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Chapter 5

United States Supreme Court Poised to Rule on the Regulatory Defence in a Pharmaceutical Case

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Introduction

Last year, we wrote in this publication about the status of pharmaceutical product liability litigation in the United States. We focused on the first federal district court to hold that civil plaintiffs' "failure-to-warn" and related claims - claims alleging that a prescription drug manufacturer failed to warn physicians (and possibly consumers) about dangerous side effects of prescription medications - were pre-empted by federal labeling regulations. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) ("*Colacicco I*"). The *Colacicco I* decision held that a civil plaintiff cannot assert failure-to-warn and related claims against a prescription drug manufacturer based on a medication's failure to include a specific warning proposed by a plaintiff that the United States Food and Drug Administration ("FDA") - the federal agency charged with ensuring that all federal regulatory requirements with respect to prescription drug labeling were satisfied - previously considered and rejected. We opined at the time that *Colacicco I*, if upheld on appeal, would become a prized weapon in manufacturers' legal arsenals.

Since *Colacicco I*, three major developments have unfolded. First, the United States Supreme Court agreed to review a decision this Fall that reached a result contrary to that in *Colacicco I*. *See Levine v. Wyeth*, 994 A.2d 179 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (Jan. 18, 2008). Second, the United States Supreme Court issued two other notable pre-emption decisions in failure-to-warn cases, *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), a medical device case (so it has limited value in prescription drug cases), and *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), a disappointing split decision without opinion or precedential value. Third and finally, Colacicco I was affirmed in full by the United States District Court of Appeals for the Third Circuit, the intermediary appellate court just below the United States Supreme Court, in an important opinion that may offer the best insight into how the Supreme Court may rule this Fall in Wyeth. *See Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008) ("*Colacicco II*"). This article discusses the significance of the Riegel, Warner-Lambert, and Colacicco II decisions, and what outcome these decisions likely augur in the *Wyeth* appeal.

The Scope of Federal Pre-emption

As we briefly summarised last year, at its most basic level, the doctrine of pre-emption, which arises from the Supremacy Clause of the United States Constitution, mandates that a plaintiff cannot recover on a state statutory or common law claim if such recovery would impose liability on a defendant for conduct that is otherwise permissible under federal law. Federal law pre-empts, or supersedes, state law in three circumstances: (1) express pre-emption (i.e., Congress explicitly states that a federal statute and/or underlying federal regulations pre-empt state law); (2) implied field pre-emption (i.e., when Congress so pervasively regulates a certain field or industry that, in spite of not explicitly stating that federal law pre-empts state law, Congress is presumed to have intended to pre-empt state law); and (3) implied conflict pre-emption (i.e., when state law stands as an obstacle to federal law, such that compliance with both is impossible or that compliance with the state law will frustrate the purpose of the federal law). *See, e.g., English v. Gen'l Elec. Co.*, 496 U.S. 72, 78-79 (1990); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1120 (3d Cir. 1990). Except where noted otherwise, we generally discuss implied conflict pre-emption in this article, as we focus on whether a party can be held liable under state law for following federal law that does not expressly bar her claim. In essence, conflict pre-emption is roughly analogous to the effect of European Union Directives, inasmuch as member states' laws cannot be at odds with Directives.

The concept of conflict pre-emption under the Food, Drug, and Cosmetic Act of 1938 ("FDCA") or FDA regulations promulgated thereunder is that a plaintiff cannot allege a failure-to-warn claim against a prescription drug manufacturer based on the alleged inadequacy of the medication's specific label if the FDA previously approved the label as compliant with federal law. This was the first-of-its-kind holding by the district court in *Colacicco I*. See our article in last year's publication for a synopsis of the specific facts and holding in *Colacicco I*.

Pre-emption in the Medical Device Context

While *Colacicco I* was on appeal, the United Supreme Court issued its pre-emption decision in *Riegel*. The plaintiffs in *Riegel*, a husband undergoing heart surgery and his wife, sued the manufacturer of a catheter that ruptured during the husband's surgery, allegedly causing lasting injuries. 128 S. Ct. at 1005. The *Riegel* plaintiffs alleged, among other things, that the catheter was "designed, labelled, and manufactured" in a manner that violated state law. *Id.* The defendant argued that such claims were pre-empted under the FDCA. Specifically, the defendant pointed out that the FDCA mandates that a medical device cannot be marketed in the United States without "premarket approval" by the FDA. *See generally* 21 U.S.C. § 360c *et seq.* (Medical Device Amendments of 1976 to the FDCA). If the FDA finds that a medical device is reasonably safe and effective, it will grant premarket approval, which means the device can be commercially sold. *See generally id.* The FDA will also impose certain "requirements" for a device's design, labelling, and manufacture to assure that marketed versions of the device possess the same attributes that led the Agency to

grant premarket approval in the first place. *See generally id.; see also Riegel*, 128 S. Ct. at 1002-1005. A provision in the FDCA expressly states that no state may establish "any requirement" for medical devices that is "different from, or in addition to, any requirement applicable" under federal law, *see* 21 U.S.C. § 360k(a), such as those imposed by the FDA during premarket approval.

