Navigating Regulatory Bans and Restrictions in Mass Tort Litigation

By David I. Schifrin & Melissa G. Baney

Critically evaluating the scope and reasoning behind a ban or restriction will help litigants adopt litigation strategies that present the most accurate regulatory and scientific picture at trial.

Chemical products involved in mass tort litigation typically come from highly regulated industries and have undergone extensive pre-market testing for both efficacy and safety. Once approved, these products are then subject to various overlapping regulatory regimes corresponding to the type of product at issue and the jurisdictions in which the product is manufactured, distributed, sold, and used. While the regulation of some chemical products is almost exclusively federal, others are subject to conditions imposed by more local jurisdictions, including states, counties, cities, municipalities, school districts, and more. Adverse regulatory action anywhere along this jurisdictional chain raises a potential problem for defendants involved in litigation concerning these products, as plaintiffs are likely to point to such action as evidence that the product is unsafe. The appropriate litigation strategy for dealing with evidence of bans or restrictions depends on understanding the nature of the ban or restriction and the regulatory framework in which it arises. Only then can defendants adopt litigation strategies that maximize the chances of keeping such prejudicial information out of the hands of juries.

Pesticide Regulation in the United States

In the United States, the Environmental Protection Agency ("EPA") regulates the use of pesticides under authority granted in two primary statutes: the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and the Federal Food, Drug and Cosmetic Act ("FFDCA"). FIFRA governs the registration, distribution, sale, and use of pesticides. 7 U.S.C. § 136a. A pesticide may be registered if, among other things, it will not cause "unreasonable adverse effects on the environment." Id. § 136a(c)(5). A pesticide may be classified as a general use pesticide, a restricted use pesticide, or both. Id. § 136a(d). A general use pesticide is one that the EPA has determined "will not generally cause unreasonable adverse effects on the environment." A restricted use pesticide is one that the EPA has determined "may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator." Id. § 136a(d)(1)(B)-(C).

States have broad authority to regulate the use of pesticides that are distributed, sold, and used within their borders. Although a state may not authorize pesticides or pesticide uses that FIFRA prohibits, states may enact stricter use conditions than those required by FIFRA. However, in all cases, FIFRA mandates uniformity in labeling, meaning that states are not permitted to impose labeling or packaging requirements "in addition to or different from those required" under FIFRA. Id. § 136v(b).

At its broadest level, a state may prohibit the use of an active ingredient entirely. For example, several states prohibited the use of chlorpyrifos, albeit with certain narrow exceptions, prior to EPA's proposed revocation of chlorpyrifos tolerances. See, e.g., S.B. 3095, 29th Leg., Reg. Sess. (Haw. 2018); Md. Code Regs. 15.05.01.02. A state

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may also impose state-wide restrictions on certain types of uses. For example, Maine has prohibited the use of certain neonicotinoids for outdoor residential use. L.D. 155, 130th Leg., 1st Spec. Sess. (Me. 2021). A state may also impose more limited restrictions on the use of pesticides on state lands.

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For example, New York State has proposed restricting the use of glyphosate on state land. [1] A state also may impose even more limited restrictions on certain types of state lands, such as New York's restriction on the use of pesticides on school playing fields and playgrounds. [2]

FIFRA is silent regarding the extent to which local subdivisions within a state may regulate pesticides. Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 606 (1991). As a consequence, the power of political subdivisions within a state to regulate pesticides is a function of state law. Most states have laws that preempt, either expressly or impliedly, local political subdivisions from regulating the use of pesticides. However, even in states that expressly preempt local authorities from enacting regulations on private use stricter than those imposed by the state, local political subdivisions may nevertheless regulate their own use of a pesticide product. For example, under Florida law, "[n]o local government or political subdivision of the state may enact or enforce an ordinance that regulates pest control...." Fla. Stat. § 482.242. Nevertheless, the Board of County Commissioners of Miami-Dade County has established a county policy prohibiting the use of products containing glyphosate by the county and by county contractors. [3] At an even more local level, school districts and other sub-jurisdictional entities within states that preempt local pesticide regulation may implement decisions regarding their own use of certain types of pesticides. For example, despite California's express preemption on local regulation of pesticides, see California Food and Agriculture Code § 11501.1, the Irvine Unified School District has adopted a policy prioritizing the use of organic pesticides. [4]

