Law and the Public's Health

COLACICCO V APOTEX INC. AND THE FEDERAL PREEMPTION OF STATE TORT REMEDIES FOR HEALTH INJURIES: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

Taylor Burke, JD, LLM

This installment of *Law and the Public's Health* reviews a federal appeals court decision in *Colacicco v Apotex Inc.*[1] and considers its implications for public health policy and practice. The *Colacicco* decision is emblematic of a fundamental change in U.S. public health policy: the federal preemption of state laws permitting individuals to recover damages for health injuries in favor of a uniform national regulatory system with public health safety enforcement powers solely in the hands of a federal agency. If affirmed by the U.S. Supreme Court (and its 2008 decision in *Riegel v Medtronic, Inc.*[2] suggests a decisive shift toward federal preemption of state tort laws as they affect the drug and device industries), this change would leave individuals who are injured by prescription drugs with no direct legal recourse. At a time when public confidence in the ability of the U.S. Food and Drug Administration (FDA) to keep the public safe is at an ebb as the result of several highly publicized regulatory failures,[3,4] the *Colacicco* decision raises significant implications for the future of public health. This decision, coupled with a newly aggressive effort on the part of the FDA to expand its preemptive reach, is the subject of this column.

BACKGROUND AND OVERVIEW

Understanding the significance of the *Colacicco* decision requires background on two concepts: the concept of liability for pharmaceutical products that are shown to cause death or injury and the doctrine of preemption.

The federalism doctrine: state law remedies for personal injuries

Since the nation's founding, states have had the legal power to protect the public's health through the direct regulation of individual and market conduct, as well as through the creation of legal remedies, rooted in common law doctrine and known as torts, that permit individuals who are injured by the conduct or product sold in the market to recover damages.[5] This power on the part of states to protect the public's health is part of the doctrine of federalism, on which the allocation of powers within the U.S. government rests. This doctrine is captured within the U.S. Constitution, which gives the federal government limited powers, while at the same time, and through the 10th Amendment, preserving to states the right to exercise powers not vested in the federal system.

The doctrine of federal preemption

At the same time that federalism rests on a constitutional platform, it coexists uneasily with the doctrine of preemption. Rooted in the Supremacy Clause of the Constitution, the doctrine of federal preemption means that so long as Congress acts within its sphere of power, its laws become the supreme law of the land, thereby invalidating state laws that interfere with or are contrary to federal law. The U.S. Supreme Court has identified three types of federal preemption: "express" preemption, which occurs when Congress expressly states its intent to preempt state law; "field" preemption, which occurs when congressional intent to preempt state law in a particular area can be inferred by a federal regulatory scheme or interest so comprehensive that it is presumed to preclude any state laws on the topic even when there is no conflict; and "conflict" preemption, which occurs when a state law is nullified because it actually conflicts with a federal law even though Congress has not displaced all state laws on the same subject.[6] Both field and conflict can be referred to as "implied" preemption.

As will be discussed in this article, *Colacicco* raised the concept of conflict preemption, because at issue was whether a state remedy permitting individual recovery for damages conflicted with congressional federal regulatory policy. To succeed in its conflict preemption claim, a pharmaceutical company would have to show that a state law claim either conflicts with the federal regulatory scheme or presents an obstacle to the execution of the full purposes and objectives of Congress.

THE *COLACICCO* DECISION

Colacicco began as two separate lawsuits against drug manufacturers brought by survivors of individuals who had committed suicide after taking certain

antidepressant medications. In one case, a husband sued drugmaker GlaxoSmithKline under state common law, alleging that his wife's suicide resulted from the company's failure to warn of the increased risk of suicidal behavior linked to the company's Paxil® antidepressant drug. The second case involved a suit brought by a daughter who sued drugmaker Pfizer Inc. following her father's suicide after he took that company's Zoloft® antidepressant. She alleged that Pfizer violated state products' liability and consumer fraud statutes by selling Zoloft without warnings regarding an increased risk of suicide.

The drug companies moved to dismiss the state claims in both cases, arguing that state remedies were preempted as a result of the FDA's drug-labeling regulatory scheme. Essentially the companies argued that without preemption, drugmakers would be subject to considerable liability under various state laws, in direct conflict with Congress's desire for a uniform drug-labeling regulatory system. The defendants claimed that because the FDA had specifically rejected adding a warning of increased suicide risk in adults to the drugs' labels, it was impossible to comply with both the FDA scheme as well as state laws that permitted a liability action to proceed even when federal labeling laws were satisfied. Plaintiffs, on the other hand, contended that there exists a presumption against preemption under federal law, that Congress never intended the federal law at issue to preempt state laws permitting individual recoveries for death and injury, and that the drugmakers could comply with both federal and state law. Plaintiffs pointed to a federal regulation that permits and encourages manufacturers to strengthen their labels without prior FDA approval.[7]

The two trial courts came to different conclusions: the federal district court in Pennsylvania sided with GlaxoSmithKline and dismissed the plaintiff's complaint based on preemption of state common law claims, while the federal district court in New Jersey denied Pfizer's motion for summary judgment that was based on the same preemption argument. The U.S. Court of Appeals for the Third Circuit consolidated the two cases to address their common question: whether state law claims for injuries arising from regulated pharmaceutical products are preempted as a result of FDA regulatory authority.

