

Over the Counter and Under the Radar

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**Although it must be considered on a case-by-case basis, preemption remains a defense that could result in big victories for pharmaceutical defendants.**

# Preemption in Nonprescription Drug Cases

Although attention has been focused on preemption in the medical device and prescription drug contexts following the recent United States Supreme Court opinions in *Riegel v. Medtronic, Inc.*, 552 U.S. \_\_\_,

128 S. Ct. 999 (2008) and *Wyeth v. Levine*, 555 U.S. \_\_\_, 173 L. Ed. 2d 51 (2009), practitioners should not overlook preemption in cases involving over-the-counter (OTC) products. Over the last several years, OTC manufacturers have successfully argued that plaintiffs' state-law based claims were preempted under Section 379r of the Food and Drug Administration Modernization Act (FDAMA). Defendants have found the most success obtaining dismissal of plaintiffs' claims based on the FDAMA's express preemption provision, particularly where plaintiffs only assert claims for economic harm. Practitioners, however, should also consider preemption in personal injury cases involving OTC products. This article begins with a brief overview of the reg-

ulatory scheme governing OTC products, and then examines recent OTC preemption cases, including the impact of *Riegel* and *Levine* on OTC preemption defense arguments.

### The Regulatory Scheme Governing OTC Products

When Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938, it established a comprehensive regulatory scheme designed to ensure that every drug on the market is "safe and effective" for its intended use. 21 U.S.C. §301 *et seq.* No OTC drug may be legally sold in interstate commerce unless it meets the conditions of an OTC drug monograph or a New Drug Application (NDA) approved by the Food and Drug Administration (FDA). 21 U.S.C. §§321(p), 331(d), 355(a); 21 C.F.R. §330.1.

### The OTC Drug Monograph Process

The FDA regulates most OTC medications through its monograph process. A monograph consists of regulations promulgated by the FDA that describe in detail the circumstances under which products containing OTC active ingredients are "generally recognized as safe and effective." A monograph is developed through three steps. First, the FDA appoints an advisory panel

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of independent experts to “review all available data” regarding a category of ingredients, such as antihistamines, and the panel reports its “conclusions and recommendations... with respect to the safety and effectiveness of the drugs” in that designated category. 21 C.F.R. §330.10(a). The panel’s recommendations cover permissible ingredients, dosage strength, dosing instructions by patient age, and labeling. The FDA publishes the panel’s recommendations and considers public comments on the panel’s proposed rules. Second, the FDA publishes a tentative final monograph for further comment. 21 C.F.R. §330.10(a)(6), (7). Again, the FDA considers comments and may conduct an oral hearing. 21 C.F.R. §330.10(a)(8). Third, “[a]fter reviewing [any] objections, the entire administrative record including all new data and information and comments, and considering the arguments made at any oral hearing,” the FDA publishes a final monograph “establishing conditions under which a category of OTC drugs [is]... generally recognized as safe and effective and not misbranded.” *Id.* §330.10(a)(9); *see also* 21 C.F.R. pt. 330, subpt. B (describing the rule-making process). An OTC drug sold in the United States must “meet[] each of the conditions contained” in the applicable monograph, including permissible ingredients, dosage strength, dosing instructions by patient age, and other mandatory labeling. *See* 21 C.F.R. §330.1; *see generally* 21 C.F.R. pts. 331–58 (setting forth monographs for various categories of drugs).

### The NDA Process

Some OTC drug products are considered “new drugs” under the FDCA and require a FDA-approved NDA, or an abbreviated NDA, before they may be marketed. *See* 21 U.S.C. §§321(p), 355(a). To approve an NDA, the FDA must individually evaluate the new drug and determine that the drug is both “safe” and “effective” when used under the conditions described “in the proposed labeling.” 21 U.S.C. §355(b), (d); 21 C.F.R. §314.125(b)(3)–(5). As part of the NDA process, an applicant must submit “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.” 21 U.S.C. §355(b). Specifically, an applicant must submit “adequate and

