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Implied Conflict Preemption May Apply In COVID-19 Cases

By **Susan Burnett and Daniel Rock** (May 15, 2020, 5:51 PM EDT)

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The COVID-19 pandemic has caused an unprecedented demand for medical products to diagnose, treat and prevent transmission of the disease. Many U.S. companies, including those not in the medical product business, are rising to the challenge to provide these critical products and are rightly concerned about exposure to possible product liability claims.

Much has been written about the express liability protections provided for "recommended activities" involving "covered countermeasures," in the secretary of health and human services' March 17 declaration of a public health emergency, which was issued pursuant to the Public Readiness and Emergency Preparedness, or PREP, Act.[1] This article addresses a different potential liability defense — the court-created doctrine of implied conflict preemption.

Medical product companies and their counsel who have faced product liability litigation likely are familiar with this doctrine, which can provide a complete or partial defense in such litigation. We provide a brief overview for those who may be unfamiliar with it and discuss how it might apply in litigation over actions taken pursuant to an emergency use authorization, or EUA, issued by the U.S. Food and Drug Administration.

Background on Emergency Use Authorizations

The FDA is an agency within the U.S. Department of Health and Human Services that regulates drugs, medical devices and biological products (e.g., vaccines).[2] It conducts this regulatory function pursuant to federal statutes and through regulations it promulgates to implement those statutes. In general, the FDA's regulations, along with certain actions the agency takes, have the force of federal law.

By statute,[3] the FDA may issue EUAs to authorize (1) "the emergency use of an unapproved medical product" or (2) "an unapproved use of an approved medical product" after the secretary of health and human services has made "a declaration of emergency or threat justifying authorization of emergency use."[4] The secretary issued such a declaration, which is different from the PREP Act declaration mentioned above, for the COVID-19 pandemic on Jan. 31.[5]

The purpose of an EUA is to facilitate availability and use of medical countermeasures, or MCMs,

including drugs, biological products and devices, that are needed to prepare for and respond to chemical, biological, radiological and nuclear emergencies.[6] This authority allows the FDA to respond to fast-paced and emerging infectious disease threats like COVID-19.[7]

The FDA has been active in issuing nonbinding guidance documents with respect to medical devices that diagnose, protect against, and provide ventilation support for patients with COVID-19.[8] These documents often include guidance for obtaining an EUA.

For instance, manufacturers that want to make ventilators should review the Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.[9] This document describes a process for contacting the FDA for EUA approval. It provides guidance both for current manufacturers of medical devices and companies that have never manufactured medical devices but have strong manufacturing capabilities and wish to help expand the country's capacity to provide these much-needed devices.[10]

Securing and complying with an EUA for an MCM may provide the necessary regulatory authorization with respect to the medical product but doing so does not necessarily immunize the company against liability for product liability claims attacking the products' safety, including the adequacy of the warnings and instructions that accompany it.

The PREP Act and the corresponding declaration from the secretary of health and human services on the COVID-19 crisis both reference EUAs, and to the extent an EUA-authorized MCM falls within the scope of PREP Act immunity, that statute could provide broad immunity from civil liability.[11]

But what about products qualifying as MCMs under an EUA that are outside the scope of the PREP Act? Case law interpreting the PREP Act is sparse, and the declaration that triggered its protections in connection with the COVID-19 crisis, while apparently covering a broad array of products, is less than two months old.

Because the scope of PREP Act protection in the context of the COVID-19 public health emergency has yet to be litigated, it is prudent for companies to examine what other potential defenses may be available in future product liability litigation. Implied conflict preemption is one such potential defense.

Background on Preemption

The concept of preemption is rooted in the supremacy clause of the United States Constitution, which makes federal law "the supreme Law of the Land." It follows that when federal law and state law directly conflict, the latter must yield to the former. For our purposes, there are two basic types of preemption, express and implied.

Express preemption is often found in statutes. The PREP Act, for example, not only includes an immunity provision, but also a section that expressly preempts the establishment or enforcement of state laws and regulations with respect to a "covered countermeasure" that (1) is different from or in conflict with requirements under the PREP Act, and (2) relates to, inter alia, the development, manufacture and distribution of a covered countermeasure.[12] This section has been broadly interpreted to cover all state law tort claims.[13]

In the absence of an express statutory provision regarding preemption, any federal law may still have an implied preemptive effect. Accordingly, a state law requirement is preempted if it would be impossible

for an actor to comply unilaterally with it without violating federal law, or when enforcement of the state law requirement would pose an obstacle to the purposes and objectives of Congress.[14]

Critically, "state law" in this context includes tort claims. For example, suppose that a state's common law would permit a jury to impose liability on a generic drug company on the ground that its drug's label inadequately warned about the adverse effect suffered by the plaintiff. Federal law requires generic drug labels to match the brand drug's label.

