Two More From The Supreme Court

Thursday, June 23, 2011

Generic Manufacturers Win Preemption In Mensing

The Court decided 5-4 in favor of generic preemption today in Pliva, Inc. v. Mensing, No. 09–993, slip op. (U.S. June 23, 2011). We'd like to talk about Mensing, but it's a metoclopramide case, and consistent with blog policy we don't comment on cases in which Dechert is involved – so we can't, at least now. Sorry, our lips are sealed.

Sorrell – Pharmaceutical Detailing Is First Amendment Protected

In the second interesting opinion of the day, the Court decided Sorrell v. IMS Health, Inc., No. 10-779, slip op. (U.S. June 23, 2011). Sorrell involved a state statute intended to interfere with pharmaceutical detailing by precluding detailing companies from obtaining access to information (available from pharmacies) about which doctors prescribe what drugs, or even if they got it, from using that information without the prior consent of each and every individual physician. Slip op. at 2-4. On top of that, the statute provided for state-financed "counter-detailing" – pushing cheaper, often generic, competing drugs. Id. at 4-5. "Data miners," who gather and sell this information, and pharmaceutical companies challenged the statute as a violation of the First Amendment.

The 6-3 opinion in Sorrell is a strong reiteration of First Amendment principles, particularly in the commercial speech arena. Justice Kennedy, the "swing justice" of the current Court, wrote the opinion. We are aware that, at various times, several of the justices have expressed disagreement with the commercial speech analysis of Central Hudson Gas & Electric Corp. v. Public Servicew Comm'n, 447 U.S. 557 (1980). Interestingly, Sorrell doesn't strictly adhere to the Central Hudson framework, which will no doubt touch off considerable academic speculation as to that case's continuing viability. We'll leave that to the First Amendment scholars to chew on. We're more interested in the prescription drug implications of the case.

In that vein, the point we're most interested we find right there in the majority opinion's first paragraph: "Speech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment." Sorrell, slip op. at 1.

Initially, the Court found an explicit content-based discrimination against speech, since the statute prohibited use of pharmacy prescriber information only in pharmaceutical detailing. Slip op. at 6-7.

"The statute thus disfavors marketing, that is, speech with a particular content. More than that, the statute disfavors specific speakers, namely pharmaceutical manufacturers."

Id. at 8. That's the first First Amendment no-no, opening the door to heightened judicial scrutiny. Id. at 7-8.

The Court had no trouble walking through that door. The state put a heavy thumb on the free speech scale, since the statute allows it to distribute the same information that it denied pharmaceutical marketers to the statute's contemplated "counter detailers." Slip op. at 8. "Vermont's law thus has the effect of preventing detailers – and only detailers – from communicating with physicians in an effective and informative manner." Id. at 9. Thus the statute "goes even beyond mere content discrimination, to actual viewpoint discrimination." Id. That's an even bigger First Amendment no-no, mandating heightened scrutiny:

"Lawmakers may no more silence unwanted speech by burdening its utterance than by censoring its content. The First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys."

Id. at 10 (citations and quotation marks omitted). And "commercial speech is no exception." Id. at 10-11.

The Court leveled the state's arguments. It wasn't an access to government-controlled information case. To the contrary, the information that the state was interfering with was already in the private hands of either the pharmacists or the drug manufacturers, and it was their use of information in their own possession that was being restricted. Slip op. at 12-14. Nor was the information merely a "commodity" like "beef jerky." Indeed, in light of what the statute in fact did, the majority had little patience with that argument:

"The State has imposed content- and speaker-based restrictions on the availability and use of prescriber-identifying information. So long as they do not engage in marketing, many speakers can obtain and use the

information. But detailers cannot. Vermont's statute could be compared with a law prohibiting trade magazines from purchasing or using ink."

Id. at 15.

The commercial nature of the speech did not insulate the content- and speaker-based prohibitions of the statute from the First Amendment. "[T]he outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied." Slip op. at 16. The Court thus left open the possibility (it did not decide the question) that the information in question may be entitled to more than the usual commercial speech protection. Id.

Even under the lesser scrutiny given restrictions on commercial speech, the statute's impositions upon pharmaceutical detailing failed.

The statute's purported justifications did not support the restrictions on pharmaceutical detailing.

First, the statute wasn't a legitimate effort to protect physician privacy. Only one use of the supposedly private information was proscribed. The statute did not prohibit disclosure of sensitive information in "only a few narrow and well-justified circumstances," but rather "made prescriber-identifying information available to an almost limitless audience" – essentially everybody in the world except pharmaceutical detailers. Slip op. at 18. Even the physician consent feature operated only to allow speech that the "state opposes," so the privacy being offered (assuming there was any) was Big Brother privacy, "only on terms favorable to the speech the State prefers." Id. Thus, "limited range of available privacy options instead reflects the State's impermissible purpose to burden disfavored speech." Id. at 19.

Scratch that flattop.

Second, that some doctors were annoyed by pharmaceutical detailing isn't a justification for the discriminatory exercise of state power. Having to "endure" annoying speech "is a necessary cost of freedom." Slip op. at 20. We could say the same about attorney advertising, or beer commercials. Everybody - our clients, not just our opponents - has a constitutional right to annoying commercial speech.

We can turn off the TV. In their offices, like in our homes, physicians can simply tell annoying speakers to go away:

"Physicians can, and often do, simply decline to meet with detailers, including detailers who use prescriber-identifying information. Doctors who wish to forgo detailing altogether are free to give "No Solicitation" or "No Detailing" instructions to their office managers or to receptionists at their places of work."
Id.

That doctors might actually act on the information provided by detailing, even if (the state would say) they do so wrongly, can't justify the restriction on truthful pharmaceutical-related speech:

"The more benign and, many would say, beneficial speech of pharmaceutical marketing is also entitled to the protection of the First Amendment. If pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. . . . [T]he fear that speech might persuade provides no lawful basis for quieting it."
Id. at 21.

Scratch another flattop.

Third, the statute couldn't be justified as a way for the state to save money by inducing physicians to prescribe cheaper drugs. Speech cannot be inhibited for this reason:

"This reasoning is incompatible with the First Amendment. . . . [T]he State may not seek to remove a popular but disfavored product from the marketplace by prohibiting **truthful, non-misleading** advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers."

Slip op. at 22 (emphasis added). While there are "divergent views regarding detailing and the prescription of brand-name drugs," "[u]nder the Constitution, resolution of that debate must result from free and uninhibited speech." Id. "The choice between the dangers of suppressing information, and the dangers of its misuse if it is freely available is one that the First Amendment makes for us." Id.

Scratch yet another flattop. It's looking like a First Amendment Battle of Midway out there.

Pharmaceutical detailers have a constitutional right to seek to persuade doctors to use their products, even if the government doesn't like the result:

> "The State may not burden the speech of others in order to tilt public debate in a preferred direction. The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. . . . [T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."

Id. at 23-24. The speech isn't "false and misleading," thus "[t]he State's interest in burdening the speech of detailers instead turns on nothing more than a difference of opinion." Id. at 24 (citing, among other cases, Thompson v. Western States Medical Center, 535 U.S. 35, 376 (2002)). Midway? Maybe the better analogy would be to the Marianas Turkey Shoot.

FDA, are you listening?

The dissent was. It observes – and we agree – that "the same First Amendment standards . . . would apply to similar regulatory actions taken by . . . the Federal Government acting, for example, through Food and Drug Administration (FDA) regulation." Dissenting slip op. at 6; see id. at 10-11 (discussing off-label use).