OTC Talc Litigation

The Hidden Preemption Defense: What You Should Know

By Anne A. Gruner and Nicholas M. Centrella, Jr.

As talc litigation expands, impossibility preemption arguments may become a viable strategy to dispose of claims against the OTC products for which FDA monographs exist.

The most recent talc verdicts have demonstrated some traction in defeating claims based on certain go-to defense strategies, including personal jurisdiction dismissals, the use of expert testimony and *Daubert* motions discrediting scientific causation, and even requests to jurors to use their "common sense" in evaluating scientific evidence. However, there is another tool that defense attorneys should consider in talc cases: federal preemption.

Part of the mass appeal of talc cases lies in the prevalence of talc-based products in the marketplace, due to the numerous uses for talc in a variety of consumer products across cosmetics, over-the-counter (OTC) drugs, and even foods. As talc litigation expands into products that may be regulated as OTC drugs, defense counsel should consider the options that they might have in invoking federal preemption as a defense strategy. While the defense remains untested, there is a sound basis for its application. This article will discuss the federal U.S. Food and Drug Administration (FDA) regulatory scheme that is applicable to talc-based products and when federal preemption may support an argument for defeating conflicting state law claims against talc-containing OTC drugs.

Regulation of Talc Products: Is It a Cosmetic or an Over-the-Counter Drug?

Talc is a naturally occurring mineral that is mined from the earth and has a variety of uses in cosmetics, other personal care products, and even foods. *See* Talc, U.S. Food & Drug Admin. (Aug. 21, 2018), https://www.fda.gov. For example, it can be used to absorb moisture, prevent caking, or make facial makeup opaque. *Id.* Asbestos is also a naturally occurring silicate mineral and may be found in close proximity to talc in the earth. *Id.* Lawsuits alleging injuries arising from talc in consumer products generally fall into two

■ Anne A. Gruner is a trial attorney representing clients nationally in complex products liability, mass tort and commercial litigation disputes. She regularly represents manufacturers of medical implant devices in both individual and consolidated cases and counsels clients in pre-litigation phases through resolution. She is based in Duane Morris' Philadelphia office. Nicholas M. Centrella, Jr., practices in the area of products liability in Duane Morris' Philadelphia office. He represents major medical device and pharmaceutical manufacturers nationally in complex personal injury matters.

main categories: (1) that talc in the product at issue is contaminated with asbestos—a known carcinogen—and exposure leads to mesothelioma; or (2) that there is a causal association between use of talc-containing powders and ovarian cancer. These lawsuits involve products such as Colgate-Palmolive's Cashmere Bouquet talcum powder (alleged to contain asbestos fibers and cause mesothelioma) and Johnson & Johnson's baby powder products (alleged to cause ovarian cancer).

Many of these talc-containing products are traditionally regarded as cosmetics, and that categorization is significant in the context of the federal regulatory scheme. This is because cosmetic products and ingredients, with the exception of color additives, do not have to undergo FDA review or approval before they are placed on the market. *See* Talc, *supra*. Instead, cosmetics must be properly labeled and must be safe for use by consumers under labeled or customary conditions of use under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA). Thus, labeling of cosmetics is relatively unregulated compared to OTC drugs. As a result, plaintiffs often pursue warnings-based claims by alleging that the product is misbranded—defined in part as either "false or misleading"—under the FDCA. *See* 21 U.S.C. §701.1.

However, some cosmetic products, including certain talcum powders, may also be subject to regulation as OTC drugs under the FDCA if they are used for a medicinal purpose. As early as 1969, circuit courts held that products could be both cosmetics and drugs under the FDCA. *See U.S. v. An Article Consisting of 216 Individually Cartoned Bottles, More or Less, of an Article Labeled in Part: Sudden Change, etc., Hazel Bishop, Inc.*, 409 F.2d 734, 739 (2nd. Cir. 1969) ("It is clear that the fact that an article is a cosmetic does not preclude its being a drug for the purposes of the Act."); *United States v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away Temp. Wrinkle Smoother, Coty"*, 415 F.2d 369, 372 (3rd Cir. 1969) (classifying face wash as a drug). These cases and their progeny adopt a broad view of the FDCA's reach, derived from 21 U.S.C. §321(g)(1): "The term 'drug' means… articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and…articles (other than food) intended to affect the structure or any function of the body of man or other animals." *See, e.g., U.S. v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 540 (D.R.I. 1994) (finding that an herbal shampoo was a drug under §321(g)(1) because the manufacturer intended for it to have "a physiological effect on the body of man").

