Preemption Vs. Public Nuisance, In Aviation And Opioids

By **Richard Dean**

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Sometimes simple fact patterns can be instructive on complicated legal issues. And, given the breadth of their respective enforcement powers, there is a crossover between preemption under the Federal Aviation Administration and the U.S. Food and Drug Administration.[1] The latest story of a connection between aviation preemption and preemption in the pharmaceutical space starts on a farm in Iowa.

The Danner farm, in Carroll County, Iowa, sits under the flight path to a municipal airport managed by the Carroll Airport Commission. Local zoning ordinances mandate a protected zone around the airport of 10,000 feet from the end of the runways and 150 feet above. The Danner farm is within the zone.

As a result of a particularly good harvest, Loren Danner needed more storage space. He built a storage tower that extended into the space governed by the airport commission regulations. The commission refused to grant a variance. It also asked the Federal Aviation Administration to perform an aeronautical study on the structure and its impact on aviation safety.

The FAA did so, and issued a "Determination of No Hazard to Air Navigation." It concluded the structure would not be a hazard if Danner painted the structure and added red lights to the top of it. Danner did so.

The Carroll Airport Commission did not seek review of that determination, although such review was available under federal law. Two years later, the commission, undeterred by the FAA determination, filed suit against Danner, alleging violation of local ordinances and that the structure constituted a nuisance and a hazard to air traffic.

The commission called various private pilots as witnesses who gave opinion testimony that the structure was indeed a hazard to air safety. The trial court gave no weight to the FAA's determination, finding that the structure violated local ordinances, and was a public nuisance. It rejected Danner's affirmative defense that the FAA's no-hazard letter preempted state and local zoning laws. The Iowa appellate court affirmed the rejection of Danner's preemption arguments.

So did the Iowa Supreme Court. In its decision in Carroll Airport Commissioners v. Danner,[2] it discussed and distinguished several cases involving no-hazard letters. The court concluded that it was possible to comply with all federal, state and local regulations. But this was an abstract conclusion, divorced from the factual setting where the federal authorities saw no hazard to aviation from the grain tower, and the local officials did.

What the larger issue comes down to is whether individual government units can make determinations about aviation safety at their airports, or whether the federal agency

charged with aviation safety should be making those determinations. There was no claim that the airport commission had any expertise in air safety. These were zoning ordinances from a local government. Should flight safety determinations about airport approaches be made individually, by thousands of airport commissions, or by the FAA?

If the FAA says an approach is safe, can a local government agency say it is not safe, in the guise of a zoning ordinance? Those questions seem to answer themselves. At a minimum, they show a conflict between federal and state law. And local regulations relating to air safety appear to thwart the purposes of the FAA. There was a brief reference to this issue in the Carroll County litigation, but no meaningful discussion of it.[3]

Many of the same policy considerations in the Carroll County case will also play out in the current opioid litigation. Can a state or local government impose public nuisance or other liability schemes where the sale and promotion of opioid drugs is heavily regulated by the FDA?

Only the FDA can approve such drugs; the state has no say in such approvals. Only the FDA can determine appropriate labeling; again, the state has no role here. And the FDA extensively regulates the marketing of such drugs. For example, Insys Therapeutics has just filed a notice for bankruptcy protection a few days after agreeing to pay $225 million to settle a federal investigation into its opioid marketing practices.[4] States have no agencies to engage in such regulation — though some have attempted to regulate by means of attorney general suits seeking damages, as opposed to classic regulatory suits.

There is limited law to date in regard to opioid preemption. Some states have gone so far as to try to order that the sale of drugs approved by the FDA be prohibited in their state. Those attempts have been rejected as violating the purposes and objectives of the FDA.[5]

A pharmaceutical company manufactured a form of hydrocodone analog, and it was the only product on the market whose only ingredient was hydrocodone. It did not have an abuse resistant formulation. It could be crushed. The FDA approved the drug in October 2013. Massachusetts issued orders prohibiting the sale of the drug until adequate safeguards could be put in place to safeguard against aversion. A court found that this state action obstructed the FDA's congressionally mandated charge of approving drugs, and was in direct conflict with the statute. The regulations were eventually rewritten in such a way as to be consistent with the labeling on the drug approved by the FDA.