The Supreme Court sided with the defendant-manufacturer. It ruled that the plaintiffs' claims would impose new "requirements" for the defendant's catheter, in the form of additional warnings not appearing on the catheter's FDA approved label, which were different from or in addition to the labelling "requirements" mandated by the FDA during the premarket approval process. *Riegel*, 128 S. Ct. at 1011.

At first blush, *Riegel* appears to be a sweeping victory for manufacturers of prescription drugs as well as medical devices. However, its value to prescription drug manufacturers is circumscribed by the FDCA's more stringent regulation of medical devices. The *Riegel* decision largely turned on the Supreme Court's interpretation of the FDCA's express pre-emption provision, which forbids state laws or state law claims that seek to impose "requirements" for medical devices that differ from, or are in addition to, those approved by the FDA. (It also recognised an interesting tangential question not before it that is beyond the scope of this article - whether a state law claim may proceed if it seeks to hold a manufacturer liable for failure to adhere to state law "requirements" that are parallel, or identical to, federal requirements. A claim based on state law that mirrors federal law may not "conflict" with federal law; therefore, arguably, no conflict pre-emption exists). The FDCA lacks an analogous express pre-emption provision respecting prescription drug "requirements."

Nonetheless, some of the underlying policy considerations cited in *Riegel* should translate into the prescription drug context. Most notably, the Supreme Court observed that FDA premarket approval of a medical device reflects the Agency's expert decision that the device, if manufactured consistent with FDA approval, is safe and effective. *Riegel*, 128 S. Ct. at 1007. Private failure-to-warn lawsuits, on the other hand, necessarily presume that an FDA-approved device was not safe or effective. Thus, private lawsuits would permit lay juries and judges to second-guess the expert judgment of the FDA and disrupt the federal regulatory scheme for medical devices. *See id.* at 1007-08. This same logic equally applies to private failure-to-warn lawsuits involving FDA-approved prescription drugs, notwithstanding the FDCA's lack of an express pre-emption provision like that at issue in *Riegel*.

In any event, *Riegel* provided little direct guidance on the scope of implied conflict pre-emption of state failure-to-warn claims in the context of prescription drugs. Many therefore hoped that the Supreme Court would continue to refine its FDCA pre-emption jurisprudence in another case, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008). Unfortunately, just weeks after its Riegel decision, the Supreme Court issued a highly anticipated, yet ultimately disappointing, split decision in *Warner-Lambert*. The 4-4 split decision meant that the Supreme Court affirmed the lower court ruling without any written opinion (the ninth Justice of the Supreme Court had recused himself).

A Lack of Guidance from *Warner-Lambert*

The underlying issue in *Warner-Lambert* was whether state law claims could *indirectly* rest on a plaintiff's allegation that a manufacturer "defrauded" the FDA when it sought and obtained approval for its FDCA-regulated product. The Supreme Court had seemingly foreclosed such allegations years ago when it held that federal law impliedly pre-empts any *direct claim* that a plaintiff was injured by a product that would not have been approved by the FDA - (and, so the argument goes, would not have been on the market and able to injure the plaintiff) - but for the defendant's fraudulent submission of inaccurate data to, or concealment of data from, the FDA. *See Buckman Co. v. Pltfs.' Legal Comm.*, 531 U.S. 341, 347-50 (2001). Such "fraud-on-the-FDA" claims are impliedly pre-empted because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the [Agency's] judgment and objectives." *Id.* at 350. The *Warner-Lambert* appeal, however, presented the situation where a plaintiff did not directly allege fraud-on-the-FDA, but rather *indirectly* alleged fraud-on-the-FDA under a pre-Buckman state statute that immunised manufacturers of FDA regulated products from liability unless a plaintiff proved fraud-on-the-FDA. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94-96 (2d Cir. 2006), *aff'd sub nom. by split decision*, *Warner-Lambert*, 128 S. Ct. 1168. Given this, the appellate court ruled that evidence of fraud-on-the-FDA was not an essential element of the *Warner-Lambert* plaintiff's claim. Rather, such evidence was merely relevant to the extent it rebutted a defendant's affirmative defence. *See Desiano*, 467 F.3d at 96-97. In reality, this is a distinction without difference. The effect of a plaintiff arguing fraud-on-the-FDA in his case-in-chief or to rebut a manufacturer's affirmative defence is the same: a jury will be asked to decide whether the defendant defrauded the FDA - a decision which is expressly forbidden by the holding in *Buckman*.