In states where no preemption law exists, political subdivisions of a state are permitted to regulate both the public and private use of pesticides within their jurisdiction. See, e.g., Montgomery Cnty. v. Complete Lawn Care, Inc., 207 A.3d 695 (Md. Ct. Spec. App. 2019) (upholding county ordinance restricting the use of certain pesticides throughout the County where state pesticide law did not preempt local regulation on pesticides). Montgomery County, MD, for example, prohibits the use of certain pesticides on private lawns, [5] and many localities in Maine have adopted various restrictions on the application, storage, and sale of synthetic pesticides. [6]

Pharmaceutical Regulation in the United States

In the United States, the Food and Drug Administration ("FDA") regulates pharmaceutical products pursuant to the FFDCA. FDA is responsible for approving and monitoring the ongoing safety, efficacy, labeling, and marketing of these products. Generally, pharmaceutical drugs must receive pre-market approval before they can be sold. Under FFDCA and FDA regulations, there are several drug approval pathways, including the New Drug Application ("NDA"), Abbreviated New Drug Application ("ANDA"), and accelerated approval processes.

The traditional approval pathway for new drugs, also known as "innovator drugs," is the NDA, which the applicant, typically the drug's manufacturer, submits to FDA. FDA must approve the NDA prior to commercialization. 21 U.S.C. § 355(a); 21 C.F.R. § 314.50; U.S. Food & Drug Admin., New Drug Application (NDA) (Jan. 21, 2022). In deciding whether to approve an NDA, the FDA considers several key questions including, among other things, "[w]hether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks." U.S. Food & Drug Admin., New Drug Application (NDA) (Jan. 21, 2022).

FDA's authority allows it to unilaterally withdraw its approval for several reasons relating to the drug's safety or effectiveness. For example, upon FDA's finding that, under the approved conditions of use, the scientific evidence indicates the drug is not shown to be safe, or that there is a "lack of substantial evidence" that the drug is effective, the agency may withdraw its approval. 21 U.S.C. § 355(e). Where FDA finds the drug poses an imminent hazard to the public health, it may suspend approval immediately. Id. Otherwise, the agency is required to give the drugmaker-applicant notice and an opportunity for hearing before withdrawing its approval. Id.

The safety-or-effectiveness determination may apply to all products containing

[1] *Dep't of Env't Conservation, DEC Proposes New Rules Prohibiting Glyphosate Use on State Properties, N.Y. State (June 8, 2022), https://dec.ny.gov/news/press-releases/2022/6/dec-proposes-new-rules-prohibiting-glyphosate-use-on-state-properties.*

[2] *Dep't of Env't Conservation, Pesticide Use at Schools and Day Care Centers, N.Y. State, https://dec.ny.gov/environmental-protection/pesticides/laws-regulations/pesticide-use-at-schools-day-care-centers#:~:text=Under%20amendments%20to%20the%20State,playgrounds%2C%20turf%20or%20athletic%20fields (last visited Aug. 13, 2025).*

[3] *The Board of County Commissioners, Miami-Dade Legislative Item File Number: 191159, Miami-Dade Cnty., Fla., https://www.miamidade.gov/govaction/matter.asp?matter=191159&file=true&fileAnalysis=false&yearFolder=Y2019#:~:text=For%20all%20contract%20extensions%2C%20contract,and%20render%20the%20contract%20voidable (last visited Aug. 13, 2025).*

[4] *Irvine Unified School District, Progressive Pest Management Program (June 7, 2023), https://iusd.org/sites/default/files/documents/00--IUSD%20PPM%20Program%20060723.pdf.*

