

compounded drugs. One legislative aide who is still working for a congressman (and wishes to remain anonymous) gave me some insight on the logic behind this provision. He said,

We thought if we would exempt compounded drugs from the new drug requirements and labeling, as long as they were manufactured under cGMPs and met the other provisions of FDAMA, we could control the “process of production.” We believed that by prohibiting the solicitation and advertising of the compounded drugs to office users, we could limit their activities as a manufacturer and force the compounders to work on a “patient pull” system. This way everything the compounding pharmacies produced would directly fill individual patient prescriptions.

In theory and in a simple world, this logic made sense. However, what happened next could be categorized as either unintended consequences or mass confusion (or both).

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### ***THOMPSON VERSUS WESTERN STATES MEDICAL CENTER***

A group of licensed pharmacies that specialize in compounding drugs (Western States Medical Center, now Kronos Compounding Pharmacy) filed suit to enjoin enforcement of the advertising and solicitation provisions in 503A, arguing that they violate the First Amendment’s free speech guarantee. The district court agreed, and held that the provisions constituted unconstitutional restrictions on commercial speech. The court of appeals concluded that the government had not demonstrated that the restrictions would directly advance its interests or that alternatives less restrictive of speech were unavailable.

The Supreme Court took the case and specifically addressed the following question: *Do the prohibitions in the Food and Drug Administration Modernization Act of 1997 with regard to soliciting prescriptions for and advertising compounded drugs violate the First Amendment?*

On April 29, 2002, in a 5–4 opinion delivered by Justice Sandra Day O’Connor, the court held that the FDAMA’s provisions in 503A amounted to unconstitutional restrictions on commercial speech. Among other findings, the court reasoned that although the speech restrictions allegedly served governmental interests in permitting drug compounding while