The determination of a product's "intended use" for purposes of classifying it as a drug or cosmetic, or both, may be established in a number of ways. Those ways include (1) the product labeling or other promotional materials; (2) consumer perception, including why the consumer purchased the product and what the consumer expects it to do; and (3) the presence of ingredients that may have a well-known therapeutic use. *See* Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?), U.S. Food and Drug Admin. (Apr. 30, 2012), https://www.fda.gov. For example, the U.S. District Court for the Eastern District of Wisconsin noted that the FDCA defines a drug "by its intended use even regarding prevention. That is so, even if that means that something like honey, cinnamon sugar or garlic fits the definition if intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." *U.S. v. Lebeau*, No. 10-CR-253, 2016 WL 447612, at *6 (E.D. Wisc. Feb. 3, 2016) (internal quotation marks omitted).

Even when a talc-containing product may traditionally be viewed as a cosmetic, the fact that it is also marketed for therapeutic purposes may subject it to regulation as an OTC drug. This distinction is critical, and it opens the door for the possibility of applying federal preemption arguments to dismiss state law tort claims due to the labeling and regulatory oversight applicable to OTC drugs.

Potential for Federal Preemption of Talc-Containing OTC Drugs

When an over-the-counter talc-containing drug is subject to an FDA "monograph," federal preemption could offer a defense.

What Is a Monograph, and How Is It Generated?

Understanding how federal preemption applies to OTC products is aided by understanding the process by which OTC drugs are marketed. The FDCA has three regulatory pathways by which OTC drug products may be approved for marketing. The first is the New Drug Application (NDA) process. *See Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 781 (E.D. Tex. 2008). The second is the Abbreviated New Drug Approval Application (ANDA) pathway. *See Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 455-56 (D.D.C. 1999). The third and most commonly used method, discussed here, is the monograph process. *See Cutler v. Kennedy*, 475 F. Supp. 838, 844–46 (D.D.C. 1979).

The FDA Office of Drug Evaluation IV in the Center for Drug Evaluation and Research has primary responsibility for OTC drug review and approval. *See* Drug Applications for Over-the-Counter "OTC" Drugs, U.S. Food and Drug Admin. (Jan. 7, 2015), https://www.fda.gov. The Nonprescription Drug Advisory Committee meets regularly to assist the FDA in evaluating and reviewing OTC products. *Id.* Because of the significant number of OTC products (more than 300,000), the FDA commonly reviews the active ingredients and the labeling of more than 80 therapeutic classes of drugs (*e.g.*, analgesics or antacids) instead of individual drug products. *Id.* For each category, an OTC drug monograph is developed and is published in the Federal Register, which serves as the "recipe book" covering active ingredients, doses, formulations, and labeling. *Id.*

The FDA's development of a monograph for a class of drugs takes place over several steps. It starts with the convening of an expert panel to review existing data to determine the conditions under which an OTC drug may be marketed without an NDA or ANDA. *See Cutler v. Hayes*, 818 F.2d 879, 884 (D.C. Cir. 1987). The panel then sends its recommendations to the FDA as a proposed monograph. *Id.* The FDA then reviews the expert panel's proposed monograph and publishes it in the Federal Register for public comment. *Id.* After review of the comments, the FDA publishes a tentative final monograph (TFM) in the Federal Register and again invites comments and objections. *Id.* After the comment period has ended and the FDA has considered any additional comments, a final monograph may be published. *Id. See also* 21 C.F.R. §330.10(a)(1)-(9). This process can be lengthy, and generally, a manufacturer may

market an OTC product while this process takes place. *See* 21 C.F.R. §330.13.

