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Western District of Texas Compounding Decision on *Medical Center Pharmacy v. Gonzales*

In an August 30, 2006 opinion in *Medical Center Pharmacy v. Gonzales*, the United States District Court for the Western District of Texas held that lawfully compounded drugs for humans and for non-food-producing animals fall outside the definition of "new drugs" and "new animal drugs" under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act"). Specifically, the court found that extemporaneous compounding of drugs is authorized under 21 U.S.C. § 353a (Section 503A of the FDCA) and such compounding is thereby exempted from the drug approval process and outside the scope of the definitions of "new drug" and "new animal drug" under sections 201(p)(1) and (v)(1) of the FDCA (21 U.S.C. § 321(p)(1) and (v)(1)). The court characterized this as a "narrow exemption."

The opinion also purports, in essence, to "reinstate" in its entirety Section 503A of the Act (21 U.S.C. § 353a) other than the solicitation and advertising provisions, which the Supreme Court held to be unconstitutional in 2004. In an earlier determination in the same case in which the Supreme Court invalidated those provisions, the Ninth Circuit had held that the solicitation and advertising provisions of Section 503A were not severable from the remainder of that statutory provision. The severability determination was never reviewed by the Supreme Court and, since that time, both the Food and Drug Administration ("FDA") and regulated industry have treated the entirety of Section 503A as unenforceable.

Finally, the opinion overturns FDA's long-standing position that compounding from bulk ingredients of drugs for non-food-producing animals is illegal.

Background

The plaintiffs in the *Medical Center Pharmacy* case sued FDA in 2004 challenging the agency's authority to regulate compounded drugs and to inspect state-licensed retail pharmacies. Plaintiffs' summary judgment motion sought declarations and corresponding injunctions against FDA enforcement in the following areas: that compounded drugs are not "new drugs" or "new animal drugs" under the FDCA; that FDA may not compel inspections in excess of what is permitted by the first sentence of Section 704(a)(1) of the Act (21 U.S.C. § 374(a)(1)) with respect to pharmacies that comply with state and local laws; and that FDA does not have the authority to declare compounding of drugs from bulk ingredients for non-food-producing animals to be illegal, or to enforce either Center for Veterinary Medicine ("CVM") Compliance Policy Guide (CPG) § 608.400 or the April 2, 2004 CVM Notice to state boards of pharmacy that restates the CPG. The plaintiffs' summary judgment motion also sought to enjoin FDA from prohibiting the receipt by pharmacies of bulk ingredients and from bringing prosecutorial action against plaintiffs for refusing to allow FDA to conduct inspections in addition to what is permitted under the first sentence of Section 704(a)(1) of the Act (21 U.S.C. § 374(a)(1)).

The court's holding that compounded drugs are not "new drugs" or "new animal drugs" and its "reinstatement" of Section 503A of the Act

The court derives its holding that compounded drugs do not fall under the definition of either "new drugs" or "new animal drugs" from Section 503A of the FDCA (21 U.S.C. § 353a). This position is curious because FDA and its regulated entities had understood that that section of the Act had been declared unconstitutional under the Supreme Court's holding in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

Section 503A of the Act took effect on November 21, 1998. That same month, seven compounding pharmacies challenged the solicitation and advertising provisions of §503A as an impermissible regulation of commercial speech. The Ninth Circuit Court of Appeals declared Section 503A unconstitutional in its entirety because that Section contained unconstitutional restrictions on commercial speech and because the Appeals Court held that the solicitation and advertising provisions could not be severed from the remainder of that Section.[1] The Supreme Court affirmed that the solicitation and advertising provisions of Section 503A were unconstitutional. Neither party requested certiorari on the issue of whether those provisions were severable from the remainder of Section 503A, so the Supreme Court did not rule on, and thus left in place, the Ninth Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of Section 503A. FDA concluded that all of Section 503A had been declared invalid and, in the intervening four years since the Supreme Court issued its ruling, has acted accordingly.

The Texas District Court reasoned that it, sitting in the Fifth Circuit, was not bound by any decision of the Ninth Circuit and concluded that, contrary to the Ninth's Circuit's determination on this point, the severability provision in the Act required that the remainder of section 503A be severed from the unconstitutional solicitation and advertising provisions. The Texas court therefore declared that, "[t]he offending portions of [Section 503A of the Act] are severed and the remainder of the statute remains in full effect." August 30, 2006 opinion at 13. The court's finding that Section 503A remains in effect laid the basis for its further finding that compounded drugs are authorized under that section and are therefore exempt from the definitions of "new drug" and "new animal drug" in the FDCA. The District Court stated, however, that the exemption from regulation as new drugs or new animal drugs only applies to compounded drugs that are made in reasonable quantities upon receipt of a valid prescription for an individual patient from a licensed practitioner. "Drugs that are compounded in large quantities before a prescription is received from a doctor do not fall within the narrow exemption this Court finds exists." *Id.* at 14.

