federal- or state-required labeling law is considered evidence that a defendant gave adequate warning to a plaintiff. A fact-finder may agree or, alternatively, it may decide instead that a more robust or different warning should have been give under a “reasonableness” test.

Where the labeling or warning requirement originates with the federal government, however, and if Congress intended to pre-empt state action that addresses the same field, a plaintiff cannot make a case based on the proposition that more or different warnings were required under state law, a point discussed in the context of the case studies below. In these

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<sup>9</sup> Indeed, it is precisely this issue, among others, that has inspired a complex constellation of “retailer” initiatives pioneered by Walmart and others.

circumstances, where a defendant who can show compliance with a federal warning or labeling law that occupies the field, the plaintiff cannot obtain recovery on a failure-to-warn theory.

Compliance with an industrial standard or one established by a non-governmental standard-setting organization also weighs more heavily on the side of the manufacturer or seller, but not as definitively as compliance with a government requirement, particularly one that preempts state tort law. A failure to meet a seller's own advertised standards is another variation, but is more aptly characterized as misrepresentation or even breach of warranty. A class action consumer suit seeking recovery for this kind of misrepresentation alleged against a large retailer was filed earlier this year in federal court in Illinois. Customers of Menard's, a home improvement chain, are asserting that dimensional lumber products sold in two of its stores measured significantly less than the dimensions explicitly specified on in-store shelf tags and signage, labels, flyers, and other advertisements.<sup>10</sup> This litigation is worth watching.

### **Other Protective Measures**

The wide net that strict liability can cast is reason enough why it is essential to consider a full range of protective measures to minimize product liability. These include contractual protections with upstream suppliers and downstream customers; implementation of best management practices; contractual representations and warranties; indemnification agreements; appropriate warnings, labeling, and related disclosure strategies; and insurance coverage. Additionally, businesses need to track post-sale consumer product complaint and incident reports, analyze these data, and respond to any of these complaints and incidents quickly and thoroughly.

Not all of these measures necessarily will be a viable fit for every situation, but seasoned retailers should have a working knowledge of the available options. Robust indemnity provisions in sales and distribution agreements are a must for retailers who could end up on the hook for liability for harm caused by products deemed defective but in whose manufacture the retailers played no role. Sales and distribution agreements also should be drafted to include meaningful producer warranties and to preclude a manufacturer or other supplier from disclaiming liability for such harm vis-à-vis the retailer who, fairly, should not bear this responsibility. In looking out for themselves and their customers, whether they are commercial entities or individual consumers, retailers should check on whether labeling, use/handling instructions, and other product information that one might expect is indeed provided by the manufacturer or any upstream supplier. For a belt-and-suspenders approach, essential even where the risk of liability is low but the magnitude of the liability could be crushing, appropriate insurance also is a must.

Retailers should manage customer relationships with care. Sales agreements with customers, where they are used, should not over-promise or take on responsibility for what the retailer cannot control. (In reality, though, the retailer is at least one step closer to the ultimate

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<sup>10</sup> Complaint, *Fuchs v. Menard, Inc.*, No. 2017-cv-01752 (N.D. Ill. Mar. 3, 2017).

source of the product than is the retailer's customer, and the retailer is better positioned to protect itself in relation to the manufacturer. This is a distinction that may have some impacts on courts making difficult decisions about damage awards.) There are limits, of course, to which warranties sellers may expressly disclaim, based on the Uniform Commercial Code (widely adopted by individual states) and on the body of each state's judge-made common law. In addition, it merits bearing in mind that a seller's efforts to overreach and disclaim everything in sight in product sales to consumers may backfire; since not all such disclaimers are legally effective anyway, writing a sales agreement that is visibly skewed against the purchaser is corrosive as a matter of customer relations and can make the retailer look dodgy.

Another aspect of customer relations that holds out potential benefits for both customers and retailers is the creation and maintenance of a system for responding to complaints or other issues that customers may raise. This should be coordinated with the retailer, insofar as reasonably possible, staying on top of product alerts, updates, and ongoing or resolved issues throughout the supply chain. Knowing the product that one distributes or sells is more important now than it used to be. The retailer, of course, should report customer complaints of concern to the manufacturer as well. For obvious reasons, it is worth taking the time to document communications to and from the manufacturer and customers, respectively, about these issues and to retain this documentation.

