

NEJM, Drug Companies, and the FDA: The Conflict Underlying *Levine v. Wyeth*¹

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“Nothing new under the sun.”² Product manufacturers, drug companies, and even tug boat owners want to set their own standards when it comes to the products they make or the work they do. Additionally, they want those standards to protect them from tort liability. Even in the 1930’s, a tug boat company tried to argue that the custom of the industry at that time should protect them from liability. Most tug boats did not have radios on board to warn them of imminent storms.³ Thus, they argued, they would not be liable for barges that sunk in a storm since the custom or standard did not include having radios on board for warning purposes. However, Judge Learned Hand thought otherwise. He told the tug boat owners that when the risks of potential losses were high and the costs to prevent the harm were low, then the industry was not allowed to determine for themselves what was negligent.

Admittedly the world has changed, especially with regard to food and drugs. Instead of Judge Hand, the Food and Drug Administration (“FDA”) supposedly looks after the consumers and protects them from unsafe drugs.⁴ The FDA attempts to be the standard bearer in this particular industry. The promise by the FDA, however, has not been fulfilled because it has been captured by the very people they are assigned to regulate.⁵ Furthermore, the FDA does not have the manpower to thoroughly investigate the drugs or their potential adverse affects after the drug is marketed.⁶ Related to these two flaws in the regulatory system, the New England Journal of Medicine (“NEJM”) has written a laudable amicus Supreme Court brief in support of plaintiff, Diana Levine, who was seriously harmed by a drug approved by the FDA.⁷ NEJM’s brief largely focuses on the policy reasons why the petitioner Wyeth’s claims are not based in fact.⁸ This editorial is related only to the NEJM’s counter-policy arguments.

As the NEJM’s brief illustrates, what happened to Ms. Levine, a musician living in Vermont, is exactly why the FDA’s rules and regulations should not be the accepted standard. Briefly, Ms. Levine went to a health center because she had a migraine headache and was nauseous.⁹ The health care center administered Phenergan by an intro-muscular injection.¹⁰ The nausea continued which prompted the staff to give her a second intravenous injection using what is called an “IV push.” The second injection hit an artery.¹¹ The drug instructions clearly said that the drip system was the preferred way to give the drug.¹² Additionally, Wyeth, the drug manufacturer, had sent the FDA new warnings stemming from reports which emphasized that inadvertent intra-arterial

injections led to gangrene.¹³ The FDA did nothing about the new warnings and Wyeth did nothing about it either even though they were fully aware of the danger associated with it.¹⁴ As a result of the injections, Ms. Levine's arm became infected with gangrene and had to be amputated.¹⁵ Ms. Levine settled with the Health Care Center and sued Wyeth.¹⁶ A Vermont jury found for Ms. Levine.¹⁷ Wyeth appealed to the Supreme Court of Vermont which affirmed the jury's decision.¹⁸ Wyeth then appealed to the United States Supreme Court arguing that despite the fact that the drug company did nothing after telling the FDA about the potential hazards, that the original FDA approved warning gave them immunity because complying with FDA requirements pre-empts any state tort law and therefore they were shielded from tort liability.¹⁹

The main counter points NEJM makes in its brief are laudable because they unravel every policy argument that Wyeth attempts to use. For instance, according to Wyeth, the FDA creates the standard and that standard reflects the health and safety needs of the American public. Since the drug company was in compliance with the standard, according to Wyeth, they should be immune from tort liability law suits. NEJM correctly argued that the FDA largely relies upon drug companies through self-reporting to warn them about dangerous effects of the drugs after marketing. However, the drug companies are slow to report.²⁰

The NEJM clearly demonstrates that the FDA's past history of monitoring drugs is marred with failures. Their brief gives examples of those failures by explaining what happened with regard to Redux/Pondimin, Vioxx, and Trasyolol drugs.²¹ One cause of the FDA's failure is that the drug companies fail to inform the FDA in a timely fashion.²² For instance, Merck knew as far back as 1997 that Vioxx "resulted in systemic reduction of a critical component to the human body's defense mechanism against heart attacks."²³ It was not until 2002 that the FDA finally insisted that Merck issue a precaution.²⁴ And to further exacerbate the problem, it was not until 2004 that Merck finally withdrew the drug from the market.²⁵ NEJM's amicus brief shows the same striking pattern for the other drugs.