The Value of *Colacicco IIx*

All told, the disappointing split decision in *Warner-Lambert* provided no guidance to how the Supreme Court might view failure-to-warn claims in the prescription drug context. The federal appellate court's *Colacicco II* decision, however, provided considerably more guidance - and possibly is the best predictor of how the United States Supreme Court might rule in *Wyeth*. By a 2-1 margin, the appellate court held that the FDA's repeated consideration and rejection of the very warnings urged by the plaintiffs - an increased risk of suicide among adults - impliedly pre-empts state law claims based on a drug manufacturer's failure to include such warnings on its drug's label. *See Colacicco II*, 521 F.3d at 269-70, 273-76. The authors refer the reader to their article from last year for a summary of the facts and holding in *Colacicco I*. In conducting its thorough analysis of federal implied conflict pre-emption principles, the *Colacicco II* court made a number of important observations beyond those made in *Colacicco I*, including the following:

1. *Deflating the Importance of the So-Called "Presumption Against Pre-emption."* The *Colacicco II* court found that "[a]lthough a presumption against pre-emption is commonly acknowledged, . . . application of such a presumption is not always appropriate." *Colacicco II*, 521 F.3d at 263 (citing Buckman, 531 U.S. at 347-48 (2001)). It further found that such a presumption, when appropriate, was not, as the plaintiffs claimed, virtually irrefutable. *Id.* at 264. In fact, the appellate court found that the "argument that the presumption against pre-emption is inapplicable in the context of implied conflict pre-emption has more force." *Id.* at 265. It so found because implied pre-emption is all about trying to divine Congressional intent in the absence of an express statement one way or the other. Thus, it is inappropriate to assume at the beginning of this analysis that Congress intended that the FDCA not pre-empt state law failure-to-warn claims. *See id.* Although the *Colacicco II* court stopped short of dismissing the presumption against pre-emption outright, it noted "the tension between such a

presumption, which emphasises the clear and manifest purposes of Congress . . . and *implied* conflict pre-emption, which analyses pre-emption in the absence of any explicit intent." *Id.* (internal citation and quotations omitted). This decreased emphasis on the presumption against pre-emption bodes well for prescription drug manufacturers.

2. "*Informal" FDA Action Entitled to Pre-emptive Effect.* Plaintiffs argue that the FDA never "officially" rejected the warnings at issue. Rather, plaintiffs argued the FDA rejected the additional warnings at issue in *Colacicco I & II* only in "informal" statements that fell short of formal agency regulations, such as approval letters sent to manufacturers, amicus briefs filed in various lawsuits, and in various other media that did not rise to the level of a published agency regulation. The *Colacicco II* court still found these "informal" statements worthy of pre-emptive force in deciding whether the state law claims at issue stood as an obstacle to the accomplishment of federal law, stating that all "actions taken in accordance with [the FDA's] statutorily granted authority" have pre-emptive effect." *Colacicco II*, 521 F.3d at 271-72.

3. *FDA's Position on Pre-emptive Force of its Own Regulations Entitled to Deference.* The *Colacicco II* court embraced the FDA's own stated position on the pre-emptive effect of the regulations it promulgated under the FDCA. 521 F.3d at 274-76.

4. *Failure to Submit Proposed Label Supplement Not Determinative.* The *Colacicco II* court still found the state law claims impliedly conflict pre-empted even though one FDA regulation seemingly permits manufacturers to strengthen drug warnings, without prior FDA approval, by filing what are commonly referred to as "changes being effected" or "CBE supplements." *See* 21 C.F.R. § 314.70. The appellate court ruled that an actual or imminent threat of a state failure-to-warn lawsuit "cannot compel the defendant companies to suggest a CBE supplement that they believe is unnecessary. Nor do we favour encouraging regulated parties to submit CBE supplements for the sole purposes of insulating themselves from liability." *Colacicco II*, 521 F.3d at 272. In other words, the fact that a manufacturer could voluntarily initiate a subsequent label change through the CBE supplement process does not otherwise invalidate the pre-emptive effect of the FDA's prior rejection of the same warning. This holding has great significance for prescription drug manufacturers.