### **Managing the Message**

Businesses also must be sensitive to the need for transparency, communication, and positive, effective public relations. It can be anticipated that workers, community residents, downstream formulators, upstream suppliers, vendors, and customers will want to know what, for example, a nano-enabled product contains, the health and safety implications from exposure to the product and its nano components, and related product safety information that stakeholders have come to expect under right-to-know laws and the assumptions they invite. Similar questions arise in connection with other evolving technologies. Forthright communications can contribute to product stewardship and customer relations initiatives. But overselling a product, making claims based on "nano-attributes" or on genetic engineering, may open a seller needlessly to unwanted liability if those claims come to naught or if the product unexpectedly should prove harmful.

The picture as it stands today is only a snapshot of the regulatory and best practices landscape that necessarily will evolve significantly. Product materials are becoming increasingly sophisticated, and their detection, characterization, and potential to cause harm are better understood with each passing day.

### **Case Studies**

The foregoing illustrates how important it is for retailers to know as much about the products they offer for sale and distribution as possible. We note below a few recent examples of the liability that retailers and others may incur for not asking the right questions about the nature of the products they market.

### *Marketing Deregulated “Natural” Pesticide Products*

The threat of the mosquito-borne Zika virus grows every day, and the need for clear information is especially pressing during pregnancy. How do you prevent getting infected with the Zika virus? What insect repellents are best? The first question is easy to answer: public health experts agree that women who are pregnant or who might be pregnant should use insect repellents.

The second question is much harder to answer. The U.S. Environmental Protection Agency (EPA) evaluates and approves pesticides, which include insect repellents. It is not easy for the average consumer to know what works and what does not, and to a large extent EPA policies have made this question more complicated, turning on important distinctions between some “natural”-type repellents and other products available in the marketplace. These complications also affect potential liability for sellers of these products.

Years ago, EPA deregulated a number of natural, non-toxic materials from being subject to the registration requirements of the broad federal pesticide law known as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This made sense at the time since garlic, pepper, rotten eggs, vinegar, and other common chemicals are sometimes used as pesticides. Before deregulation, pesticide uses of these products were subject to the same requirements as synthetic chemical pesticides with long unpronounceable names like diethyltoluamide, better known as the mosquito repellent DEET, for which EPA requires the submission of volumes of efficacy and safety test data. Being natural, however, does not mean a substance is non-toxic. It also does not mean that the particular substance is unexplored; some, though not all, widely-used natural ingredients are fully evaluated. But in the interest of efficient use of resources, some two decades ago EPA identified a list of products that could be sold as pesticides, but would not be subject to EPA data requirements and review. EPA refers to these products, which it believes pose little or no risk to human health or the environment, as “minimum risk pesticides.”<sup>11</sup>

This list of pesticides which are not subject to EPA evaluation, and for which EPA does not require data to prove they are effective, includes botanical ingredients, such as oil of citronella, geranium, rosemary, peppermint, and others. Many of these products can be used as pesticides -- some may work better than others -- and many are effective for their intended use. For example, rotten eggs, or as EPA refers to them, “putrescent whole egg solids” are used as a deer repellent. Many such ingredients have been marketed as “natural” insect repellents, and labeled as “safe” or “non-toxic,” using words that will not appear on products where EPA reviews and approves the instructions on the product label.

This is where the bureaucratic distinction that matters greatly to EPA, but will not be well understood by consumers, comes into play. If the repellent label includes “public health claims” -- claims that it repels mosquitoes that may cause a disease (like the Zika virus or the West Nile virus) -- then EPA requires the submission of data to show that the product works. If,

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<sup>11</sup> The “minimum risk pesticide” exemption provisions are found at 40 C.F.R. ¶ 152.25(f).

however, the product label states only that it “repels mosquitoes,” no such efficacy data are required, and the product may very well be ineffective for its stated purpose.

Few, if any, humans outside of EPA label experts grasp this important distinction and the impact on consumers that it creates: if there is no health claim on the label, then it is, in effect, a situation of buyer beware. EPA’s deregulation of these natural products means it is legal to sell products that do not work, as long as the ingredients appear on EPA’s minimum risk pesticides list.