[5] *Dep't of Env't Prot., What Pesticides Are Allowed, Montgomery Cnty. Md., https://www.montgomerycountymd.gov/DEP/property-care/lawns/law/allowed-pesticides.html (last visited Aug. 13, 2025).*

the drug in question, or limit the determination to only certain indications, formulations, or dosages of products containing the drug. For example, FDA has withdrawn all drug products containing cerivastatin sodium, previously marketed under the brand name Baycol. See 21 C.F.R. § 216.24. By contrast, there are multiple examples where FDA has found that withdrawal of only certain dosages of or indications for medications was appropriate based on safety or effectiveness reasons: ondansetron hydrochloride (formerly marked at Zofran) for products containing more than 16 mg per dose; bromocriptine mesylate for the indication of post-partum lactation only, not other indications such as Parkinson's disease; and oral over-the-counter (but not prescription) phenylephrine as a nasal decongestant only, based only on a finding of lack of efficacy. Id.; see also U.S. Food & Drug Admin., FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review (Nov. 7, 2024), *https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after*.

The FDA's regulatory scheme comprehensively governs the approval, labeling, and marketing of pharmaceutical drugs in the U.S. Although states have occasionally attempted to restrict or prohibit the sale or use of FDA-approved drugs, litigation concerning those restrictions is rare. [7] Where state law imposes a ban or restriction that conflicts with FDA approval, courts have held that the conflicting state laws are preempted. Id. One example arose out of Massachusetts' repeated attempts to prevent the sale of Zohydro, an opioid painkiller, based on allegations that the drug did not incorporate sufficient abuse-deterrent features. These regulations led to a series of cases known as the Zogenix trilogy, which highlight the preemptive relationship between federal law under FFDCA as administered by FDA and state laws attempting to place additional bans or restrictions on FDA-approved drugs. See id.; Lars Noah, State Affronts to Fed. Primacy in the Licensure of Pharm. Prods., 2016 Mich. St. L. Rev 1, 5-6 (2016). More recently, similar preemption issues have been raised by state restrictions on the use of the FDA-approved drug mifepristone following the Supreme Court's decision in Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022).

Cosmetics Regulation in the United States

FDA has long been authorized to regulate cosmetics in the U.S. under FFDCA and the Fair Packaging and Labeling Act ("FPLA"). [8] Recently, U.S. cosmetic regulations underwent seismic changes under the Modernization of Cosmetics Regulations Act of 2022 ("MoCRA"), which promised to be "the most significant expansion of FDA's authority to regulate cosmetics since [FFDCA] was passed in 1938." [9]

FFDCA defines "cosmetic" as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." 21 U.S.C. § 321(i). MoCRA further provides a definition of "cosmetic product," which refers to "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product." Id. § 364(2).

The new facility registration provisions under MoCRA grant FDA the authority to suspend a facility's registration if the agency determines that a product the facility manufactures or processes has a reasonable probability of causing serious adverse events and reasonably believes that other products from the facility may be similarly affected. Id. § 364c(f)(1). A facility whose registration is suspended is prohibited from distributing or selling cosmetic products from the facility in the United States. Id. § 364c(f)(6). MoCRA also grants FDA mandatory recall authority over misbranded or adulterated cosmetic products. Where FDA determines there is a reasonable probability that a cosmetic product is misbranded or adulterated, and that its use will cause serious adverse events, FDA must first provide the responsible per-