Further demonstrating the power of the FDA to control opioid abuse, the FDA requested that Endo withdraw a reformulated version of Opana which users were liquefying and injecting. Endo agreed to that request. This was the first time the FDA had sought to stop the sale of a prescription opioid due to abuse risks. The FDA announced that it was examining abuse patterns with other opioids and might take further action. So a state may not order a drug off the market; the FDA can.[6]

The interplay between FDA determinations that a drug is safe and state efforts to negate it through public nuisance or common-law approaches was specifically commented on by U.S. Supreme Court Justice Samuel Alito'sdissent in Wyeth v. Levine:[7]

Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance "safe," our conflict preemption cases prohibit any State from countermanding that determination. See, e.g., Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (after the FDA has struck "a somewhat delicate balance of statutory objectives" and determined that petitioner submitted a valid application to manufacture a medical device, a State may not use common law to negate it); International

Paper Co. v. Ouellette, 479 U.S. 481, 494, 107 S.Ct. 805, 93 L.Ed.2d 883 (1987) (after the Environmental Protection Agency has struck "the balance of public and private interests so carefully addressed by" the federal permitting regime for water pollution, a State may not use nuisance law to "upse[t]" it); Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 321, 101 S.Ct. 1124, 67 L.Ed.2d 258 (1981) (after the Interstate Commerce Commission has struck a "balance" between competing interests in permitting the abandonment of a railroad line, a State may not use statutory or common law to negate it).

The fact that this appeared in a dissent does not mean that it is not a valid point. The issue before the court in Wyeth was a much narrower one. All the three cases cited here are still good law.

The Iowa Supreme court never mentioned the Kalo Brick case its Carroll County opinion. That is an interesting omission, since it is a 1981 case where the Iowa Supreme Court was unanimously reversed for not giving preemptive effect where a federal agency had clearly spoken on the critical issue in a state court damage action. The Interstate Commerce Act granted authority to the U.S. Interstate Commerce Commission to regulate railroad activities, including the decision to cease service on branch lines. But under Iowa law, a rail shipper could recover damages for a common carrier's failure to provide adequate service to shippers.

The railroad stopped service on one branch line after it was damaged by a mudslide. The railroad filed a petition with the Interstate Commerce Commission seeking permission to do so. The ICC granted the petition, finding the abandonment was due to conditions beyond the control of the railroad.

The shipper then sued for damages under the Iowa statutes, claiming the railroad had a duty to provide service on the branch. The trial court found preemption, but that was reversed by the intermediate Iowa Court of Appeals. The Iowa Supreme Court declined review. The U.S. Supreme Court found that there was a conflict between federal and state law — "there can be no divided authority over interstate commerce."[8] And that "as to abandonments, this authority is exclusive."[9] .

The Iowa Supreme Court also failed to cite U.S. Supreme Court justice Robert Jackson's famous ode to aviation:
Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under the intricate system of federal commands. The moment a ship taxies onto a runway it is caught up in an elaborate and detailed system of controls. It takes off only by instruction from the control tower, it travels on prescribed beams, it may be diverted from it intended landing, and it obey signals and order. Its privileges, rights, and protection, so far as transit is concerned, it owes to the Federal Government alone and not to any state government."[10]

That memorable language has some obvious parallel applications to opioid litigation.

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[1] Sikkelee v. Precision Airmotive Corp., 822 F.3d 680, 702, 703 (3rd Cir. 2016).

[2] Carroll Airport Commissioners v. Danner, _ N.W.2d _, 2019 WL 2063392 (May 10, 2019).

[3] The leading decision on this issue is Geier v. American Honda Motor Co., 529 U.S. 861 (2000).

[4] New York Times, June 11, 2019.

[5] Zogenix v. Patrick, 2014 WL 1454696 (D.Mass. 2014).

[6] "Bowing to FDA, Endo Halts Opioid Painkiller Sales," Law 360, July 6, 2018.

[7] Wyeth v. Levine, 555 U.S. 555, 609 (2009).

[8] Chicago & N.W. Transp. Co. v. Kalo Brick, 450 U.S. at 318.

[9] Chicago & N.W. Transp. Co., 450 U.S. at 323.

[10] Northwest Airlines v. State of Minnesota, 322 U.S. 292, 303 (1944).