Legal Backgrounder

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COURT RULING CASTS DOUBT ON FDA'S USE OF GUIDANCE DOCUMENTS

by
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A federal court in Florida held recently that the Federal Food and Drug Administration ("FDA") lacked the authority to enjoin the practice of pharmacists filling a veterinarian's prescription for a non-food producing animal by compounding from bulk substances. *United States v. Franck's Lab, Inc.*, No. 5:10-cv-147-Oc-32TBS (M.D. Fla. filed Sept. 9, 2011**)** at 80. After undertaking a thorough historical, regulatory and legal analysis of pharmaceutical compounding, the court found that FDA's assertion of authority over "traditional pharmacy compounding in the context of a pharmacist-veterinarian-patient relationship is contrary to [the] congressional intent" of the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id*. at 70. The court also held that the undisputed evidence in the case demonstrated that allowing FDA to enjoin a pharmacist's traditional, widespread, and state-authorized practice of bulk compounding of animal drugs "could destabilize the pharmacy profession and leave many animal patients without necessary medication." *Id.* at 74-75.

FDA focused on Franck's Lab after 21 polo ponies that it had treated died as a result of a drug compounding mathematical error. Despite the Florida state pharmacy board's thorough investigation and resolution of the matter, FDA proceeded to inspect Franck's facility and to cite Franck's for allegedly violating the FDCA. FDA then sought an injunction in federal court to stop Franck's distribution of animal drugs compounded from bulk substances, claiming that it was engaging in illegal animal drug manufacturing in violation of the FDCA.

FDA argued to the court that its case against Franck's was a "simple" one. It based its legal theory solely on the assertion that compounding animal drugs from bulk substances constituted a "per se" violation of the FDCA, 21 U.S.C. § 301, *et. seq*., even when conducted "by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription." *Id.* at 7- 8. To counter FDA's allegations, Franck's provided declarations by multiple experts. Relying entirely on its statutory construction argument, FDA provided no contrary evidence.

The court waded through the various guidance documents that FDA had issued over the course of several decades addressing pharmacy compounding, both for humans and animals. These documents laid out FDA's criteria for when it would decline to exercise "enforcement discretion," and instead initiate enforcement action against a compounding pharmacy. The court focused on the 2003 FDA policy guide addressing animal drug compounding, which FDA issued in final form (to much public outcry) without any opportunity for prior public comment. Despite the numerous

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negative comments FDA received after the guidance document was issued, FDA had never revised it or publicly addressed the criticisms. *See* FDA Compliance Policy Guide Sec. 460.400, Pharmacy Compounding of Drugs for Use in Animals (July 2003).

Turning also to the FDCA's statutory language, the court determined that, to the extent that Congress addressed the issue of compounding in the FDCA, it decided to "focus governmental resources upon the commercial distributors of drugs rather than upon the trained pharmacists and physicians who must reconstitute drugs for a patient to use on a smaller scale." *Id.* at 60 (emphasis omitted). The court stated that whether FDA was authorized to regulate compounding that is used as a "disguise for manufacturing" (which arguably may be within FDA's broad reach) was not the issue. Instead, using a "first-of-its-kind enforcement action," the FDA was seeking to expand its statutory authority by enjoining an "individual pharmacy which is engaged in traditional compounding of animal drugs in compliance with state law. In so doing, FDA overreaches." *Id.* at 69. The court found equally troubling FDA's long-overdue promise that it would publish new guidance on animal drug compounding, yet it had failed to do so. Thus, FDA could not use a guidance document to upset industry expectations that it helped to create "without explanation." *Id*. at 76.

While Franck's case involved pharmacy compounding of bulk pharmaceuticals in non-food producing animals, its implications extend broadly to other areas of FDA law, particularly as it relates to FDA's increasing use of guidance documents to expand regulatory requirements. In the past year, FDA has issued dozens of important draft guidance documents and final guidance documents, while releasing very few significant regulations. Given FDA's penchant for issuing guidance documents instead of proceeding through notice and comment rulemaking, the court's decision may have broad applicability concerning FDA's ability to regulate or enforce its laws through guidance instead of rules. Indeed, FDA often applies draft guidance documents as if they represented binding obligations. It sometimes even references the contents of the document in communications with industry before the document is finalized.

FDA's attempt to regulate and enforce its laws through its guidance often imposes new obligations or confers new rights on the regulated industry.[1] Courts have long recognized that an agency policy creating new rights or duties requires notice and comment rulemaking. *See Community Nutrition Institute v. Young*, 818 F.2d 943, 946 (D.C. Cir.1987); *American Hospital*, 834 F.2d 1037 (D.C. Cir 1987); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997).

A recurring criticism of FDA – one which WLF itself has expressed many times – is FDA's use of guidance documents instead of rulemaking; thus the agency does not "attempt[] to test its views" through the more rigorous rulemaking process. *See Franck's Lab* at 74. When FDA issues guidance documents, it tends not to acknowledge the negative comments. The agency typically offers no explanation for why it has opted to stick with its proposed language, rather than making changes to address adverse comments.[2] This failure to respond to comments is not permitted for agencies when they engage in rulemaking. If the district court's ruling is upheld, its analysis on FDA's use of guidance documents is likely to be cited in other FDA proceedings and legal

[1] FDA's attempt to regulate and enforce its laws through its guidance documents should be considered "substantive," and thus "rulemaking," if it imposes new obligations or confers new rights on the regulated public. *See Chamber of Commerce v. OSHA*, 636 F.2d 464, 468 (D.C. Cir. 1980); *Paralyzed Veterans of America v. D.C. Arena L.P.*, 117 F.3d 579, 588 (D.C. Cir. 1997).

