
COMMENTS

of the

WASHINGTON LEGAL FOUNDATION

to the

**FOOD AND DRUG ADMINISTRATION,
U.S. DEPT. OF HEALTH AND HUMAN SERVICES**

Concerning

**DRAFT GUIDANCE ON
EMERGENCY USE AUTHORIZATION
OF MEDICAL PRODUCTS
[Docket No. 2004D-0333]**

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September 6, 2005

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Lester M. Crawford, D.V.M., Ph.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

**Re: Draft Guidance On Emergency Use Authorization Of Medical Products
[Docket No. 2004D-0333]**

Dear Dr. Crawford:

The Washington Legal Foundation (WLF) supports FDA's issuance of guidance on emergency use authorization of medical products pursuant to 21 U.S.C. § 360bbb-3. This statute allows FDA (via powers delegated by the Secretary of Health and Human Services) to authorize the use of unapproved medical products or to authorize unapproved uses of an approved product in response to a heightened risk of attack from biological, chemical, radiological, or nuclear weapons. WLF is submitted these comments to express certain concerns regarding the draft guidance document's preemption section. *See* Office of Counterterrorism Policy and Planning, Food and Drug Administration, *Draft Guidance: Emergency Use Authorization of Medical Products* 37-39 (June 2005) (hereinafter "Draft Guidance").

As detailed below, we believe the discussion of preemption should be clarified to establish that it covers labeling matters and should be revised to cover tort liability. The emergency powers created by Congress in § 360bbb-3 to protect the public health would be frustrated by assertions of state or local authority in either of these areas – either to establish

contrary or supplemental labeling requirements or to impose tort liability where a manufacturer is acting in compliance with an emergency use authorization.

I. Interests of Commenter

Commenter WLF is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government, including in the area of patients' rights. For example, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

In addition, because federal preemption plays an important role in protecting both the public and free enterprise from the excesses of state and local regulators and juries, WLF has frequently appeared in the U.S. Supreme Court and lower courts to address the proper scope of federal preemption. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. American Honda Co.*, 529 U.S. 861 (2000); *Greater N.Y. Metro. Food Council v. Giuliani*, 195 F.3d 100 (2nd Cir. 1999); *Lindsey v. Tacoma-Pierce County Health Dept.*, 195 F.3d 1065 (9th Cir. 1999); *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127 (Mich. 2003); *Etcheverry v. Tri-Ag Services*, 22 Cal. 4th 316, 993 P.2d 366 (Cal. 2000). WLF's Legal Studies Division has published papers to educate policymakers and thought leaders about

the role of federal preemption in the areas of drugs, medical devices, and biologics. *See, e.g.*, John G. Powers, *Federal Preemption of State Tort Suits Available For “PMA” Medical Devices* (2005); Eric G. Lasker, *FDA Position on Federal Preemption Consistent With Law and Public Health* (2005).

II. FDA’s Guidance Should Make Clear That Contrary Labeling Requirements Are Preempted

The draft guidance document properly states that “the terms and conditions of an EUA [Emergency Use Authorization] under section 564 [21 U.S.C. § 360bbb-3] preempt state law – legislative requirements and common-law duties – imposing different or additional requirements on the dispensing or administration of the medical product for which the EUA was issued. . . .” Draft Guidance at 37.

The document does not, however, explicitly state that requirements or common-law duties related to product labeling are preempted to the extent they conflict with FDA label requirements. The document impliedly asserts such preemption with its statement that preempted state laws “may include, but *are not limited to*,” the laws enumerated in the guidance. Draft Guidance at 38 (emphasis added). In view of the importance of product labeling and the potential for conflict with FDA requirements – particularly in the context of state law tort actions based on mislabeling or failure to warn – the document should assert such preemption expressly.

FDA has aptly noted in an amicus brief that the public’s reluctance to use a medicine “based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of

beneficial, possibly life-saving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects." *Amicus* Brief for the United States, *Motus v. Pfizer, Inc.*, Nos. 02-55372 & 02-55498 at 2 (9th Cir. Sept. 19, 2002) (quoted in Eric G. Lasker, *FDA Position on Federal Preemption Consistent With Law and Public Health* (2005)). This is no less true in the case of an emergency in which federal authorities must urge the public to accept vaccines, antidotes, or other agents for the protection of public health.

III. FDA's Guidance Should Explicitly Assert Preemption of Tort Liability For Actions Taken In Compliance With An Emergency Use Authorization

The draft guidance document asserts that "Section 564 of the FD&C Act does not offer liability protection to manufacturers or others who carry out any activity for which an EUA is issued, and liability protection is beyond the mission and authority of the FDA." Draft Guidance at 39. This statement, which may well deter companies from producing needed products under an EUA, is unsupported and ill-considered.

As an initial matter, the document's gratuitous statement that "liability protection is beyond the mission and authority of the FDA" is simply not true. Although the U.S. Supreme Court has indicated in a splintered set of plurality opinions that FDA device approvals under the so-called "§ 510(k) process" do not preempt state tort actions, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492 (1996), numerous courts have found that other FDA approvals do preempt state tort actions. Less than two weeks ago, the U.S. Court of Appeals for the Seventh Circuit held that

state tort suits based on a failure to warn of risks in a medical device subject to FDA premarket approval fall within the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a). *McMullen v. Medtronic, Inc.*, 2005 U.S. App. LEXIS 18418 (7th Cir. 2005).

Numerous other federal courts of appeal have also found preemption of state law claims based on the design, testing, manufacturing, and labeling of such devices. John G. Powers, *Federal Preemption of State Tort Suits Available For "PMA" Medical Devices* 3 n. 9 (2005). A number of courts have also found – consistent with the FDA’s own position set out in amicus briefs – that the FDA’s authority over new drug approvals impliedly preempts some state law tort claims. Eric G. Lasker, *FDA Position on Federal Preemption Consistent With Law and Public Health* 4 & n. 10 (2005).

Rather than forsaking its own preemption powers with regard to liability, FDA should instead declare that its exercise of emergency use authority preempts state law tort claims. The U.S. Supreme Court has stated that under the doctrine of implied preemption, “We will find preemption where . . . ‘under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (citations omitted) (brackets in original). “The exercise of the federal executive authority means that state law must give way where, as here, there is evidence of clear conflict between the policies adopted by the two.” *Am. Ins. Ass'n v. Garamendi*, 539 U.S. 396, 421 (2003). In the context of emergency use authorizations, the specter of hundreds of millions of dollars in tort liability would plainly frustrate Congress’s intention in enacting 21 U.S.C. § 360bbb-3 – namely, to

expedite the availability of medical products needed by Americans in the event of a terrorist attack or an attack by an enemy state.

CONCLUSION

For the foregoing reasons, the Washington Legal Foundation respectfully requests that FDA withdraw and revise its draft guidance on emergency use authorization of medical products.

Respectfully submitted,

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