Once complete, the "final monograph" is published "in the Code of Federal Regulations" and "[t]hose regulations establish conditions under which a category of over-the-counter drugs is recognized as safe and effective and not misbranded." *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 786 (Cal. Ct. App. 2002) (citing 21 C.F.R. §330.10 (2001)). After the FDA approves a monograph, the product must meet the specifications (including all labeling requirements) established in the monograph. *See id.* at 786. If a product doesn't, the product is "liable to regulatory action." 21 C.F.R. §§330.1, 330.10(b).

The Diaper Rash Product TFM

Products containing talc may fall under an FDA monograph if they are marketed for a therapeutic purpose. For example, certain talc-containing baby powder products fall under the purview of the FDA's TFM on diaper rash drug products, which covers products that help treat and prevent diaper rash. *See* Skin Protectant Diaper Rash Drug Products, 55 Fed. Reg. 25,206 (June 20, 1990) (codified at 21 C.F.R. §347.3 *et seq.*). In a discussion on the safety of talc products, the diaper rash products TFM notes that "talc can be used for the treatment of diaper rash provided it contains the same warning, *i.e.* not to use on broken skin, as the Panel recommended for prevention of diaper rash." *Id.* at 25,224. The TFM also states that despite instances in which children had accidentally inhaled talcum powder during use, "the agency believes that talc can be labeled appropriately for safe OTC use." *Id.*

Accordingly, the FDA classified talc "in Category I for use in the treatment and prevention of diaper rash with labeling that includes [the approved warnings]." *Id.* at 25,224–25. Those warnings are "1. Do not use on broken skin; and 2. Keep powder away from the child's face to avoid inhalation, which can cause breathing problems." *Id.* at 25,224. Products containing talc that are used for skin protection or treatment of diaper rash are therefore subject to the labeling requirements of this TFM. This regulation under an FDA monograph, including tentative but not-yet-final rules, in the form of a TFM, significantly curtails the ability of manufacturers to alter their labeling schemes unilaterally. *See* 21 C.F.R. §330.13(b)(2).

What Are the Effects of a Monograph on an OTC Drug?

Federal preemption as applied to OTC drugs has not garnered the limelight that it has received in the arena of generic drugs. But the same essential principles outlined in the well-known cases of *Wyeth v. Levine*, *PLIVA, Inc. v. Mensing* and *Mutual Pharmaceutical Co., Inc. v. Bartlett* are relevant. In general, preemption comes in two forms: express or implied. And when Congress regulates a commercial area, generally "state laws regulating that aspect of commerce must fall… whether Congress' command is explicitly stated in [a] statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Over-the-counter drug preemption is governed by 21 U.S.C. §379r, which expressly preempts state law tort claims imposing requirements "different" than or "otherwise not identical with, a requirement under [the FDCA]." This statute, however, also contains a savings clause that exempts state law product liability claims from preemption. *See* 21 U.S.C. §379r(e). As discussed more fully below, there are arguments that the savings clause only applies to product liability claims that are expressly preempted, and in light of this structure, implied preemption has greater application in the OTC drug context.

Conflict preemption is a type of implied preemption. It occurs "where compliance with both federal and state regulations is a physical impossibility…. or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth v. Levine*, 555 U.S. 555, 588–89 (2009) (internal citations omitted). Importantly, the Supreme Court has recognized that an "agency regulation with the force of law can preempt conflicting state requirements." *Id.* at 576. While the monograph system for OTC drugs involves labeling regulations for classes of drugs rather than for one drug in particular, courts have held that the monograph establishes a federal requirement for drug labeling. *See, e.g.*, *Mills*, 581 F. Supp. 2d at 787. It is within this framework that impossibility preemption comes into play in determining whether state tort law would impose a requirement on the marketing and sale of an OTC drug that conflicts with, or is impossible under, the FDCA's requirements, *i.e.*, the monograph.

In this analysis, impossibility preemption asks a court to determine two essential questions:

Products containing talc may fall under an FDA monograph if they are marketed for a therapeutic purpose.

1. "Whether the private party could independently do under federal law what state law requires of it"; and
2. If a party could take independent action, does "clear evidence" show that the FDA would have rejected such action after the fact.

