

## ALERTS AND UPDATES

### Fifth Circuit Rules in Favor of Compounding Pharmacies, in *Medical Center Pharmacy v. Holder*

March 4, 2011

On February 25, 2011, in the latest scrimmage between the U.S. Food and Drug Administration (FDA) and compounding pharmacies, the U.S. Court of Appeals for the Fifth Circuit held—in *Medical Center Pharmacy v. Holder*<sup>1</sup>—that the "waiver" doctrine precluded the FDA from arguing its right to conduct limited inspections of compounding pharmacies, which mix or compound drugs to fill unique prescriptions for patients.

In *Medical Center Pharmacy*, 10 pharmacies that compounded prescription drugs filed suit, challenging the FDA's authority to regulate compounded drugs.<sup>2</sup> The district court granted summary judgment in favor of the pharmacies and held that the compounded drugs were not "new drugs" and the pharmacies were exempt from the FDA's inspection authority pursuant to 21 U.S.C. § 374(a)(2)(A). The FDA appealed the holding. The Fifth Circuit reversed and remanded.<sup>3</sup> On remand, the district court reversed its original inspection ruling that the FDA had authority to conduct limited inspections of pharmacy records notwithstanding § 374(a)(2)(A).<sup>4</sup>

The pharmacies appealed.<sup>5</sup> On this second appeal, the Fifth Circuit held that the FDA forfeited the issue of its inspection authority when it failed to raise the objection in the first appeal.<sup>6</sup> Further, the Fifth Circuit held that the district court's original inspection ruling—that "state-law-compliant pharmacies are exempt from FDA records inspections under 21 U.S.C. § 374(a)(2)(A)"—was not plainly erroneous, even in light of the Fifth Circuit's first ruling that compounded drugs were "new drugs."<sup>7</sup>

#### For Further Information

If you have any questions about this *Alert*, please contact [Frederick \(Rick\) R. Ball](#), any [member](#) of the [Pharmaceutical, Pharmacy & Food](#) industry group or the attorney in the firm with whom you are regularly in contact.

#### Notes

1. *Medical Ctr. Pharm. v. Holder*, 2011 U.S. App. LEXIS 3784 (5th Cir. Tex. Feb. 25, 2011).
2. *Id.* at 3.
3. *Id.* at 4; *see also Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).
4. *Id.* at 2, 5.
5. *Id.*
6. *Id.* at 8–9.
7. *Id.* at 2, 10.

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