*Consumer Reports (CR)* reported in 2016 on studies conducted on repellents. It concluded that using a “natural” mosquito repellent, with active ingredients such as citronella or clove, lemongrass, or rosemary oils, might seem like a good idea, especially for women who are pregnant or planning to be. But five of the six plant-based repellents it tested reportedly lasted just one hour or less against *Aedes* mosquitoes, the kind that can spread the Zika virus. Not all repellents with the same ingredients are equally effective, and *CR* found that some formulations of the chemical repellents also do not work for very long in its tests. Some botanical pesticides are effective and also have public health claims on the label (an example is lemon eucalyptus, a botanical ingredient not on the exempt product list, which *CR* testing did find to be effective).

To reduce confusion about what works, EPA for years has struggled to correct the situation, which involves conducting a rulemaking that requires a long and bureaucratic administrative process to complete. The good news is that EPA is working on such a solution. The bad news is that it has been working on that solution for over ten years and still has more work to do.

The confusion created by the absence of reliable efficacy data could invite liability for both the product manufacturer and the retailer. It is not difficult to imagine a scenario in which a pregnant woman, who purchased a “natural” repellent product and used it as directed, nonetheless became ill with the Zika virus. She, and her affected child, might sue the manufacturer and the retailer on the grounds that the ineffective repellent is a “defective product,” such that those in the supply chain should be held strictly liable. Even in a litigation scenario in which a retailer escaped legal liability, the defense costs in that kind of lawsuit and also the potential reputational harm, even if a retailer escaped legal liability to the plaintiffs, still could be painful and present unwanted expenses. Until it can address the very real potential for consumer confusion through a completed rulemaking, EPA needs to be clear in its communication about two crucial distinctions -- the one between untested “minimum risk” pesticides and those that have undergone FIFRA review; and the one between pesticide label claims to “repel mosquitoes” and those claiming to “repel mosquitoes that cause the Zika Virus” -- even if it cannot take immediate action to reduce the confusion.

### **Undisclosed, Unregistered Pesticide Products**

Another source of potential tort liability awaits shoe distributors and retailers. No one expects to find a pesticide issue while trying on or buying shoes. But every year millions of consumers, including large numbers of children, are exposed to unknown quantities of anti-mold

pesticides when they open a shoe box. Although the active ingredient in these unregistered anti-mold pesticides is undisclosed and the products are marketed as all natural, through independent testing it appears most of the unregistered pesticide products used in packaging imported shoes and leather goods contain allyl isothiocyanate (AITC), a pesticide. The presence of AITC and other pesticides is not disclosed to the consumers; the consumers do not know they are being exposed to them; and the consumers have no way to prevent those exposures, nor even to know how much exposure they are receiving. These anti-mold products have not been registered for this use, nor has this use or the resulting exposures to consumers been reviewed for safety by EPA under FIFRA, or by any other regulatory agency.

The potential tort liability that retailers and distributors could face based on these facts is significant; the health of millions of unsuspecting and unprotected consumers, including children, can easily be alleged to have been jeopardized by the products at issue. Moreover, any consumer claim of injury from exposure to an unregistered pesticidal agent cannot be subject to preemption under FIFRA Section 24(b), 7 U.S.C. § 136v(b) because the products are unregistered and not reviewed by EPA.<sup>12</sup> U.S. distributors or retailers could be liable for any resultant injury, especially if the distributor or retailer knew that an unregistered pesticide was present in the product and failed to warn consumers. These U.S. entities could find themselves targeted by consumer plaintiffs who face greater obstacles and frustrations in trying to pursue litigation against foreign manufacturers.

That consumers are being exposed routinely to unknown amounts of unregistered AITC and other antimicrobial pesticides in packaged shoes and leather goods is demonstrably true: walk into any shoe store and open a shoe box. There is a high probability that an unregistered antimicrobial sticker or chip will be located inside. Foreign manufacturers of those unregistered pesticides claim that they are intended to protect the packaged product from the time of initial treatment until the packaged product reaches the ultimate consumer, and claim also that their antimicrobial products remain efficacious for up to 180 days. Data from independent efficacy tests show that AITC, the most commonly used pesticide in these products, remains active and alive for at least 150 days. As the packaged shoes or leather accessory products containing these pesticides can reach U.S. channels of trade in as little as 14 days, consumers are thus repeatedly exposed every time they try on or purchase a new pair of shoes.