Despite the novel route it followed to reach its holding, the Texas court's decision on this point would appear to conform to FDA's traditional policies and practice both before the enactment of Section 503A and since the Supreme Court's *Western States* decision. FDA has continuously allowed pharmacies to compound for a specific patient in response to a specific prescription by a licensed practitioner. Thus, the court's ruling on what constitutes legal compounding is really not a departure from FDA's historical practice in this area.

[1] *Western States Medical Center v. Shalala*, 238 F.3d 1090 (9th Cir. 2001).

FDA's Inspection Authority

The court's holding does represent a departure, however, with respect to FDA's ability to inspect compounding pharmacies. Section 704 of the FDCA (21 U.S.C. § 374) gives FDA the jurisdiction to inspect pharmacies to make sure they are complying with the law. Under the first sentence of Section 704(a)(1), FDA may inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" within a compounding pharmacy. The third sentence of 704(a)(1), generally referred to as the "records provision," allows FDA to inspect:

> all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter.

Section 704(a)(2)(A) exempts from the records provision,

> pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

The court interpreted this exemption as allowing FDA to inspect the records of a compounding pharmacy only if FDA can demonstrate that the pharmacy is not in compliance with applicable local laws. August 30, 2006 opinion at 19. The court concluded, therefore, that under Section 704, FDA has the authority to inspect a compounding pharmacy's equipment, finished and unfinished materials, containers and labeling, but that its authority to inspect records only exists if it can show that the pharmacy does not qualify for the exemption. The court found that FDA has not demonstrated that any of the ten pharmacy plaintiffs in the case before it were violating state or local laws and thus prohibited FDA from compelling inspections that exceed the limited authority granted by the first sentence of Section 704(a)(1).

Compounding from Bulk Ingredients Drugs for Non-Food-Producing Animals

Plaintiffs also asserted that the FDCA did not preclude them from compounding from bulk ingredients drugs for non-food producing animals. FDA had initially contended that the Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA") precludes compounding from bulk ingredients. CVM has consistently taken the position compounded veterinary drugs must use as starting materials approved human or veterinary drugs. 21 C.F.R. § 530.13 provides, "This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs."[2]

[2] In CPG § 608.400, however, CVM had advised that it would take regulatory discretion with respect to the compounding of drugs for animals using as starting materials any of a list of nine bulk active ingredients.

Apparently, FDA abandoned the argument at the summary judgment stage that AMDUCA prohibits the compounding from bulk ingredients of veterinary drugs for non-food-producing animals. August 30, 2006 opinion at fn 4, p. 20. Instead, FDA argued that such drugs are unsafe and adulterated under Section 512 of the FDCA (21 U.S.C. § 360b). The court disposed of this argument when it found that compounded drugs do not fall within the definition of "new animal drugs" and that they are therefore outside Section 512 of the Act. The court also rejected FDA's argument that such drugs were misbranded as lacking adequate directions for use because the exemption from adequate directions for use in 21 C.F.R. § 201.122 only applies to bulk ingredients if the finished product is neither a new drug nor a new animal drug. Because the court had concluded that compounded animal drugs are not new animal drugs, it found that the requirement for adequate directions for use did not apply.[3] The court therefore concluded that drugs for non-food-producing animals compounded from bulk ingredients do not violate the FDCA's unsafe, adulterated or misbranded provisions.

In so finding, however, the court denied plaintiff's motion to invalidate CPG § 608.400, which prohibits the compounding from bulk ingredients of drugs for non-food-producing animals, on the basis that the CPG is non-substantive and non-binding. Under the same analysis, the court refused to invalidate an April 2, 2004 notice issued by CVM's Director of Compliance to all state boards of pharmacy advising that CVM had issued inspection assignments to its field offices and seeking the participation and assistance of the state boards in these inspections. The court held, however, that to the extent that portions of the CPG and notice contradicted the court's rulings, FDA would no longer be permitted to enforce those portions.

Injunctions

Finally, the court denied without prejudice plaintiffs' motion to enjoin FDA from declaring that compounded drugs are new drugs or new animal drugs, enforcing the records provision of Section 704, enforcing the portions of the CPG stating that compounding of drugs from bulk ingredients for non-food-producing animals is illegal, prohibiting the plaintiffs or similarly-situated pharmacies from receiving bulk ingredients, or bringing prosecutorial, enforcement or punitive actions against plaintiffs for refusing to allow FDA to conduct other than limited inspections in the absence of independent evidence from the state pharmacy board that the pharmacies are non-compliant. The court warned, however, that if FDA "continue[s] to violate the Act," the court would consider re-urged injunction petitions at a future date.

[3] The court also found that the misbranding provision of Section 502 of the Act (21 U.S.C. § 352) does not apply to the plaintiff pharmacies because, per Section 510(g)(1) of the FDCA (21 U.S.C. § 360(g)(1)), plaintiffs were compliant with the law and thus not required to register under Section 510 as drug manufacturers. The court concluded that these pharmacies therefore were not automatically subject the to Act's misbranding provisions.

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