well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved.” *Id.* §355(d). In determining whether an applicant’s NDA satisfies safety and efficacy requirements, the “FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards.” 21 C.F.R. §314.105(c). The FDA will approve an NDA after determining that the “drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling.” *Id.* §314.105(c); *see also id.* §314.125. Final approval of a NDA is conditioned on the manufacturer’s use of the labeling that the FDA has approved, as well as making specific wording changes that the FDA has requested. *Id.* §314.105(b). Marketing a product using unapproved labeling could violate the FDCA, subjecting a manufacturer to federal enforcement action. *See* 21 U.S.C. §§331(a), (b), (k), 332–34, 352. Safeguards are in place if the FDA later determines that a drug is unsafe or ineffective. *See* 21 U.S.C. §355(e)(1), (3); 21 C.F.R. §314.150(a)(2).

### Preemption as a Defense in the OTC Context

The Supremacy Clause of the U.S. Constitution governs federal preemption of state law. It provides that “the Laws of the United States... shall be the Supreme Law of the Land.” U.S. CONST. art. VI, cl. 2. Under this provision, “state law that conflicts with federal law is without effect.” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Pharmaceutical defendants have argued successfully that because plaintiffs’ state law actions conflict with FDA OTC medication regulations, those actions are preempted.

### Plaintiffs’ Claims

Individual plaintiffs’ claims related to OTC medications largely fall into one of two categories: personal injury cases or cases alleging economic harm. Plaintiffs in economic harm cases specifically disclaim personal injury and instead seek compensation for money spent purchasing the medication at issue. Regardless of the type of relief sought, plaintiffs’ generally allege

that (1) the medication at issue contains incomplete or inadequate warnings; (2) the labeling of the medication contains false or misleading statements about the drug’s effectiveness; or (3) the medication simply does not work. In essence, plaintiffs’ suits argue that even though the FDA has determined that medications are safe and effective and the FDCA specifies that their labels

Both the OTC monograph and NDA approval processes establish “federal requirements” for drug labeling under Section 379r.

must state that the medications safely and effectively treat certain conditions, the medications are unsafe, ineffective or both, and should not have been labeled and marketed as such.

### Express Preemption Defense

**The FDAMA’s Express Preemption Provision**  
Express preemption occurs when Congress has made its intent to preempt known through explicit statutory language. Pharmaceutical defendants most often and most successfully argue that plaintiffs’ state law-based claims are expressly preempted by Section 379r of the FDAMA, which amended the FDCA. Section 379r, titled “National Uniformity for Nonprescription Drugs,” provides:

- (a) ... [N]o State or political subdivision of a State may establish or continue in effect any requirement—
- (1) that relates to the regulation of a[n OTC] drug...; and
  - (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under th[e FDCA]...

21 U.S.C. §379r(a).

Notably, Section 379r’s express preemption clause is quite similar to the express preemption provision at issue in *Riegel*, which applies to medical devices submitted under the FDA’s pre-market approval

(PMA) process. 21 U.S.C. §360k(a). Under Section 360k(a), states cannot establish “any requirement... that is different from, or in addition to” any requirement imposed by the FDCA. Section 379r adds, “or that is otherwise not identical with.” Courts deciding OTC preemption cases have compared the rigorous PMA process to the comprehensive regulatory scheme for OTC

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products, relying on *Riegel* to find preemption of plaintiffs’ claims in OTC cases.

**The Analysis to Determine Express Preemption under Section 379r**

Courts generally follow a three-step approach when analyzing express preemption under Section 379r. First, a court determines whether the FDA’s drug-approval and labeling regulations constitute a federal requirement under Section 379r(a). Second, a court considers whether plaintiffs’ state law-based claims would establish a state requirement regulating a drug. Third, a court decides if the state requirement “is different from, in addition to, or is otherwise not identical with” the federal requirement. Under this analysis, courts unequivocally have held that plaintiffs’ claims have been expressly preempted in OTC cases in which plaintiffs have claimed economic harm. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 122 Cal. Rptr. 2d 72 (Cal. Ct. App. 2002); *Berenguer v. Warner-Lambert Co.*, No. 02-02542, 2003 WL 24299241 (Fla. Cir. Ct. July 31, 2003); *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772 (E.D. Tex. 2008); *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271 (C.D. Cal. 2008).

