Legal Opinion Letter

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HAS CALIFORNIA PROVIDED A NEW END-RUN AROUND PREEMPTION?

by
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Preemption of tort claims in federally-regulated areas of law is a hot topic for plaintiffs and defendants alike. The reason is simple. When a plaintiff's cause of action conflicts with a federal statute, then the claim fails and the case concludes. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 894 (2000); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Approximately 350 federal statutes contain express preemption provisions, half of which were enacted within the last decade. James T. O'Reilly, Federal Preemption of State and Local Law, Legislation, Regulation and Litigation (ABA 2007) at 2. And courts have concluded that hundreds of other statutes preempt state-law claims under the doctrine of implied preemption. *Ibid.* Not surprisingly, there has been a sharp increase in the use of this defense and in attempts by plaintiffs to avoid it.

Plaintiffs likely will use two recent decisions to attempt to avoid dismissal on preemption grounds in the future. In *Riegel v. Medtronic, Inc.,* 522 U.S. ____, 128 S. Ct. 999, 1011 (2008), the United States Supreme Court acknowledged that common law claims premised on "a violation of FDA regulations" are not preempted under the federal Food, Drug, and Cosmetic Act ("FDCA") because "the state duties in such a case 'parallel' rather than add to federal requirements." And in *Farm Raised Salmon Cases*, 42 Cal.4th 1077, 1095-99 (2008), the California Supreme Court concluded that the FDCA does not preempt claims for deceptive marketing of food brought under California's Unfair Competition Law ("UCL") and Consumer Legal Remedies Act ("CLRA"). Defendants should anticipate that plaintiffs will jockey to get their cases into the California courts and will start adding allegations that the defendant violated the FDCA as well as California's UCL and CLRA to avoid preemption. Most if not all of those claims, however, ultimately will be unsuccessful.

Attempting to Avoid Preemption. *Riegel* involved the preemption of a plaintiff's state-law claims for negligence, strict liability, and breaches of implied and express warranties against a medical device manufacturer of a balloon catheter. *Riegel, supra,* 128 S.Ct. at 1011. The United States Supreme Court held that these claims were expressly preempted under 21 U.S.C. § 360(k), the express preemption provision of the Medical Device Act, which provides that no state may establish with respect to a medical device any requirement that "is different from, or in addition to . . . any requirement of this Act . . . ." *Ibid.* In doing so, the Court concluded that the balloon catheter was subject to the federal device-specific requirement to comply with the particular standards set forth in the FDA's premarket approval process. Successful state-law claims would result in a state "requirement" that differed from, or added to the FDA-approved standards. Thus, the common-law claims were preempted. The Court, however, noted that the FDCA does not "prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations" and that such parallel claims would not be preempted. *Ibid.*

Farm Raised Salmon Cases. In *Farm Raised Salmon Cases*, 42 Cal.4th 1077 (2008), the plaintiffs sued several grocery stores claiming they violated the UCL and CLRA by selling artificially colored farm-raised salmon without disclosing this information to consumers. The unlawful act serving as a predicate for

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plaintiffs' claims was the grocers' misbranding of salmon in direct violation of the FDCA and its identical state equivalent, California's Sherman Food, Drug and Cosmetic Law (Sherman Law). Federal law preempts state law claims arising from food misbranding to the extent that the state claims are inconsistent with federal labeling requirements.[1] The grocers argued that Section 337(a) of the FDCA, which precludes private enforcement of FDCA regulations relating to the labeling of food, preempted plaintiffs' state- law claims. The Superior Court agreed and dismissed the action and the appellate court affirmed:

> In section 337(a), Congress clearly expressed its intention to preclude private enforcement of the FDCA . . . . To allow a private person to prosecute a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and federal government oversight, and conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme. These circumstances seem to demonstrate that a state law private right of action based on a violation of the FDCA necessarily would conflict with section 337(a).

In re Farm Raised Salmon Cases, 48 Cal.Rptr.3d 449, 455 (2006) *reversed by Farm Raised Salmon Cases*, 42 Cal.4th 1077 (2008). The appellate court rejected the Attorney General's *amicus* argument that only private actions seeking to "directly enforce" the FDCA were preempted:

> The Attorney General argues that such allegations constitute a permissible 'indirect' enforcement of the federal act that is not subject to preemption. The critical issue, however, is not whether the plaintiffs' complaint is seeking 'direct' or 'indirect' enforcement of the federal act, but whether the defendants' conduct upon which the plaintiffs' claims rest involves violations of the FDCA that the plaintiffs will necessarily have to prove in order to recover under their state law claims. Thus, the proper standard to be applied rests upon what facts the plaintiffs will be required to prove under the allegations of their complaint. If those facts demonstrate violations of the FDCA, then preemption will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs. To hold otherwise would sanction a patent evasion of section 337(a) and would permit the plaintiffs to do the very thing that adherence to federal law would preclude.

Id. at 456.

The California Supreme Court, however, reversed and reinstated the plaintiffs' action after concluding that the FDCA did not preempt plaintiffs' claims. Focusing on section 343-1 of the FDCA, which permits states to establish laws that are "identical to" federal law, the Court concluded that Congress never intended to preclude all state law claims under Section 337(a). *Farm Raised Salmon, supra,* 42 Cal.4th at 1095-99. Thus, where a state requirement (Sherman Law's labeling requirement) is identical to a federal one (i.e., the FDCA's labeling requirement), there is no preemption, because the parallel state and federal requirements are not in conflict. Because California's Sherman Law imposes identical requirements and is explicitly authorized by the FDCA in section 343-1, the Court held that plaintiffs could avoid preemption and predicate their UCL and CLRA claims on violations of obligations imposed under Sherman Law. *Ibid.*

Implications for Future Cases. Although plaintiffs have already begun to cite to these cases in opposition to motions to dismiss and for summary judgment, most claims will not survive regardless of whether litigants assert violations of the FDCA, the UCL, or the CLRA. The exceptions set forth in *Riegel* and *Farm Raised Salmon* apply only to a handful of situations where a plaintiff can show not only that: (1) the state passed a statute with the express intent of creating a remedy for analogous violations of federal law; but also (2) that the purported violation relates to a duty the defendant owed to the public and not the FDA; and (3) that the violation of that duty caused plaintiff's harm.

[1]The Food and Drug Administration (FDA) is responsible for ensuring that food, cosmetics, drugs and medical devices are safe and effective under the FDCA, 21 U.S.C. §§ 301-397. The FDCA authorizes the United States to bring enforcement actions. It does not, however, create a private cause of action for violation of its provisions. 21 U.S.C. § 337(a).

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