Wyeth, 555 U.S. at 573 ("*Wyeth*"); *PLIVA, Inc. v Mensing*, 564 U.S. 604, 620 (2011) (*Mensing*); *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013) (*Bartlett*).

Courts have applied the preemption holdings of *Wyeth*, *Mensing*, and *Bartlett* to OTC drug products and recognized that federal law preempts design-defect claims when a plaintiff's claims related to an OTC drug would require either a redesign of the allegedly defective product or simply pulling the allegedly defective product from the market. *See, e.g.*, *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 148–49 (Cal. Ct. App. 2017). Similarly, warnings-related claims for OTC drug products have been held preempted when a plaintiff's claims "attempt to place on nonprescription drug manufacturers a duty to warn that is broader in scope and more onerous than that currently imposed by applicable statutes and [FDA] regulations." *Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 555 (Cal. 1993).

The reasoning behind decisions applying federal preemption to OTC drug prod-

ucts is premised in part on the familiar logic that manufacturers and distributors cannot unilaterally change the manufacturing or labeling for their products because they lack the power to change a monograph or TFM. *See Eckler v. Neutrogena*, 189 Cal. Rptr. 3d 339, 353 (Cal. App. 2015). As noted, the federal regulations require a product sold under the OTC guidelines to conform to the "applicable monograph" or it will be subject to regulatory action. 21 C.F.R. §330.1. The federal regulations also treat the addition of comments, new data, or information related to a TFM as a petition to amend. 21 C.F.R. §330.10(a)(7)(ii)–(v).

There are grounds for arguing that preemption applies to tentative final monographs as well as final monographs. Manufacturers may still be subject to regulatory action if they produce a noncompliant product with an ingredient covered by a TFM, particularly when there is no corresponding final monograph. *See* 21 C.F.R. §330.13(b)(2). Further, permitting conflicting state requirements before the FDA has imposed a final rule would lead to "states imposing a premature patchwork of disparate requirements." *Eckler*, 189 Cal. Rptr. 3d at 360.

For example, diaper rash products TFM specifies the requirements to market an OTC drug legally that has undergone the monograph process and is not marketed under an NDA or an ANDA. 21 C.F.R. §330.10(a)(7)(i); 21 C.F.R. §330.13(b)(2). The diaper rash products TFM sets forth the warnings that are permitted for the class of products. *See, e.g.*, 21 C.F.R. §347.50; 55 Fed. Reg. 119, 25,204, 25,244. A manufacturer or supplier must use the exact language for warnings as set forth in the TFM, and they may only market a product whose label diverges from the TFM if the FDA allows it. 51 Fed. Reg. 16,258, 16,262, 1986 WL 93492 (May 1, 1986).

To take this example to its conclusion, it is an improper attempt to usurp the FDA's careful consideration of the appropriate labeling requirements by alleging that manufacturers and distributors of OTC drugs that are subject to an applicable monograph should have changed the design or labeling of their products. *See Eckler*, 189 Cal. Rptr. 3d at 359. Stated differently, conflicting state law claims against an OTC drug that is otherwise compliant with an applicable monograph should be barred as preempted.

Avoiding Pitfalls in Presenting an OTC Drug Preemption Defense

While applying federal preemption in an OTC drug case is not without complexities, not all of which can be addressed in this article, it bears noting that any preemption defense must confront the savings clause in the FDCA. 21 U.S.C. §379r. As referenced above, §379r is the foundation for OTC drug preemption and expressly preempts certain state regulations that are not identical to federal requirements for OTC drugs. *See* 21 U.S.C. §379r(a). The caveat is that the statute's "savings clause" preserves, or "saves," state product liability claims that the regulation may have otherwise preempted. *See* 21 U.S.C. §379r(e) (titled "No effect on product liability law" and stating that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.").

