

guaranteeing that compounding was not conducted on such a scale as to undermine the drug approval process, it had not been demonstrated that the speech restrictions were not more extensive than necessary to serve such interests.<sup>3</sup>

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## ARE WE MAKING PROGRESS?

Unfortunately, the Supreme Court did not address whether the remaining provisions in 503A remained “good law.” After five years, the compounding pharmacy industry was now in a total state of confusion. What was the current status of compounding drugs, and what was expected from the compounding pharmacies in terms of compliance? What regulatory body was responsible for monitoring compounding pharmacies? Were the advertising and solicitation provisions “severable” from 503A, or was the entire 503A section struck down?

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## SO WHERE ARE WE?

On July 30, 2002, the FDA came out with a draft of its FDA Compliance Policy Guidelines and said in essence it was not in a hurry to address the issue of 503A. It said, “Moreover, the practice of pharmacy, including compounding, is heavily regulated by the State Boards of Pharmacy.” Ultimately, the FDA would decide it had a case for enforcement.<sup>4</sup>

A group of pharmacies pushed back against the FDA’s authority for oversight. On July 18, 2008, the Fifth Circuit Court in *Medical Center Pharmacy v. Mukasey* found that the other provisions in 503A were lawful and still in effect. The FDA would go on to say that it could exercise discretion in taking action against a compounding pharmacy that violated the 503A provisions.<sup>5</sup>

So in 2001 we have the Ninth Circuit Court in *Western States v. Shalala* determining that 503A was struck down in its entirety, leading up to the Supreme Court decision in 2002.<sup>6</sup> We have the Fifth Circuit Court determining that the free speech provision was severable and the remaining 503A section was in force. What we ended up with was a situation of nonuniform enforcement by the FDA—and total confusion.