[2] FDA's Good Guidance Practices, 21 C.F.R. § 10.115, establish some procedural requirements for the issuance of guidance documents. These procedures, though, provide far fewer protections for regulated entities than does agency compliance with the Administrative Procedure Act, e.g., there is no obligation to respond to key issues raised by commenters.

challenges testing the agency's right to enforce through guidance in lieu of regulations.

Examples abound of FDA relying on guidance documents to interpret or enforce the FDCA, and those examples are growing in number. In 1999, FDA issued 82 guidance documents in accordance with Good Guidance Practices; by 2009 it had swelled to 169. K.M. Lewis, *Informal Guidance and FDA*, FOOD AND DRUG LAW J. (2011).

For example, FDA has declared its intent to regulate laboratory developed tests ("LDTs") through guidance documents. There are many parallels with FDA's efforts to regulate compounding: The lack of clear statutory authority; the broad assertion of jurisdiction; the stance that a medically necessary procedure is inherently unlawful under the FDCA (all LDTs are devices and virtually all would need FDA approval or clearance to be compliant with the FDCA); the long delay between enactment of the statute and FDA's initial assertion of the regulatory authority (16 years for labs); and FDA's decision to pursue the guidance document route, not rulemaking. If FDA were to pursue regulation of LDTs, the *Franck's Lab* case probably would be cited in any defensive proceeding or laboratory-initiated suit.

Another recent example is FDA's draft guidance on Research Use Only (RUO) products. These products play an indispensable role in advancing research; they are also sometimes used by laboratories to diagnose patients. In its proposed draft guidance, FDA said that a manufacturer which became aware that an RUO product was being used diagnostically must immediately halt sales to that customer. This limitation would be highly disruptive to manufacturers, customers, and researchers. Significantly, even though this is a draft guidance, FDA officials have stated it represents *existing* policy; the document was even cited in a warning letter issued this past September. The draft guidance typically offers no explanation for why the change was needed, or an analysis of the effects – positive or negative – on affected parties.

Similarly, FDA issued a draft guidance in June 2011 titled, "Guidance for Industry and FDA Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues," purporting to distinguish devices from drugs. Although called "guidance," FDA states that its new policy would subject products that have long been devices to the different – and more stringent – requirements of drug regulation. This, too, represents a substantive change in applicable requirements via the guidance document process in lieu of rulemaking. In this instance, FDA began to apply the criteria set forth in the *proposed* draft guidance even *before* the draft guidance was publicly released.

FDA also is relying on guidance documents to announce its long-awaited policy addressing new dietary ingredients ("NDI") as part of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). FDA released its game-changing draft dietary ingredient guidance on July 1, 2011. Despite Congress' enactment of the DSHEA governing dietary supplements back in 1994, FDA's recent lengthy guidance on the topic addresses significant additional and onerous requirements for dietary supplement manufacturers and distributors. For example, in order for certain dietary ingredients to remain beyond the requirements of the DSHEA, manufacturers and distributors must substantiate through detailed submissions to FDA that the ingredient was marketed before October 15, 1994 (i.e., a "grandfathered" ingredient beyond the reach of the DSHEA). The draft guidance also requires companies to submit to FDA complicated NDI notifications for ingredients marketed after 1994, contrary to long-standing industry practice with respect to such ingredients. Though issued in draft form and subject to public comment, the guidance was not issued pursuant to notice and comment rulemaking under the Administrative Procedure Act. Nevertheless, it will have broad, industry-wide economic implications for dietary ingredient manufacturers and distributors that have been marketing safe products for years or even decades.

In *Franck's Lab*, the court noted the FDA "has not undertaken the necessary steps to find the facts, explain its rationale, and allow for public discourse on the issue."[3] The same criticism applies to many of the guidances and draft guidances issued by FDA.

If upheld on appeal,[4] the *Franck's Lab* decision will be invoked by interested parties seeking to constrain FDA's use of non-binding guidance documents to define prohibitions against which FDA may take enforcement action or impose new requirements on applicants, and to attack FDA assertions that it is entitled to *Chevron* deference. FDA's desire to use guidance in lieu of rulemaking is understandable. Guidance documents take less work to promulgate, go through less review, and can be revised more readily. However, ease of use does not excuse FDA from the need to comply with the Administrative Procedure Act. Before FDA can enforce a rule in a legal forum, it must craft that rule through proper rulemaking proceedings. The agency should revisit its practice of using guidance documents – or even draft guidance – to establish substantive requirements for the companies it regulates.

[3] *Franck's Lab* at 74-75.
[4] The United States filed with the district court a Notice of Appeal to the United States Court of Appeals for the Eleventh Circuit on November 10, 2011.