**Step 1: Do the FDA’s Drug Approval and Labeling Regulations Constitute a Federal Requirement?**

The first step of a preemption analysis

determines whether the FDCA’s drug-approval and labeling regulations constitute a “federal requirement” under Section 379r(a). All of the published opinions that have considered the question have determined that both the OTC monograph and NDA approval processes establish “federal requirements” for drug labeling under Section 379r. *See Kanter*, 99 Cal. App. 4th at 794, 122 Cal. Rptr. 2d at 83; *Berenguer*, 2003 WL 24299241, at \*4; *Mills*, 581 F. Supp. 2d at 785–88; *Carter*, 582 F. Supp. 2d at 1280.

With NDA products, as mentioned above, courts have relied on the “striking” parallels between the NDA process and the PMA process under the Medical Device Amendments of 1976 (MDA) to the FDCA. For example, in *Kanter*, the California Court of Appeal noted that both the NDA and PMA processes require product applicants to submit proposed labeling to the FDA, as well as a FDA finding that the drug or device is safe and effective under the specified conditions of use in the proposed labeling. Further, both processes give the FDA the power to withdraw approval of a new medical device or drug if it determines that the device or drug is not effective as represented on its labeling. *Kanter*, 99 Cal. App. 4th at 793–94, 122 Cal. Rptr. 2d at 83. The court specifically held that this substantial similarity “compels the conclusion that the [NDA process]... establishes a federal requirement with respect to labeling that can have preemptive effect.” *Id.* at 794, 122 Cal. Rptr. 2d at 84. *See also Mills*, 581 F. Supp. 2d at 785–86 (setting forth the similarities between the PMA and NDA processes and finding the NDA approval process establishes a federal requirement for drug labeling under Section 379r).

Likewise, courts have found that the monograph process establishes a “federal requirement” under Section 379r. In *Mills*, the court concluded that the monograph at issue established a federal requirement with respect to drug labeling because the medications “must conform to the conditions contained in the monograph, including the labeling requirements, or be subject to FDA action.” *Id.* at 788; *see also id.* at 787 (“While the monograph system for OTC drugs involves labeling regulation for classes of drugs rather than for one drug in particular, the Court likewise concludes that it establishes a federal require-

ment for drug labeling.”). *See also Kanter*, 99 Cal. App. 4th at 795, 122 Cal. Rptr. 2d at 84 (finding that because the monograph at issue was specific to drugs designed to kill head lice “and set[] forth explicit and detailed federal requirements regarding the content of their labels,” state law claims “that would result in the imposition of different or contradictory labeling” were preempted).

**Step 2: Do a Plaintiff’s Actions Seek to Impose State Regulatory Requirements on an OTC Drug?**

The second step of a preemption analysis determines whether plaintiffs’ state law-based claims would establish “state requirements” regulating a drug. In *Riegel*, the Supreme Court held that state “requirements” include not only statutes and regulations, but also obligations imposed by common law. *Riegel*, 128 S. Ct. at 1008. Specifically, the Court stated, “Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.” *Id.*

Relying on *Riegel*, courts have held that state law claims that argue that an FDA-approved label should be changed, or a previously approved FDA product should be banned, constitute state drug regulatory “requirements.” *See Mills*, 581 F. Supp. 2d at 788–89; *Carter*, 582 F. Supp. 2d at 1281–82.

Importantly, for OTC products, the definition of state “requirements” is expanded by Section 379r’s language. Section 379r(c) (2) provides: “Safety or effectiveness. For the purposes of [Section 379r(a)], a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.” 21 U.S.C. §379r(c)(2) (emphasis added). This provision broadens the scope of federal preemption, allowing a manufacturer to assert that a plaintiff’s claims regarding advertising statements for OTC products are also preempted. As one court has held, “[a] reasonable reading of §379r(c) (2) is that it expands the universe of potentially preempted state law claims to include those that require additional warnings in

the advertising for nonprescription drugs, and not only on the labeling.” *Carter*, 582 F. Supp. 2d at 1282.

