that contention, ruling that FDA's decision to allow the sulfite warning was entitled to substantial deference.*

The Hatch–Waxman Amendments permit an ANDA to omit an indication or other aspect of labeling that is protected by a patent or by exclusivity. This subject is discussed in Three-Year Exclusivity for Product "Improvements."

A provision added to the FDC Act in 2010 prevents, in most situations, changes to the labeling of the innovator product within 60 days of the anticipated date of generic competition from blocking generic competition.† An ANDA sponsor can receive approval based on "old" labeling, based on a commitment to submit revised labeling within 60 days. This exception does not apply if the change is to the "Warnings" section of the innovator's product labeling or if FDA determines that the "old" labeling raises a safety issue. The FDA has used this authority on several occasions.‡

In 2011, the US Supreme Court effectively foreclosed most state law product liability "failure to warn" lawsuits against generic drug companies.§ The Supreme Court held that, because generic drug products must use the "same" labeling as the innovator products being copied, generic manufacturers have no ability to revise their labeling. The result is that state laws imposing a "duty to warn" are preempted because compliance with both federal law and state law is impossible. Legislative action in this area is possible.

Bioequivalency

As enacted in 1984, the Hatch–Waxman Amendments defined bioequivalency solely in terms of the rate and extent of absorption of the innovator and proposed generic products.¶ Nevertheless, on several occasions, the courts upheld FDA decisions to permit alternative means of establishing bioequivalence for nonsystemically absorbed drug products.** In 2003, the MMA amended the definition of bioequivalency to provide the FDA with express authority to determine scientifically valid assessments of bioequivalency for nonsystemically absorbed drug products.††

Other FDA decisions regarding bioequivalency have also been upheld by the courts. For example, in upholding FDA's decision to rely on an assay for the metabolite rather than the parent drug itself in assessing bioequivalency, one court concluded that the appropriate method to be used for determining bioequivalency is a matter of scientific judgment, squarely within FDA's discretion.‡‡ Another court

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* *Zeneca, Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000) (involving propofol).

† 21 USC § 355(j)(10) (added by Pub. L. No. 111-148).

‡ E.g., FDA November 26, 2010 approval letter to Ranbaxy Inc. for donepezil hydrochloride tablets. Available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/076786s000ltr.pdf. Accessed June 13, 2013.

§ *Pliva, Inc. v. Mensing*, 131 S. Ct. 2568 (2011).

¶ Former 21 USC § 355(j)(8) (amended by MMA).

** *Fisons Corporation v. Shalala*, 860 F. Supp. 859 (D.D.C. 1994) (involving cromolyn sodium for inhalation); *Bristol-Myers Squibb Company v. Shalala*, 923 F. Supp. 212 (D.D.C. 1996) (involving cholestyramine); *Schering Corp. v. Food and Drug Administration*, 51 F.3d 390 (3rd Cir. 1995) (involving inhalation and topical drug products).

†† 21 USC § 355(j)(8) (as amended by MMA).

‡‡ *Somerset Pharmaceuticals, Inc. v. Shalala*, 973 F. Supp. 443, 453 (D. Del. 1997) (involving selegiline).