In a 2-to-1 opinion, the Third Circuit Court agreed with the drug manufacturers and held that the plaintiffs' state law claims conflicted with federal law and, therefore, should be dismissed. The appeals court relied heavily on the fact that the FDA had, on numerous occasions, publicly rejected adding a warning to the drug labels of these types of antidepressants. In its view, this amounted to conflict preemption, as this regulatory action could not be reconciled with any attendant state law claims that the label should have been supplemented by additional warnings. The court noted that these legal actions, whether arising under common law or state statutes, stand in the way of achieving federal objectives.

The court's rationale stems from the fact that under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA has the authority and obligation to prohibit false or misleading labeling—including labels that are considered too alarmist because they restrict potential safe use. Thus, a state law obligation to enhance a drug label regarding risks would directly conflict "with the FDA's oft-repeated conclusion" to the contrary.[1] The court rejected plaintiffs' arguments that anything less than an explicit FDA rejection of a company's request to add a contested warning to the label—which was not the case here—should not be treated as preemptive. Indeed, the FDA itself, in its amicus brief on behalf of the drug companies, stated that the basis for federal conflict preemption was not the federal labeling scheme itself, but rather the agency's repeated public statements that insufficient evidence existed of this association between the drug and suicide. In fact, the court did narrow its holding only to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires. In a similar case, however, the U.S. Supreme Court will decide whether the FDA's mere approval of drug labeling is sufficient to preempt state-based legal claims alleging that the label failed to warn of a given danger.

In *Levine v Wyeth*, which involved a common law failure-to-warn claim against the drug manufacturer Wyeth for neglecting to warn of certain dangers involved in the administration of nausea medication, the Vermont Supreme Court rejected the preemption argument in part because "the FDA has not indicated that a stronger warning would be misleading. . ." and the labeling regulations allow drug companies to strengthen labels without prior FDA approval.[8] The U.S. Supreme Court very well may take this opportunity to reverse the Vermont ruling and solidify the federal preemption of state law claims in this area.

The majority in *Colacicco* summarily rejected the arguments of the plaintiffs and the dissenting judge, who claimed that a labeling regulation specifically permitting drugmakers to augment and strengthen warnings without prior FDA approval—which the defendants did not utilize—proved that state law should be viewed as complementary to FDA regulations. The dissent claimed that clear congressional intent—that is, express preemption—should be required to preempt

"failure-to-warn claims [that] stand near the heart of the states' police powers over matters of health and safety," and argued that even the majority's narrowed holding "threatens the institutional framework we have for balancing safety and efficacy in the pharmaceutical industry while compensating victims of wrongful injuries."[1]

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

This case represents a growing trend toward what some commentators have dubbed "silent tort reform"[9] or "backdoor federalization,"[10] through the use of the preemption doctrine. Until a few years ago, the FDA practiced nonparticipation in litigation, in line with the view that its regulatory efforts could live comfortably alongside state injury law claims. State-based litigation uncovers risks that may not be apparent to the agency during the drug approval process. The FDA viewed this "feedback loop" as essential to better enable the agency to do its job—particularly given the absence of post-marketing oversight resources. Permitting state law remedies allowed federal policy-making to avoid the "harsh implications" of eliminating "judicial recourse for consumers injured by defective" drugs.[11]

The past few years, however, have witnessed a sea change in FDA policy. The agency now maintains that its ability to protect the public's health is severely threatened by state tort claims because these state actions could result in label changes not approved by the FDA and thus render drugs misbranded. The agency has announced this new policy in several amicus briefs filed in recent cases.

In the absence of an express preemption provision itself from Congress in the FDCA, the FDA is vigorously pursuing the implied preemption argument with gaining success. Indeed, in 2006 the agency formalized its position in the preamble to a rule that revises drug-labeling requirements by asserting broad preemption of state law: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary state law."[12] The FDA justifies its new position on implied conflict preemption by arguing the policy preference for uniformity, agency expertise, and drug safety, claiming that preemption helps avoid defensive labeling resulting from disparate state liability regimes.[12]

In taking this position, the FDA intends that under the principle of deference to administrative agencies,[13] courts will respect this agency position when deciding implied preemption issues. The *Colacicco* court did just that. Although in the end the Vermont Supreme Court did not afford any deference to the FDA's position because the litigation predated the promulgation of the preamble, in *Levine*, the court did take great pains in discussing what level of deference should be afforded the agency in these situations. The U.S. Supreme Court could take the opportunity to clarify the strength and applicability of this type of backdoor federalization. Its decision will have major implications regarding the ability of states to create a right of redress for injury from regulated health products, a power that goes to the heart of public health policy and practice.[2,5]

The *Colacicco* decision comes at a time when the public trust in the FDA's ability to adequately protect the public's health is at an all-time low.[14] Indeed, public confidence in the FDA fell from 80% in the 1970s to a mere 36% in 2006.[15] Examples of perceived FDA failures include the withdrawal of Merck & Co.'s Vioxx® drug and the adulteration of the country's supply of heparin, a blood-thinning drug. Proposals abound to restructure the agency or redesign its official mission, but one thing is clear: the FDA lacks the resources necessary to protect the population from dangers, particularly in the case of drugs that already are on the market.