### **Step 3: Do a Plaintiff’s Actions Seek to Impose State Requirements That Are “Different From, In Addition To, or Otherwise Not Identical with” Federal Requirements?**

Finally, courts must determine whether plaintiffs’ state law-based claims challenging OTC monograph and NDA products impose state “requirements” that are different from, in addition to, or not identical with federal requirements. In finding that Section 379r preempted breach of warranty, fraud, false advertising, and violation of consumer protection statute claims premised on allegedly ineffective products, the *Kanter* court explained:

While the legal theories underlying [plaintiffs’] causes of action may differ, each is bottomed on the assertion that this approved label is no longer accurate or adequate and that the label should be changed or the product banned. Each cause of action would result in the establishment of a state requirement regarding labeling that would be “different from” and “otherwise not identical with” the federally required label (§379r(a)), and each is therefore preempted.

*Kanter*, 99 Cal. App. 4th at 796, 122 Cal. Rptr. 2d at 85.

Following *Kanter*, several courts have found that Section 379r preempts these types of claims. *See Mills*, 581 F. Supp. 2d at 790 (“Defendants can market their products in compliance with the FDA requirements, or they can refrain from marketing their products in order to comply with the requirements (and avoid liability) imposed by Plaintiffs’ lawsuit. They cannot do both. As such, it is clear that the requirements that Plaintiffs’ suit would impose on Defendants’ drugs are ‘different from or in addition to, or otherwise not identical with[.]’ the requirements imposed by the FDA.”); *Berenguer*, 2003 WL 24299241, at \*4 (“An award of damages here would be an order ‘different from,’ ‘in addition to,’ and ‘otherwise not identical with,’ the FDA requirement that the medications be labeled as effective ‘for the treatment of head lice.’”); *Carter*, 582 F. Supp. 2d at 1282–86 (holding that plaintiffs’ claims,

regardless of the common law or state law theory upon which they rely, are preempted); *see also Gaeta v. Perrigo Pharms. Co.*, 562 F. Supp. 2d 1091, 1098 (N.D. Cal. 2008) (holding that the plaintiffs’ causes of action seeking to hold the defendant liable for failing to warn of certain risks on the product labeling approved and required by the FDA were preempted); *Green v. BDI Pharms.*, 803 So. 2d 68, 74–75 (La. Ct. App. 2001) (finding that the defendant’s compliance with federal drug labeling laws preempted plaintiffs’ state law failure to warn claims).

### **Can the Savings Clause Spare a Plaintiff’s Claims from Preemption?**

Plaintiffs frequently argue that their claims escape preemption under the FDAMA’s “savings clause,” found in Section 379r(e). The FDAMA’s savings clause states that the express preemption provision cannot “be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any state.” 21 U.S.C. §379r(e); *see also Wyeth v. Levine*, 173 L. Ed. 2d 51, 66 n.8 (2009) (noting that “[i]n 1997, Congress pre-empted certain state requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions.”).

### **Economic Harm Cases**

Defendants have successfully defeated plaintiffs’ savings clause arguments in cases in which plaintiffs sought recovery only for economic harm. Because most states’ definitions of “product liability” require proof of actual injury either to the plaintiff’s person or to his or her property, and most plaintiffs specifically deny personal injury when asserting economic harm, the FDAMA’s preemption exception found under Section 379r(e) does not apply. *See, e.g., Kanter*, 99 Cal. App. 4th at 791, 122 Cal. Rptr. 2d at 81 (applying California law); *Mills*, 581 F. Supp. 2d at 793 (applying Texas law); *Carter*, 582 F. Supp. 2d at 1287–88 (applying California law).

### **Personal Injury Cases**

Despite the Section 379r(e) savings clause, defendants should still consider arguing that personal injury claims are preempted, particularly where a plaintiff asserts an

OTC product has inadequate labeling or warnings. Reading the savings clause in the context of Section 379r in its entirety (“National Uniformity for Nonprescription Drugs”), reveals that it arguably applies only to product liability claims that do not challenge product labeling and design, such as the ingredients and the quantities in use, which leaves only true manufacturing defect claims. Otherwise, a nonsensical result ensues. If a plaintiff asserted only economic injury based on an allegedly inadequate label, the claim would be preempted, but if a plaintiff asserted personal injury based on the exact same inadequacies in the label, it would be spared by the savings clause. The Supreme Court has held that courts should not interpret a savings clause so that it undercuts or dilutes an express preemption clause. *See Am. Tel. & Tel. Co. v. Cent. Office Tel., Inc.*, 524 U.S. 214, 228 (1998). Based on this reasoning, product liability plaintiffs’ labeling claims should not survive the Section 379r(e) savings clause.