Wyeth also clings to the idea that over-warning about drugs hazards will scare sick people away from taking the drug. However, NEJM correctly observes that no empirical data exists which demonstrates this hypothesis and in the meantime, the public's health is jeopardized.²⁶ The drug companies are essentially playing doctor by making decisions for and on the behalf of patients.

None of the policy arguments, as the NEJM correctly notes, satisfy the scrutiny requirements. The antidote is a "robust" state tort system.²⁷ Since many drug problems come to light only after the drug is marketed²⁸ and the FDA cannot compel drug companies to reveal internal documents that track reports made by doctors and users regarding side effects, torts suits are an effective remedy.²⁹ During these suits, state courts can provide the stop gap via the discovery process or a court subpoena.³⁰ What is hidden from the FDA comes to light during this important stage of the trial. Further, potential high tort damages provide an incentive to ensure that drug companies warn the public.³¹ As the FDA's budget decreases, so does needed oversight and

investigation. The tort liability system gives the FDA a powerful tool in which to poke the drug companies into warning the consumers.³² Finally, the FDA has no independent power to make those who have been seriously harmed whole.³³ Hurrah for the independence of the NEJM for making a case for the consuming public.

Acknowledgements

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¹ See generally *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006); Brief for New England Journal of Medicine Editors and Authors as Amici Curiae Supporting Respondents, *Wyeth v. Levine*, No. 06-1249 (U.S. filed August 14, 2008) (Hereinafter Brief for New England Journal of Medicine Editors and Authors); Brief for the United States as Amicus Curiae Supporting Petitioner, *Wyeth v. Levine*, No. 06-1249 (U.S. filed June 2008) (Hereinafter Brief for the United States).

² The quotation is "...adapted from the Book of Ecclesiastes; the author complains frequently in the book about the monotony of life." E. D. HIRSCH, JR. ET AL., *THE NEW DICTIONARY OF CULTURAL LITERACY* (3d ed. 2002), available at <http://www.bartleby.com/59/1/nothingnewun.html> (last visited October 29, 2008).

³ *The T.J.Hooper*, 60 F.2d 737 (2nd Cir. 1932).

⁴ The Food and Drug Administration: An Overview (Jan. 11, 1999), <http://www.cfsan.fda.gov/fdaoview.html> (last visited October 29, 2008).

⁵ Vale Krenik, "No One Can Serve Two Masters": A Separation of Powers Solution for Conflicts of Interest Within The Department of Health and Human Services, 12 TEX. WESLEYAN L. REV. 585, 620 (2006). See MARCIA ANGELL, M.D., *THE TRUTH ABOUT THE DRUG COMPANIES* 211–12 (2004). Dr. Angell was the NEJM's Executive Editor between 1988 and 1999 and its Editor-In-Chief between 1999 and 2000.

⁶ U.S. GOV'T ACCOUNTABILITY OFFICE, TESTIMONY, FED. OVERSIGHT OF FOOD SAFETY: FDA'S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL 2 (2008), available at <http://www.gao.gov/new.items/d08435t.pdf> (last visited October 29, 2008); U.S. GOV'T ACCOUNTABILITY OFFICE, TESTIMONY, FED. OVERSIGHT OF FOOD SAFETY: FDA HAS PROVIDED FEW DETAILS ON THE RESOURCES AND STRATEGIES NEEDED TO IMPLEMENT ITS FOOD PROTECTION PLAN 2–3 (2008), available at <http://www.gao.gov/new.items/d08909t.pdf> (last visited October 29, 2008).

⁷ See generally Brief for New England Journal of Medicine Editors and Authors, *supra* note 1.

⁸ See generally *Id.*

⁹ *Levine v. Wyeth*, 944 A.2d 178, 182 (Vt. 2006).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.* at 185.

¹⁴ *Id.*

¹⁵ *Id.* at 182.

¹⁶ *Id.*

¹⁷ *Id.* at 182.

¹⁸ *Id.* at 196.

¹⁹ Brief for the United States, *supra* note 1, at 7.

²⁰ *Id.*

²¹ Brief of New England Journal of Medicine Editors and Authors, *supra* note 1, at 12–30.

²² *Id.* at 12.

²³ *Id.* at 19 n.26.

²⁴ *Id.* at 20.

²⁵ *Id.* at 23.

²⁶ *Id.* at 5.

²⁷ See *id.* at 38.

²⁸ *Id.* at 38–39.

²⁹ *Id.* at 39.
³⁰ *Id.* at 39.
³¹ *Id.* at 39.
³² *Id.* at 40.
³³ *Id.* at 41.