



STATE “UNFAIR TRADE PRACTICE” SUITS UNDERMINE FDA WARNING LETTERS

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Many state attorneys-general have treated the pharmaceutical industry as their own private cash cow. They have brought more than 100 enforcement actions against healthcare companies at a steadily increasing pace and collected many billions of dollars. Even so, the recent decision of the South Carolina Supreme Court in *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 414 S.C. 33 (2015), *cert denied*, 136 U.S. 824 (2016), stands out from the enormous herd.

Since 1993, Janssen has marketed Risperdal, an FDA-approved anti-psychotic drug. In September 2003, FDA required that all drugs in Risperdal’s class include in their label a warning about an increased risk of diabetes and other hormonal abnormalities. Risperdal added the warning, but two months later, sent a letter to doctors describing peer-reviewed research indicating that Risperdal is *not* associated with an increased risk of diabetes and, in fact, compared to some drugs in its class, presents a lower risk of the condition.

FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC)—now the Office of Prescription Drug Promotion—took issue with Janssen’s statements. In April 2004, DDMAC sent the Company a Warning Letter asserting, per its standard formulation, that Janssen’s Dear Doctor Letter was “false or misleading.” Although Janssen believed that the scientific data supported the statements, it issued a corrective letter. FDA took no further action.

State attorneys-general, however, showed no such restraint. A number of them sued Janssen under their states’ unfair trade practices acts and initially won large verdicts—\$4.5 million in West Virginia, \$257 million in Louisiana, \$1.2 billion in Arkansas, and \$327 million in South Carolina. On appeal, however, the Supreme Courts of West Virginia, Louisiana, and Arkansas reversed the verdicts in those states. Not so in South Carolina. The Supreme Court there let the verdict stand, paring it to a modest \$124 million. *Wilson*, 414 S.C. at 207.

Janssen sought review in the United States Supreme Court, arguing that the penalty exacted by South Carolina violated the First Amendment, federal preemption principles, and the Eighth Amendment’s Excessive Fines Clause. Despite strong *amicus* support for Janssen from Washington Legal Foundation, Pharmaceutical Research and Manufacturers of America (PhRMA), and the U.S. Chamber of Commerce, the Court denied certiorari.

The South Carolina Unfair Trade Practices Act permits both private parties and the state Attorney General to sue for “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” S.C. Code Ann. § 39-5-20(a). An individual plaintiff must show injury resulting from the defendant’s conduct. The Attorney General, by contrast, can sue with no showing of harm. In fact, in the South Carolina case, the State could not show that Janssen’s actions injured anyone.

As Janssen argued, when wielded against pharmaceutical manufacturers in this manner, this statute conflicts with FDA regulation. The South Carolina Supreme Court therefore should have found that federal law preempted the Attorney General's claim. The Attorney General, not surprisingly, invoked *Wyeth v. Levine*, 555 U.S. 555 (2009), where the US Supreme Court held that FDA regulation of prescription drugs did not preempt personal-injury claims under state law. Congress, the Court said, had "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574. Be that as it may, South Carolina's Attorney General is not an injured consumer. The South Carolina statute, as applied in Janssen's case, had no compensatory function. The penalty South Carolina imposed was purely regulatory, and it sought to regulate what FDA already regulates intensively—Janssen's communications with healthcare providers. Moreover, this additional layer of government mandates is not merely supplemental or benign. In fact, it undercuts FDA's efforts.

In addition to a more general attack on the Risperdal label, the South Carolina Attorney General took the FDA's Warning Letter to Janssen as an invitation for the state to exert its regulatory power, and he capitalized at trial on DDMAC's formulaic assertion that Janssen's letter was "false or misleading." A warning letter, however, is not an FDA finding. Generally, it is what its name denotes, a warning, which FDA conveys "to achieve correction" voluntarily. FDA, Guidance Documents for FDA-Regulated Products, at 4-1-1. It is usually the opening shot that commences FDA's negotiations with regulated companies, not the definitive determination that ends the discussions. In amplifying the impact of warning letters by orders of magnitude, South Carolina and other states impair their cooperative function.

If acquiescing in a warning letter risks nine-figure verdicts in state court, as occurred here, companies will not negotiate with FDA. They will contest the letters, vigorously. From 1995 to 2007, FDA issued 8,962 warning letters. Just since 2010, and with regard only to advertising and promotion of pharmaceutical products, the agency issued more than 150 warning letters or similar admonitions. It would not take many nine-figure verdicts obtained by the 50-plus attorneys-general to make the relationship between FDA and industry more adversarial, more costly, and less productive.

The mischief created by the South Carolina Supreme Court's decision goes beyond vandalizing FDA regulation. In issuing its Dear Doctor Letter in 2003, Janssen took a side in an ongoing and legitimate scientific debate about Risperdal and similar products. So long as Janssen's statements were not false and misleading, it had a First Amendment right to make them. DDMAC's and its successor's overuse of the term "false and misleading" in dealing with such communications is problematic in its own right. But allowing the stock phrase of a division or office in FDA to become a weapon in the hands of state attorneys-general across the country intensifies the chill on legitimate and truthful commercial and scientific speech. It compounds the infringement on First Amendment rights.

Janssen petitioned for certiorari, but the South Carolina Supreme Court had worked hard to "cert-proof" its decision. For example, the court found Janssen to have waived many claims because it had lodged a continuing objection on certain points at the outset of the trial rather than objecting each time the points came up. *Wilson*, 414 S.C. at 59-61. The trial court had taken no issue with this approach, and the plaintiff did not challenge it on appeal. However dubious the ruling, the prospect that a state-law procedural default might keep the US Supreme Court from reaching a federal issue if it took the case may have deterred the Court from granting review.

It is hornbook law that denials of certiorari are not precedential. See Eugene Gressman *et al.*, SUPREME COURT PRACTICE 345 (9th ed. 2008). The way the South Carolina Supreme Court insulated its case from review makes the denial of certiorari an even less reliable barometer of the US Supreme Court's view on the merits, or the likelihood that it will grant review if this type of activity continues. Given South Carolina's regrettable success in *Wilson*, pharmaceutical companies have likely not seen the last of this type of suit. The corrosive impact of cases like *Wilson* on FDA regulation, the pharmaceutical industry, and the First Amendment ultimately may lead the Court to grant review in a future suit.