How North Carolina's FDA Defense Will Differ From New Jersey's and Michigan's FDA Defense

Michigan and New Jersey law both contain FDA defenses. If enacted, the North Carolina defense would be more easily rebutted than the defenses in both of these states.

I. North Carolina Presumption

Bill Draft 2011-TG-14A would enact an FDA defense in product liability lawsuits. The defense could be "rebutted only by clear and convincing evidence." Bill Draft 2011-TG-14A, § 2.2. The defense would also not apply if a plaintiff proved that the manufacturer: (1) promoted the medicine for an off-label use that impacted the plaintiff; (2) disregarded an FDA order to withdraw the drug or an order that altered the drug's approval; (3) withheld or misrepresented relevant material information to the FDA; or (4) made an illegal payment to receive or maintain approval of the drug. *Id.* The bill also does not apply to False Claims Act lawsuits if they are not based on allegations of that the drug is not safe, is not effective, or has inadequate warnings.

II. New Jersey

New Jersey also provides a rebuttable presumption that FDA-approved warnings are adequate. New Jersey courts have interpreted this defense as being "virtually dispositive" in the absence of "deliberate" misconduct. *Perez v. Wyeth Labs.*, 161 N.J. 1, 25 (1999); *Rowe v. Hoffmann-La Roche Inc.*, 189 N.J. 615, 626 (2007) (same). Specifically, the New Jersey Appellate Division recently stated that the *only* way to overcome the defense is to prove either (1) deliberate concealment or nondisclosure of information to the FDA or (2) intentional, economically-driven manipulation of the FDA's post-market regulatory process. *See DeBoard v. Wyeth, Inc.*, 422 N.J. Super. 360, 362 (N.J. Super. Ct. App. Div. 2011) (affirming *Bailey v. Wyeth, Inc.*, 424 N.J. Super. 278 (N.J. Super Ct. Law Div. 2008)); *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 63 (N.J. Super. Ct. App. Div. 2008). Thus, New Jersey's defense can be overcome in more limited circumstances than would be possible with North Carolina's defense.

III. Michigan

Michigan's FDA defense states that a "manufacturer or seller is not liable . . . [if] the drug and its labeling were in compliance with the United States food and drug administration's approval." *Id.* § 600.2946(5). One court has described Michigan's defense as an "absolute defense" from allegations of fault in the "standards, testing, warning, instruction, marketing, selling, advertising, or labeling" of an FDA-approved and compliant product. *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1027 (W.D. Mich. 2008). The only exceptions are if the manufacturer or seller "[i]ntentionally withholds or misrepresents" information to the FDA concerning the drug, or if the manufacturer makes an illegal payment to a government employee to receive or maintain approval of the drug. *Id.* Michigan's defense is thus also more difficult to overcome than North Carolina's would be.