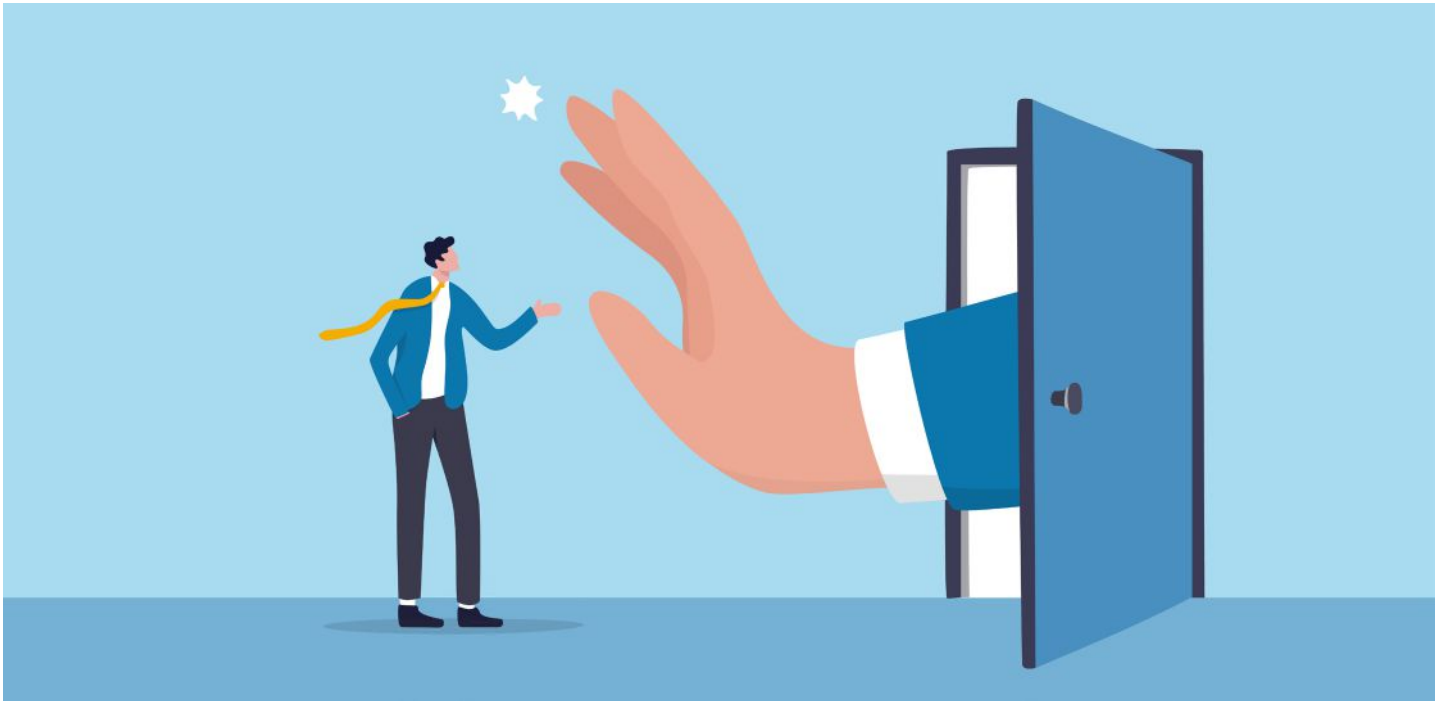
In states where no preemption law exists, political subdivisions of a state are permitted to regulate both the public and private use of pesticides within their jurisdiction.

[6] *Maine Dep't of Agric., Conservation & Forestry, Municipal Pesticide Ordinances, https://www.maine.gov/dacf/php/pesticides/public/municipal_ordinances.shtml (last visited Aug. 13, 2025).*

[7] *James M. Beck, Federal Preemption of State Attempts To Ban FDA-Approved Abortion Drugs After Dobbs, Drug & Device L. Blog (Jun. 28, 2022), https://www.druganddevicelawblog.com/2022/06/federal-preemption-of-state-attempts-to-ban-fda-approved-abortion-drugs-after-dobbs.html.*

[8] *U.S. Food & Drug Admin., FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated (Mar. 2, 2022), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated.*

[9] *U.S. Food & Drug Admin., Modernization of Cosmetics Regulation Act of 2022 (MoCRA) (Jan. 17, 2025), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra.*



son with the opportunity to voluntarily recall and cease distribution of the offending products within a prescribed time and manner. Id. § 364g(a). If this fails, FDA may issue an order requiring the responsible person to immediately cease distribution of the product. Id. The responsible person will be provided with an opportunity for an informal hearing within ten days of such an order to determine whether the order is justified by adequate evidence. Id. § 364g(b).