From 1988 to 2007, 137 specific federal laws, 18 statutes of general applicability, and 14 executive orders imposed additional responsibilities upon the FDA. At the same time, the FDA's 2007 federal appropriation was only $1.57 billion—less than three-fourths of the annual budget for the Maryland school district in which the FDA is located.[16] Federally appropriated FDA personnel have also dropped from 9,167 in 1994 to 7,856 in 2007, even though the agency now regulates products that amount to one-quarter of consumer spending in the U.S. Eighty percent of the FDA's computer servers are more than five years old, and most critical clinical trial records are still stored on paper in warehouses—indeed, the technology budget for the FDA is only 40% of that for the Centers for Disease Control and Prevention.[16]

FDA scientists and doctors agree that problems persist—70% believe that the FDA lacks sufficient resources to protect the public's health, and two-thirds worry that the agency is not adequately monitoring the safety of drugs once they are on the market.[17,18] The FDA's Office of Drug Safety, which is charged with post-marketing surveillance efforts, has only 100 professional employees to monitor the continued safety of more than 11,000 approved drugs.[11]

This context raises substantial questions about the wisdom of preemption policy. State laws that create remedies for injury may incentivize pharmaceutical manufacturers to stay abreast of health risks associated

with their products and take action. Federal preemption of state failure-to-warn claims effectively removes this incentive; furthermore, litigation may uncover vital information that exists only within the control of manufacturers and is otherwise unavailable to the FDA. It remains to be seen whether the U.S. Supreme Court will side with the market forces favoring preemption or will in fact reaffirm the concept of presumed state public health powers.

Taylor Burke is an Assistant Research Professor in the Department of Health Policy at The George Washington University School of Public Health and Health Services in Washington, D.C.

Address correspondence to: Taylor Burke, JD, LLM, Department of Health Policy, The George Washington University School of Public Health and Health Services, 2021 K St. NW, Ste. 800, Washington, DC 20006; tel. 202-530-2301; fax 202-530-2361; e-mail <taylorb@gwu.edu>.

REFERENCES

1. 521 F.3d 253 (3rd Cir. 2008).
2. 128 S. Ct. 999 (2008).
3. Harris G. Report assails F.D.A. oversight of clinical trials. The New York Times 2007 Sep 28.
4. Harris G. F.D.A. chief writes Congress for money. The New York Times 2008 May 14.
5. Gostin LO. Public health law: power, duty, restraint. Berkeley (CA): University of California Press; 2000.
6. 521 F.3d 253 (3rd Cir. 2008) citing *Hillsborough County v Automated Med. Labs., Inc.*, 471 U.S. 707 (1985).
7. 21 C.F.R. §314.70(c).
8. 944 A.2d 179 (Vt. 2006).
9. Labaton S. "Silent tort reform" is overriding states' powers. The New York Times 2006 Mar 10; Sect. C:5.
10. Sharkey CM. Preemption by preamble: federal agencies and the federalization of tort law. DePaul Law Rev 2007;56:227.
11. Kessler DA, Vladeck DC. A critical examination of the FDA's efforts to preempt failure-to-warn claims [citing Porter MJ. The Lohr decision: FDA perspective and position. Food Drug Law J 1997;52:7-11]. Georgetown Law J 2008;96:461-95.
12. Requirements on content and format of labeling for human prescription drugs and biological products, 71 Fed. Reg. 3922, 3934 (2006 Jan 24) (to be codified at 21 C.F.R. pts. 201, 314, 601).
13. *Skidmore v Swift & Co.*, 323 U.S. 134 (1944).
14. Schweitzer SO. Trying times at the FDA—the challenge of ensuring the safety of imported pharmaceuticals. N Engl J Med 2008;358:1773-7.
15. Food and Drug Administration (US). FDA science and mission at risk: report of the subcommittee on science and technology. Rockville (MD): FDA (US); November 2007.
16. Wood AJ. Playing "kick the FDA"—risk-free to players but hazardous to public health. N Engl J Med 2008;358:1774-5.
17. Union of Concerned Scientists. News and views: scientific integrity update: dangerous interference in science at the FDA. Cambridge (MA): Union of Concerned Scientists; September 2006.
18. Office of Inspector General, Department of Health and Human Services (US). FDA's review process for new drug applications: a management review. Washington: DHHS (US); 2003.