5. *Direct "Fraud-on-the-FDA" Claims Still Impliedly Pre-empted.* As discussed above, the Supreme Court's *Buckman* decision foreclosed direct claims against manufacturers based on the allegation that they misreported or withheld data from the FDA during the approval process. The plaintiffs in *Colacicco II* suggested this occurred in their case. The appellate court flatly rejected this argument, noting that "[t]his contention borders on the charge that GSK defrauded the FDA by manipulating or withholding such information. . . .[s]uch a claim, if supported by sufficient evidence, should be brought before the FDA." *Colacicco II*, 521 F.3d at 272.

In short, the *Colacicco II* decision is the first appellate court decision to find that state failure-to-warn claims are impliedly pre-empted by the FDCA and underlying FDA regulations. It conducted a thorough legal analysis which undercuts many of the common arguments plaintiffs raise against pre-emption in pharmaceutical product liability litigation. The decision by its terms, however, is limited "to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires." *Colacicco II*, 521 F.3d at 272. It left open the more common situation "such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated." *Id.* at 271. The United States Supreme Court will address this situation this Fall when it decides *Wyeth*.

Nevertheless, the *Colacicco II* court's holding is instructive. It is consistent with the more general recent trend in federal pre-emption jurisprudence in all contexts, not just that of prescription drugs, and therefore may suggest the most likely result in *Wyeth* - that a finding of implied conflict pre-emption will only lie where existing evidence suggests the FDA formally or informally considered the warnings at issue and explicitly or implicitly rejected them. For example, the Supreme Court held in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) that federal regulations impliedly pre-empt state law claims under which a plaintiff sought to hold an automobile manufacturer liable for failure to equip its automobiles with airbags. In *Geier*, the pertinent federal agency, in its expert judgment, had promulgated regulations that permitted manufacturers to equip its automobiles with a variety of different passive restraints devices, airbags being only one option. *Geier*, 529 U.S. at 878-79. The Supreme Court reasoned that state law claims that would hold a defendant liable for choosing to equip its automobiles with a different, yet equally permissible, passive restraint device besides airbags would stand as an obstacle to the objective of the federal regulations. *Id.* at 881-82. In so ruling, the Geier court looked to the pertinent federal agency, which explained the rationale for its regulations. *Id.* at 877-84. Other federal courts have ruled similarly in many other contexts. *See, e.g., Pet Quarters, Inc. v. Depository Trust & Clearing Corp.*, -- F. Supp. 2d --, 2008 WL 544742, at *5-6 (E.D. Ark. Feb. 25, 2008) (state law claims challenging stock borrow program approved by federal agency impliedly conflict pre-empted); *ConocoPhillips Co. v. Henry*, 520 F. Supp. 2d 1282, at 1329-1330 (N.D. Okla. 2007) (federal Occupational Safety and Health Act requiring workplace to be free from hazards likely to cause death or serious physical harm impliedly conflict pre-empted state statute that prevented employers from providing storage receptacles on-site for firearms); *Synagro-WWT, Inc. v. Rush Twp., Pa.*, 299 F. Supp. 2d 410, 419 (M.D. Pa. 2004) (under Pennsylvania law, municipal ordinance impliedly pre-empted by state sewage act to the extent ordinance imposed additional procedural "hurdles, over and above those imposed" by state act and implementing state regulations).

The Future of Pre-emption

The Supreme Court might continue to follow this trend in *Wyeth*. Like the court in *Colacicco II*, the Supreme Court may focus on both the FDA's interpretation of its own regulations and the FDA's specific decisions vis-à-vis the drug label at issue in *Wyeth*. The FDA clearly believes its regulations impliedly pre-empt all state law failure-to-warn claims, regardless of whether it considered or rejected the specific additional warnings at issue. It has said so repeatedly. *See, e.g.*, Preamble to Requirements on Content and Format of Labeling for Human Prescription and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. § 201, 314, and 601) (discussed in last year's article). If the Supreme Court agrees with the FDA that the agency's regulations are not minimum standards, but provide both a "ceiling" and a "floor" - i.e., the regulations completely define the scope of a manufacturer's obligations because the Agency has already weighed all safety and efficacy concerns - then it may find the FDCA and FDA regulations impliedly pre-empt the Wyeth

plaintiff's claims. If, on the other hand, it finds that the plaintiff's claims are not pre-empted per se by the FDCA and FDA regulations, it may still find that the *Wyeth* plaintiff's claims are still impliedly pre-empted if the record shows that the FDA considered and rejected the specific warning at issue; this would be consistent with the holdings in *Colacicco I & II*, and other federal implied pre-emption jurisprudence. Either of these outcomes will be substantially beneficial to prescription drug manufacturers, who will have an incentive - especially under a *Wyeth* ruling that tracks *Colacicco I & II* - to submit fulsome, accurate data to the FDA so down the road the manufacturer can say that the FDA considered and rejected any proposed warning later raised in a private failure-to-warn lawsuit.

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