Thus, the generic drug company would have violated federal law by changing the label without prior FDA authorization. Accordingly, the state law failure-to-warn claim would be impliedly preempted by federal law.[15]

Implied conflict preemption also can apply when federal law permits a company to distribute a regulated product, but state law prohibits the distribution of that product. In the litigation context, this conflict could arise when, for example, the plaintiff argues that a drug is too dangerous to be sold — i.e., that its risks outweigh its benefits for all classes of patients. In the context of generic prescription drugs, the U.S. Supreme Court rejected this "stop selling" theory of liability, finding it impliedly preempted by federal law which permitted the sale of the drug.[16]

Emergency Use Authorizations and Implied Preemption

So does a state law, or more precisely, the imposition of civil liability by jury verdict, that effectively prohibits or penalizes activities authorized by an EUA impliedly conflict with federal law? The FDA thinks so.[17]

In its 2017 guidance on EUAs, the FDA stated that "the terms and conditions of an EUA ... preempt state and local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of an emergency declared under section 564."[18] These different or additional state and local requirements, the FDA said, stand as an obstacle to the implementation of Congress' purposes and objectives.[19]

The FDA justifies this conclusion by noting, inter alia, that the conditions within an EUA have been determined necessary or appropriate to protect the public health, and in such circumstances it is critical that no other conditions be imposed — after all, the FDA's actions are "intended to protect the public health by enabling rapid public access to potentially life-saving medical products during an emergency."[20]

The FDA's position on implied conflict preemption in this context does not have the force of law,[21] and the degree to which courts may defer to it is governed by complex and ambiguous legal precedents. For example, the U.S. Supreme Court has cautioned that it will not defer to an agency's legal conclusion that state law is preempted, but it may give weight to an agency's explanation of a state law's impact on the purposes and objectives of Congress.[22] Ultimately, predicting the effect of the FDA's guidance in the courtroom requires research tailored to the specific jurisdiction and facts of the case.

Nonetheless, the FDA's position bolsters a potential preemption defense should litigation arise from activities conducted pursuant to an EUA. Of course, to maximize the chances of success in making this argument, it is critically important that manufacturers follow, and document that they have followed, the precise terms and conditions of the EUA and any other relevant FDA standards and guidance.

In sum, companies responding to the current public health crisis by developing and manufacturing necessary medical products should anticipate possible product liability litigation and plan for defending it. Counsel should familiarize themselves with the doctrine of implied conflict preemption as applied in the medical product context and determine how best to position their clients to take advantage of this potentially important defense.

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[1] 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

[2] See https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart.

[3] 21 U.S.C. §360bbb-3(b)(1)(C).

[4] Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders (FDA Jan. 2017) at 3 (hereinafter "2017 Guidance on EUAs"). This document can be found at https://www.fda.gov/media/97321/download.

[5] See https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[6] 2017 Guidance on EUAs at 4.

[7] Id. at 1.

[8] https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

[9] Available at: https://www.fda.gov/media/136318/download.

[10] On March 31, 2020, FDA announced a Coronavirus Treatment Acceleration Program (CTAP), available at: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap. This program is not a guidance and does not create EUAs but expresses the FDA's commitment to rapidly responding to written requests for novel pharmacological trials, approving protocols for proposed novel pharmaceutical treatments, and around-the-clock review of proposed single patient trials.

[11] 85 F.R. 15198, 15201-02 (Mar. 17, 2020) (referencing EUAs in the definition of who may receive immunity under the PREP Act); 42 U.S.C. §247d-6d(i)(7)(B)(iii) (referencing EUAs in the definition of what countermeasures are covered by the immunity provided by the PREP Act).

[12] 42 U.S.C. § 247d-6d(b)(8).

[13] Parker v. St. Lawrence Cty. Pub. Health Dep't, 102 A.D.3d 140, 144, 954 N.Y.S.2d 259, 262 (2012).

[14] PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2012); Wyeth v. Levine, 555 U.S. 555, 568, 573–74 (2009).

[15] Mensing, 564 U.S. at 617.

[16] Mut. Pharma. Co., Inc. v. Bartlett, 570 U.S. 472, 488 (2013) ("Our preemption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

[17] See 2017 Guidance on EUAs at 39-40.

[18] Id.

[19] Id.

[20] Id. at 41.

[21] The guidance itself states that it is not binding on the FDA or the public, and "does not establish any rights for any person." Id. at 1.

[22] Wyeth v. Levine, 555 U.S. 555, 576-77 (2009) ("While agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"); see also Farina v. Nokia Inc., 625 F.3d 97, 126 (3d Cir. 2010) ("In concluding that state-law causes of action ... may disturb the FCC's balance of its statutory objectives, we afford some weight to the views of the FCC itself.").