FDA has also long exercised its authority to restrict cosmetics when it determines that an ingredient may be harmful when used as directed or expected. [10] It does so through rulemaking, codifying finalized regulations at 21 C.F.R. § 700.11-700.35. Such restrictions include mercury compounds, certain cattle materials, bithionol, and aerosol products containing zirconium. Id. More recently, FDA made headlines for its proposed rule banning formaldehyde and formaldehyde-releasing chemicals as an ingredient in hair smoothing or straightening products, [11] although implementation of this proposed rule has been delayed. [12]

MoCRA directly addresses preemption of state regulation of cosmetics. The statute expressly preempts state and local laws that differ from the Act's requirements regarding "registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation." 21 U.S.C. § 364j(a). However, the statute also expressly limits preemption to those enumerated requirements. Id. § 364j(b) ("Nothing in the amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a)"). It also clarifies that, notwithstanding the express preemption provisions, "nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in a cosmetic product." Id. In other words, states may restrict the use of certain cosmetic ingredients, and such regulations will not be preempted by federal law. See id. Accordingly, state restrictions

[10] *U.S. Food & Drug Admin., Prohibited & Restricted Ingredients in Cosmetics (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics.*

[11] *Jonathan Franklin, The FDA is proposing a ban on hair relaxers with formaldehyde due to cancer concerns, NPR (Oct. 21, 2023), https://www.npr.org/2023/10/21/1207127777/fda-proposal-ban-hair-relaxers-formaldehyde.*

[12] *Katie Kindelan, As FDA delays proposal to ban formaldehyde in hair relaxers, dermatologist shares safety tips for women, ABC News (July 23, 2024), https://abcnews.go.com/GMA/Wellness/fda-delays-proposal-ban-formaldehyde-hair-relaxers-dermatologist/story?id=112195034#:~:text=The%20Department%20of%20Health%20and,of%20a%20person%20inhaling%20formaldehyde https://abcnews.go.com/GMA/Wellness/fda-delays-proposal-ban-formaldehyde-hair-relaxers-dermatologist/story?id=112195034#:~:text=The%20Department%20of%20Health%20and,of%20a%20person%20inhaling%20formaldehyde; Michelle Garcia & Berkeley Lovelace, Jr., Federal regulations paused, halting FDA's proposed ban on formaldehyde in hair products, NBC News (Jan. 22, 2025), https://www.nbcnews.com/news/nbcblk/fda-formaldehyde-ban-limbo-trump-executive-order-rcna187961.*

and bans on cosmetic products are common, with many states imposing bans or restrictions on cosmetic product ingredients. For example, although the proposed federal rule banning formaldehyde in cosmetic products has been delayed, Maryland and California already prohibit the sale of cosmetic products containing formaldehyde, as well as other ingredients. H.B. 603, 2021 Gen. Assemb., 442nd Sess. (Md. 2021); A.B. 496, 2023 State Assemb., Reg. Sess. (Cal. 2023).

Bans and Restrictions in Litigation

How are Bans and Restrictions Used in Litigation?

Evidence of bans or restrictions may be used in mass tort litigation in a few different ways. First, a ban or restriction of a product in one jurisdiction may be used to undercut other scientific determinations about the product's safety. For example, if a defendant is permitted to introduce evidence that a product is lawfully sold in the United States, the plaintiff may seek to introduce evidence that the product has been banned or restricted in certain jurisdictions within the United States. Given the multi-tiered regulatory framework for pesticide and cosmetics products in particular, the number of state and local jurisdictions in which a product is used and sold dwarfs the number of entities that undertake a scientific review of a product at the national level. Permitting evidence that these local jurisdictions have banned or restricted a product can therefore create misimpressions about the degree to which governmental entities agree or disagree about a product's safety.

Second, a party may seek to use evidence of bans or restrictions as proof of causation. However, given the vastly different standards that apply to regulatory action and the burden of proof for causation in litigation, reliance on regulatory action to establish proof of causation is improper and should lead to the expert being excluded under Federal Rule of Evidence 702.