In fact, at least two courts have held that Section 379r preempted plaintiffs’ product liability claims based on failure to warn or inadequate labeling. In *Gaeta v. Perrigo Pharmaceuticals Co.*, 562 F. Supp. 2d 1091 (N.D. Cal. 2008), the court held that the plaintiffs’ personal injury claims were expressly preempted, despite the FDAMA savings clause, because the warnings asserted by the plaintiffs conflicted with the defendant’s labeling obligations under federal law. *Id.* at 1098. In *Green v. BDI Pharmaceuticals*, 803 So. 2d 68 (La. Ct. App. 2001), the Louisiana Court of Appeal, without addressing the savings clause, affirmed summary judgment for an OTC manufacturer, finding that the product labels at issue complied with FDA regulations and a plain reading of Section 379r requiring national uniformity for nonprescription drugs “shows a clear intent to override any State labeling requirements.” *Id.* at 75. *But see Orso v. Bayer Corp.*, No. 04C0114, 2006 U.S. Dist. LEXIS 73647, at \*14 (N.D. Ill. Sept. 27, 2006) (allowing the plaintiffs’ personal injury claims to proceed, in part, because the savings clause explicitly excludes product liability claims from express preemption under Section 379r); *Peters v. AstraZeneca*, 417 F. Supp. 2d 1051, 1056 (W.D. Wis. 2006) (denying the

defendants' motion to dismiss the plaintiff's personal injury claims because the savings clause "leaves room explicitly for state product liability laws to supplement the drug labeling process.").

### Implied Preemption Defenses after *Wyeth v. Levine*

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*Levine*, in addition to arguing express preemption, OTC manufacturers often argued that plaintiffs' claims were impliedly preempted on two grounds: (1) it is impossible for a manufacturer to comply with both the state law duties fundamental to a plaintiff's claims and its federal labeling duties, and (2) to require a defendant to comply with a state law duty to provide a different warning obstructs congressional objectives regarding drug labeling regulation. These arguments found mixed success. Most often, courts that found express preemption under Section 379r did not consider whether plaintiffs' claims were also impliedly preempted. *See, e.g., Kanter*, 99 Cal. App. 4th 780, 122 Cal. Rptr. 2d 72 (Cal. Ct. App. 2002); *Mills*, 581 F. Supp. 2d 772 (E.D. Tex. 2008).

The Supreme Court addressed implied preemption in *Levine*, which did not involve an express preemption provision. Wyeth argued that the plaintiff's claims were impliedly preempted, due to the "impossibility" and "frustration" theories. *Levine*, 173 L. Ed. 2d at 59. The Supreme Court rejected Wyeth's arguments, holding that federal law did not preempt the plaintiff's claim that Phenergan's label contained an inadequate warning about the IV-push administration method. *Id.* at 71. Despite

this holding, OTC pharmaceutical defendants should still be able to assert limited implied preemption arguments due to several important distinctions between *Levine* and OTC cases, but should carefully consider it on a case-by-case basis.

#### Impossibility

Wyeth first argued that the plaintiff's state law-based claims were preempted because it was impossible for Wyeth to comply with both the state law duties fundamental to those claims and its federal law labeling duties. *Id.* at 62. The *Levine* majority rejected this argument, largely relying on the FDA's "changes being effected" (CBE) regulation that allows a manufacturer to change a drug label previously approved by the FDA to add or strengthen a warning without prior FDA approval. *Id.* The Court also determined that Wyeth failed to present evidence that the FDA would not have approved a change to the Phenergan label and, without this evidence, it would not conclude that it was impossible for Wyeth to comply with both federal and state requirements. *Id.* at 64–65. The Court further noted that it had no evidence that either the FDA or Wyeth gave more than "passing attention" to the warning at issue, and the FDA previously had not made an affirmative decision about whether to include the IV-push warning on the Phenergan label. *Id.* at 65.