While the savings clause appears formidable, several courts nationwide have interpreted it narrowly to exempt only the express preemption claims identified in 379r itself—thus leaving room for implied preemption arguments. For example, in *Reckis v. Johnson & Johnson*, the Supreme Judicial Court of Massachusetts applied the savings clause only to express preemption arguments under §379r. 28 N.E.3d 445, 456 (Mass. 2015). The court stated that the "savings or exemption from preemption provided by §379r(e), however, does not extend beyond the provisions of section 379r, and in particular does not preclude 'the ordinary working of conflict pre-emption principles.'" *Id.* (citation omitted). Following this principle, the court concluded that "the principles of conflict preemption would bar any claim of failure to warn advanced by the plaintiffs on the premise that the OTC Children's Motrin label should have [been altered]." *Id.* at 460.

And in *Eckler v. Neutrogena Corp.*, the California Court of Appeal acknowledged that the §379r savings clause applied to product liability claims, and the court noted that the savings clause was limited by FDA commentary in the Final Rule for the sunscreen products at issue—which stated that the clause "exempts only those common law claims that are based on State product liability law" and that "implied preemption may arise, [although] such scenarios are necessarily case specific." 189 Cal. Rptr. 3d at 349 (citation omitted).

Presenting this explanation, that the savings clause applies narrowly, and only to express preemption under 379r, is crucial in asserting an impossibility preemption defense against state law product liability claims in an OTC drug case. Counsel should review the applicable precedent, and when it is possible, they should rely on any guidance in the applicable monograph or final rule to bolster the argument that the savings clause applies narrowly. To refer back to *Eckler*, the FDA itself reserved the possibility of applying the implied preemption doctrine in certain product cases, permitting counsel to argue persuasively that implied preemption applies on a fact-specific basis. *See Eckler,* 189 Cal. Rptr. 3d at 349.

This Area Is Ripe for Adjudication

Despite preemption precedent dismissing claims in cases involving OTC drugs such as ibuprofen, sunscreen, and Listerine mouthwash, few readily available court opinions have considered preemption as a defense in the talc context. One case in which preemption was raised that involved a talc-containing product was *Feinberg v. Colgate Palmolive Co.*, No. 190070/11, 2012 WL 954271 (N.Y. Sup. Ct. Mar. 22, 2012). In this case the plaintiff alleged that she was exposed to asbestos from the use of Colgate's Cashmere Bouquet talcum powder from approximately 1950 through the 1980s. *See Feinberg*, 2012 WL 954271, at *1. Colgate argued that the plaintiff's common law failure-to-warn claim was preempted under the FDCA. *Id.* However, the court treated the product as a cosmetic, and therefore, the court reasoned, no argument could be made that the product was subject to a monograph. *Id.* at *4. The fact that there was "no competing federal requirement, and therefore Colgate could have warned talc consumers consistent with state product liability law regarding hazards associated with asbestos," was fatal to Colgate's impossibility preemption argument. *Id.* at *7. This decision leaves the door open for future cases in which the product at issue is marketed for therapeutic purposes consis-

tent with a monograph, such as the diaper rash products TFM, to assert federal preemption with potentially greater success.

Indeed, when a federal regulation in the form of an FDA monograph is applicable, courts have reached the opposite conclusion and found competing state law claims preempted. For example, a California Court of Appeal rejected a challenge to Neutrogena's sunscreen labels, in *Eckler v. Neutrogena Corp.,* holding that the FDCA preempted the plaintiffs' consumer protection claims. 189 Cal. Rptr. 3d at 358–59. The court premised its analysis on the fact that the sunscreen at issue was an OTC drug, subject to "extensive" FDA regulation through the monograph process. *Id.* at 346–47. Reviewing the case law regarding preemption of OTC drugs, the *Eckler* court concluded that claims were almost always preempted, except when courts found statutory exceptions or when label uniformity was not at issue. *Id.* at 357. Otherwise, the court's survey of decisions uncovered "a clear standard" that "[s]tate suits seeking to require product labels inconsistent with the federal objective of national labeling uniformity" are preempted. *Id.* Since the FDA issued regulations for the labeling of sunscreen in its final Rule and previous proposed rulemaking, the plaintiffs' claims for alternate labeling were expressly and impliedly preempted because they would "usurp the federal agency's careful consideration of appropriate labeling requirements and restrictions" and "pos[e] an obstacle to Congress' objective of national labeling uniformity." *Id.* at 358–59.