The AITC used in many if not most of the unregistered pesticide products used in the packaging of imported shoes and leather goods is not registered by EPA for use in packaging, but was recently registered under FIFRA as a fumigant.<sup>13</sup> AITC is also a potential sensory irritant in the same class of compounds as methyl isothiocyanate (MITC), the active fumigating agent that is released following use of the agricultural fumigant metam sodium. The routine

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<sup>12</sup> See the discussion of this point later in this section.

<sup>13</sup> EPA typically registers pesticide products for specific uses; one active ingredient registration does not extend to diverse uses. In fact, EPA may expressly exclude specified uses when it registers a pesticide product.

exposure of consumers to unknown quantities of an antimicrobial agent for which the manufacturer has given no information to the consumer and for which there has been no proper analysis by EPA or any other reputable agency of the potential hazards associated with such exposure must be of grave concern to any business involved in selling or distributing these products. This is not only due to the potential tort liability, but also because of the unintended potential harm posed to unsuspecting and unprotected consumers, including children. The potential exposure of children to AITC is of special concern. Not only are children's shoes among the packaged products that are routinely treated with AITC, but their often brightly colored packaging is clearly intended to attract children. Moreover, parents typically do not know that this packaging includes a pesticidal agent and, therefore, are unlikely to exercise any heightened vigilance.

Claims that AITC or any other unregistered and unexamined pesticidal products are "all natural" and therefore presumably not harmful will provide no sturdy shield against possible liability. As noted above, many "natural" chemicals are highly regulated and are viewed by regulators as posing significant toxicity and risk concerns. Falling back on the claim that a pesticidal product is all natural simply will not by itself protect a company against potential tort liability; "all natural" is not a synonym for harmless.

In most instances, when a consumer claims an injury as a result of use of an EPA-registered pesticide, and the product has been used in compliance with label directions approved under FIFRA, state tort claims that are based on the premise that the label directions are inadequate will be preempted under FIFRA Section 24(b), 7 U.S.C. § 136v(b), as discussed by the Supreme Court in *Bates v. Dow AgroSciences L.L.C.*, 544 U.S. 431 (2005). FIFRA Section 24(b) provides that a state may not impose labeling or packaging requirements in addition to or different from those prescribed under FIFRA. Accordingly, compliance with an EPA-approved pesticide product label is a defense to a tort suit based on state statutory or common law because federal law, in explicitly occupying the field, has shut out any claims based on state law.

In contrast, when a consumer claims an injury as a result of exposure to an *unregistered* pesticidal agent, preemption under FIFRA Section 24(b) is not a valid defense. This is because, in the absence of registration under FIFRA, EPA has not evaluated the potential toxicity of or exposure to the pesticidal active ingredient, and there are no approved label directions that could serve as the basis for preemption under this provision. Although it may seem unfair, the failure of a remote manufacturer to register a pesticide product under U.S. law can come back to bite distributors and sellers if a consumer is harmed by exposure to the product.

This goes back to the operative principle under the Restatement Third Section 4(a), mentioned above, that "a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation,"<sup>14</sup> whether for liability for defective design or inadequate

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<sup>14</sup> Restatement (Third) of Torts: Products Liability ¶ 4(a).

instructions or warnings. Consistent with this principle, the vast majority of both state and federal courts addressing the issue have concluded that violations of product safety statutes or regulations make the products at issue defective as a matter of law.

FIFRA is a product safety statute. Reiterating that Congress' 1972 amendments transformed it "from a labeling law into a comprehensive regulatory statute," the *Bates v. Dow* Court observed that "[t]he 1972 amendments also imposed a new criterion for registration -- environmental safety."<sup>15</sup> EPA's review of the scientific data submitted by an applicant to document that the product meets the statutory standard for safety is a central element of the registration process. Therefore, non-compliance with FIFRA's registration requirement makes a persuasive argument that packaged products which include an unregistered pesticide are defective with respect to the risks to health and the environment that the registration process is intended to address in the first place.