Third, a party may seek to use evidence of bans or restrictions as proof of notice that the product is capable of causing the harm alleged. However, introducing evidence of a ban or restriction for such a limited purpose risks running afoul of Federal Rule of Evidence 403 given the potential for such evidence to confuse the jury and prejudice the defense.

Addressing Bans and Restrictions Before and at Trial

Understand the Context

Understanding the context in which the ban or restriction was enacted is the first step in determining the appropriate litigation strategy. This involves, first and foremost, understanding the scope of the ban or restriction at issue. Whereas some bans or restrictions prohibit all product uses, far more often they are narrower restrictions that permit some uses in certain circumstances. The appropriate litigation strategy for dealing with sweeping restrictions on any use may be different than the appropriate litigation strategy for responding to a narrower restriction in which certain uses of the product are still authorized.

It is equally important for defendants to pinpoint the reason behind a ban or restriction: why was the product banned or restricted and on what scientific basis? Often times, bans or restrictions apply to broad classes of products and are not specific to the particular product at issue in the litigation. Bans or restrictions may also not be based on the same human health outcome that is the subject of the litigation. Indeed, some bans or restrictions are not based on human health concerns at all.

Where the ban or restriction is based on the same human safety endpoint that is the subject of litigation, defendants should take great care to evaluate the reasoning on which the ban or restriction is based. Bans or restrictions at the local level are often political decisions that account for a multitude of factors and are almost never based on an independent and complete evaluation of all relevant scientific data. Although many of these entities lack the resources necessary to make scientific determinations regarding product safety, they are often first to restrict the sale or use of a product when any question of product safety is raised, regardless of merit. While many cite public safety as a motivating concern, these restrictions often run counter to the determinations of the very entities charged with evaluating the safety of products in the countries in which these jurisdictions are located. As discussed further below, even where a ban or restriction is based on an independent review of the full scientific evidence, regulatory evaluations typically employ different standards than the standard for causation in tort litigation.

Critically evaluating the scope and reasoning behind a ban or restriction will help litigants adopt litigation strategies that present the most accurate regulatory and scientific picture at trial.

Defendants should keep in mind that motions in limine are a two-way street, and plaintiffs will likely file such motions to frame the regulatory and scientific history in a way they think advances their case.

Use the Right Terminology

After situating the ban or restriction within its proper context, litigants should then use the right terminology to describe the ban or restriction. "Ban" is a loaded term, and there are often far more appropriate terms that more accurately describe the nature of the restriction or prohibition at issue. This could be as simple as using the term "withdrawn" instead of "banned" to refer to a pharmaceutical that is no longer on the market. A product may also not be "banned" in its entirety. Many of the most stringent pesticide regulations prohibit some – or even most – uses but still permit others. Referring to a restriction as a "ban" can create misimpressions about the degree to which certain uses are permitted or prohibited. For this reason, defendants should take great care to describe with particularity the nature of any restriction in discovery responses, court filings, and in court so as not to allow the judge or

jury to be misled about the nature of the ban or restriction at issue.