Likewise, the U.S. District Court for the Eastern District of Texas concluded that a plaintiff's challenge to the labeling of OTC lice treatments was preempted by the FDCA. *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d at 793. The plaintiffs brought a breach of warranty claim, contending that the lice treatments "amount[ed] to snake oil" and were ineffective. *Id.* at 776. The plaintiffs sought to impose labeling requirements on Warner-Lambert under the Texas Deceptive Trade Practices Act by arguing that the lice treatments should not be labeled as pediculicides (chemicals used to kill lice). *See id.* Concluding that the lice treatments were subject to an FDA monograph that contained specific labeling requirements, the court noted that Warner-Lambert was bound by the labeling terms of the monograph. *Id.* at 790. Because the plaintiffs proposed barring Warner-Lambert from selling its lice treatments with language that complied with the FDA monograph, the court determined that their claims were preempted because the plaintiffs' proposed labeling requirements were "different from or in addition to… the requirements imposed by the FDA." *Id.* The impossibility existed in that Warner-Lambert could "refrain from marketing their products," or the company could "comply with the requirements (and avoid the liability) imposed by Plaintiffs' lawsuit," but the company could not "do both." *Id.*

The Supreme Judicial Court of Massachusetts applied federal preemption principles in the personal injury context when it decided, in *Reckis v. Johnson & Johnson*, that the plaintiffs' challenges to nonprescription Children's Motrin labeling scheme were preempted. 28 N.E.3d 445, 460 (Mass. 2015). In that case, a girl and her parents sued Johnson & Johnson when the girl developed a rare and painful skin condition after taking Children's Motrin; the plaintiffs claimed that the labeling made the product defective in that it "failed to warn adequately" of the "serious risk of developing a life-threatening disease" from taking the Children's Motrin. *Id.* at 448–49, 454. Johnson & Johnson's preemption argument was denied at the trial court level, and the jury returned a significant verdict for the plaintiffs. *Id.* at 454. On appeal, the defendants renewed their preemption argument with greater success. The court determined that the failure-to-warn claims related to the Children's Motrin's labeling should have been dismissed as preempted before the trial. *Id.* at 460. Noting that the plaintiffs' common law failure-to-warn claims may not be expressly preempted, the court nevertheless held that such claims were impliedly preempted by conflict preemption principles. *See id.* Specifically, the warnings that the plaintiffs argued should have been included in the labeling were explicitly rejected by the FDA, "putting the defendants in the impossible position of having to comply with conflicting Federal and State requirements." *Id.* at 455. The verdict stood, however, because the court did not have sufficient evidence to conclude that the jury based its finding of liability on this preempted failure-to-warn theory. *Id.* at 461.

At least one court has held that FDCA requirements may also preempt design-defect claims pertaining to OTC drugs. The U.S. District Court for the District of Connecticut held that the design-defect claims in *Batoh v. McNeil-PPC, Inc.* could not survive summary judgment because doing so would have forced the defendant, McNeil-PPC, to change the chemical composition of OTC Motrin unilaterally to avoid liability. 167 F. Supp. 3d 296, 322 (D. Conn. 2016). The court said that state law could not impose a duty on McNeil to change an active ingredient in nonprescription Motrin from ibuprofen to dexibuprofen because it was a "major change" that required FDA approval. *Id.* At the time of the suit, McNeil could not have complied with both its duties to the FDA and the alleged state law duty. *Id.* As a result, the design-defect claim was preempted. *Id.*

At least one court has held that FDCA requirements may also preempt design-defect claims pertaining to OTC drugs.

Conclusion

As talc litigation expands to claims against products that may be classified as OTC drugs that are subject to an FDA monograph, impossibility preemption arguments may become a viable strategy to dispose of claims at the pretrial stage of litigation, avoiding costly jury trials and adverse verdicts subject to appeal. Moreover, companies advertising talc-based products as delivering therapeutic benefits should be fully familiar with the requirements of any applicable monograph or TFM to ensure compliance and thereby afford the possibility of a preemption defense.