To mitigate potential exposure to tort or other liability for harm to consumers, where an antimicrobial product is to be employed, it is always best to use a registered product that has been subject to EPA's rigorous safety testing. Such testing protects both the retailer and the consumer by providing a high degree of comfort and assurance that the antimicrobial product will provide the intended product attributes, and will not expose either the consumer -- or the retailer -- to any unintended health risks or commercial harm.

### **Synthetic Squalene: Being Prepared to Respond to Questions**

A third potential stumbling block for retailers involves the question of how to answer if a customer asks what the ingredients are in a product derived from synthetic biology. An example identified in the 2015 report by the Wilson Center/Synthetic Biology Project is raised by the commercialization of a synthetically derived form of squalene, an emollient used in skin-softening cosmetic products.<sup>16</sup> A hydrocarbon compound, squalene is readily found in shark liver oil, as well as in other fish oils and in smaller amounts in plants. In response to vocal opposition to the use of shark liver oil as a source -- given the federal endangered and/or protected status of some shark species -- and the relative expense of distilling squalene from lower-yield plant sources, the biotechnology firm Amyris turned to synthetic biology to produce and bring to market synthetic squalene based on engineered hydrocarbon molecules from proprietary yeast strains.

Participants in the distribution and sales chain for a product such as synthetic squalene face at least one legal and regulatory unknown, whether the squalene produced through applied synthetic biology can be considered the same cosmetic ingredient as squalene derived from shark liver oil or other natural sources -- or is it more correctly described as something separate and different?

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<sup>15</sup> 544 U.S. at 437-438.

<sup>16</sup> See Wilson Center/Synthetic Biology Project report, *supra*, at pp. 21-24.

These issues arise in the context of the U.S. Food and Drug Administration (FDA) regulatory and compliance structures. FDA regulates cosmetics under the Federal Food, Drug, and Cosmetics Act (FFDCA), under which most cosmetic ingredients, with only a few exceptions, do not require pre-market approval. Cosmetics that have a therapeutic effect are considered drugs, and are differently regulated, but squalene, with an intended use in emollients and moisturizers, does not fall into this category. This means that cosmetics containing squalene are among the vast majority that become of concern to FDA only if they are misbranded or adulterated under FFDCA Sections 301 and 402, respectively, in which case FDA is empowered to pursue enforcement measures. Cosmetics must be labeled properly under applicable law and regulations, and ingredients must be declared, among other obligations that manufacturers must meet.

Because no standard by which to identify and distinguish synthetic squalene has been adopted or recognized by the authoritative bodies, it is not possible to conclude with confidence that it is correctly depicted by conventional nomenclature. Nor is it clear which, if any, cosmetic ingredients developed through synthetic biology can be appropriately termed as “natural” if this descriptor is used. Given that FDA becomes interested in cosmetics most often if something goes wrong, as opposed to preemptively at the start, it could well take a consumer’s claim to have suffered harm from the use of synthetic squalene or some other bio-engineered cosmetic ingredient to kick start a compliance investigation and enforcement activities. Still, the specter is out there that if a problem arises, the misbranding provisions of FFDCA Section 301 stand out as the basis for a product liability suit against the manufacturer and other entities in the distribution chain. As discussed above in connection with unregistered pesticides, noncompliance with a federal regulatory statute supports a determination that a product is “defective.” The twist in this example is that it is unknown at this juncture whether the use of conventional nomenclature to describe a product of synthetic biology will be considered to be an instance of misbranding.

### **Conclusion**

Against this backdrop of potential liabilities, regulatory initiatives and governance mechanisms become all the more important. As EPA, other federal and state regulatory bodies, and stakeholders alike have the benefit of better information about the health and environmental impacts of advanced materials of all types, the regulatory pathway forward will be more informed and, from a stakeholder’s perspective, less obscure. While a more developed regulatory framework is still years away, businesses also need to be mindful of potential citizen action suits under federal and state laws seeking the imposition of liability for cleanup of hazardous substances and/or natural resource damages. Even if such actions are unsuccessful, their nuisance value and potential for inviting unwanted media attention should not be underestimated.