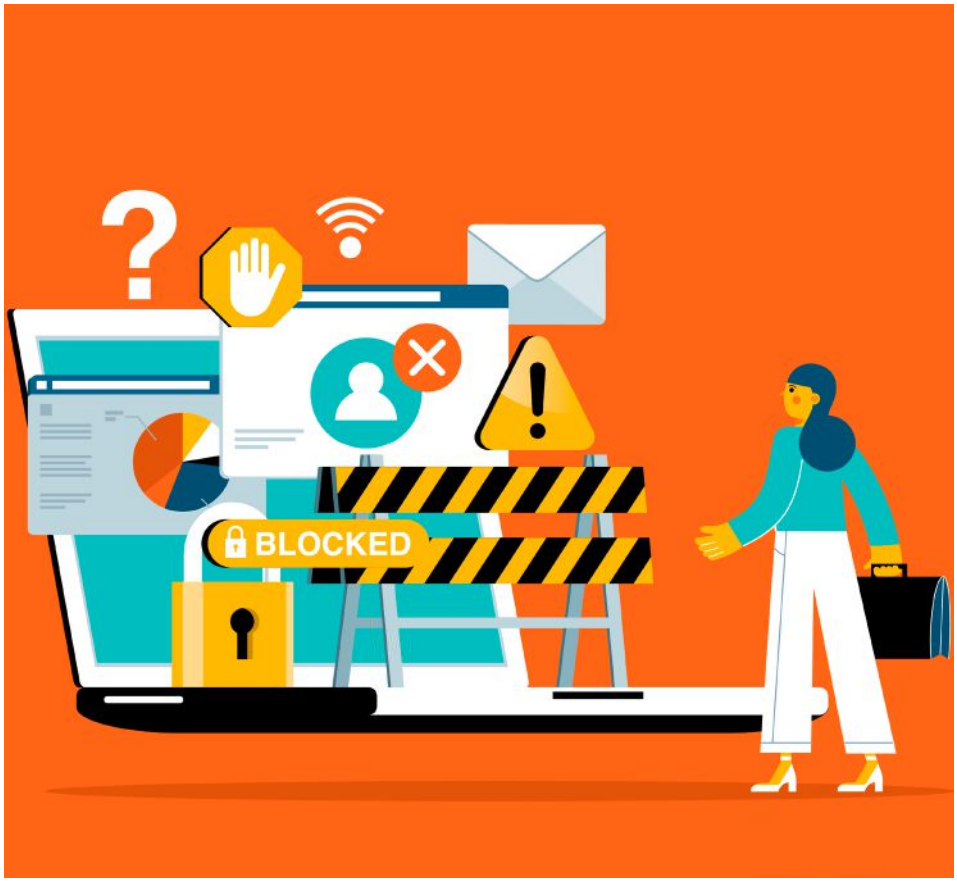
Leverage Pretrial Filings

After determining the scope of and reasoning behind the ban or restriction at issue, litigants should pursue a trial strategy that allows them to present the most accurate regulatory and scientific picture to the jury. This is accomplished through various pretrial filings such as motions to exclude experts under Federal Rule of Evidence 702, motions for summary judgment under Federal Rule of Civil Procedure 56, and through the filing of motions in limine.

A key to these pretrial filings is to articulate how the ban or restriction is not relevant to issues to be decided in the case. For one, although a ban or restriction may reference human safety concerns, many are not based on an independent evaluation of the full set of scientific data. Rather, many are political decisions based on various considerations enacted without any independent scientific analysis demonstrating that a safety concern exists. As discussed above, the ban or restriction also may involve a certain type of product generally, including, but not specific to, the particular product involved in the litigation. Or the ban or restriction may involve the specific product at issue in the litigation but have nothing to do with the health effect alleged in the litigation – or for that matter, any human health effect. In none of these circumstances is the ban or restriction probative of issues that a jury will address in tort litigation, which should lead to exclusion of the evidence.

Even where the ban or restriction is based on an independent review of the full scientific evidence, there still may be important differences between regulatory standards and the burden of proof in tort litigation that should prevent introduction of such evidence at trial. Regulatory standards typically "result[] from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances." Allen v. Pa. Eng'g Corp., 102 F.3d 194, 198 (5th Cir. 1996). As such, they are often more conservative than the standard of causation applicable in tort litigation. See, e.g., Junk v. Terminix Int'l Co., No. 4:05-CV-0608-JAJ, 2008 WL 5142188, at *6 (S.D. Iowa Aug. 15, 2008) (citing Glastetter v. Novartis Pharms. Corp., 252 F.3d 986, 991-92 (8th Cir. 2001)) (excluding under Federal Rule of Evidence 403 evidence that EPA will prohibit indoor residential use of pesticide products containing chlorpyrifos because "the EPA's standard for prohibiting indoor residential use of pesticides is different than the standard of causation in a products liability action"). Reliance on a ban or restriction as proof of causation is therefore misplaced and should lead to exclusion. See Hollander v. Sandoz Parms. Corp., 95 F. Supp. 2d 1230, 1233 n.9 (W.D. Okla. 2000), aff'd in part and remanded, 289 F.3d 1193 (10th Cir. 2002) ("The agencies' threshold of proof is reasonably lower than that appropriate in tort law, which traditionally makes more particularized inquiries into cause and effect and requires a plaintiff to prove that it is more likely than not that another individual has caused him or her harm."); accord In re Zantac (Ranitidine) Prods. Liab. Litig., 644 F. Supp. 3d 1075, 1093 (S.D. Fla. 2022) ("[A] regulatory agency's risk-benefit analysis 'does not directly focus on the question of causation in... [a] toxic tort case.'" (quoting McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1250 (11th Cir. 2005)).