Of particular importance to OTC manufacturers, the CBE regulation relied on in *Levine* applies to medications approved through the NDA process, 21 C.F.R. §314.70 (titled "Supplements or other changes to an approved application," found under "Applications for FDA Approval to Market a New Drug"). That CBE regulation does not apply to monograph products. For monograph products, if either a manufacturer or a citizen wishes to address new information, the FDA requires that the manufacturer bring that information to the FDA or the citizen file a citizen petition so that the FDA may evaluate it to determine appropriate action. 21 C.F.R. §330.10(a)(12).

Accordingly, a potential defense is that to change a label a manufacturer must adhere to this regulatory process. In addition, future cases involving monograph products will focus on the regulatory record of the FDA's assessment of the labeling,

and specifically, whether the FDA considered and made a label determination about the risks raised by plaintiffs. Defendants must comprehensively study the regulatory record, including the Code of Federal Regulations, panel findings, reports in "The Tan Sheet," correspondence between the defendant and the FDA, and any FDA statements related to the product or the risks at issue. Defendants should consider what information they had about the specific risk, whether and when they supplied that information to the FDA, and whether the FDA determined if the specific risk should be mentioned on the product label.

Future cases involving an OTC product approved under an NDA, and thus arguably subject to the CBE regulation, are more analogous to *Levine*. In these cases, defendants will have to demonstrate that the proposed label change would have made the product a "new drug" or that the FDA would not have permitted the label change that a plaintiff alleges that state law requires. Again, the regulatory approval record for the product is key, and defendants should pay attention to whether the FDA has assessed the specific risk involved in the case. Defendants may also have an argument that the CBE regulation has no effect if a plaintiff argues that a medication label should be completely different. For example, a plaintiff might argue that a particular medication simply does not work. Arguably, the CBE regulation allows a manufacturer to change a drug label to add or strengthen a warning, but not to change a label entirely so that it becomes something completely opposite of the FDA-approved label. Under those circumstances, and depending on the strength of the regulatory record, defendants may still have a viable implied preemption argument.

#### Frustration of Congressional Objectives

Defendants also have argued that state tort claims premised on the inadequacies of FDA-mandated labels would frustrate the purposes Congress sought to achieve through national uniformity of labeling of nonprescription products. For instance, in *Levine*, Wyeth argued that because the FDCA requires the FDA to determine that a drug is safe and effective under the conditions set forth in its label, it must be presumed that the agency precisely weighed

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the risks and benefits to establish a specific labeling standard that leaves no room for different state law judgments. *Levine*, 173 L. Ed. 2d at 66. The *Levine* majority rejected this argument, finding that the history of the FDCA did not show that Congress intended to preempt state law failure to warn claims. *Id.* In future OTC cases, defendants may still argue that, under a “frustration” implied preemption prong, Congress’ objective in enacting the FDCA’s Section 379r was to achieve national uniformity of labeling of OTC drugs, and plaintiffs’ state law tort suits for inadequate labeling would obstruct that objective.

### Conclusion

Express preemption under Section 379r of the Food and Drug Administration Modernization Act remains a viable and most likely successful defense to OTC product lawsuits, particularly where plaintiffs assert only economic harm claims. Personal injury claims, however, should not be overlooked. Defendants’ arguments based on implied conflict preemption should be considered carefully in light of the *Levine* decision. In evaluating implied preemption arguments, defendants should determine whether the product at issue was approved under the NDA or monograph process and whether the CBE regulation discussed

above applies. Defendants must also carefully examine a product’s regulatory record, with particular attention to FDA consideration of the specific risk allegation and the FDA’s determination about the appropriate product labeling. While implied preemption remains a viable defense, defendants may choose to abandon implied preemption arguments in cases in which the regulatory record is weak or if a plaintiff has evidence that could justify a label change under the CBE regulation. In sum, preemption is a complex subject. It must be considered on a case-by-case basis, but it remains a defense that could result in big victories for pharmaceutical defendants. 