Permitting the introduction of evidence relating to bans or restrictions also risks creating unfair prejudice, confusing the jury, and wasting time. Evidence of a ban or restriction carries with it an official character. See Junk, 2008 WL 5142188, at *6; Bright v. Firestone Tire & Rubber Co., 756 F.2d 19, 23 (6th Cir. 1984) (upholding the district court's partial exclusion of a government report and noting that "[t]here was a substantial danger of unfair prejudice because the jury may have been influenced by the official character of the report to afford it greater weight than it was worth"). Thus, the jury may not only be misled into thinking that the ban or restriction offers proof of causation but also give it "greater weight than it [is] worth." Id. Evidence of bans or restrictions without their full context implicitly suggests that a governmental entity has independently and appropriately evaluated the safety of a product using the same standard for causation that the jury must apply; when that is not the case, such evidence is likely



to be unfairly prejudicial and should be excluded.

Defendants should keep in mind that motions in limine are a two-way street, and plaintiffs will likely file such motions to frame the regulatory and scientific history in a way they think advances their case. Just as a defendant might want to exclude evidence of bans or restrictions, so too will a plaintiff want to exclude evidence of regulatory conclusions or scientific determinations favorable for the defense. However, the same rationale that favors excluding evidence of bans or restrictions as proof of causation does not apply where a competent regulatory authority has conducted a thorough scientific review and determined the product is safe for use. Given the more conservative standards to which they are applied, such evidence is in fact supportive evidence that the product did not cause the alleged injury. It should also be noted that scientific determinations regarding product safety may be probative of issues other than causation, such as the defendant's reasonableness.

Contextualize the Evidence

Depending on pretrial rulings, it is possible that some evidence of bans or restrictions may be introduced at trial. In that case, contextualizing the evidence will be key, and defendants should take care to separate for the jury the rationale behind a ban or restriction and the question that the jury itself will be deciding. That said, bans and restrictions are likely to be an ancillary issue in any case dealing with questions of medical causation, and the amount of time that should be spent addressing such evidence will depend on the specific circumstances. Defendants may not wish to leave such evidence unaddressed but also may not want to spend additional time on what is ultimately an ancillary issue. Defendants should keep these considerations in mind as they weigh whether and how to address evidence of bans or restrictions in openings, closings, and witness examinations.

Conclusion

The number of jurisdictions at the federal, state, and local level that have authority to regulate pesticide, pharmaceutical, and cosmetic products in the United States makes it likely that litigants involved in mass tort litigation will be faced at some point with evidence of some type of ban or restriction concerning the product involved in the litigation. Although these bans and restrictions are rarely based on an independent evaluation of the scientific data and do not answer the ultimate questions of causation that a jury must decide, plaintiffs often seek to use evidence of these bans or restrictions as proof of causation or to undermine other regulatory or scientific conclusions regarding product safety. The proper strategy for a defendant will invariably involve a careful assessment of the full regulatory and scientific picture involving the product at issue. Only after fully assessing the regulatory and scientific picture can a defendant adopt and implement the litigation strategy that presents the most accurate information to the jury and maximizes its chances of success at trial.

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