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Richard Merrill

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## FDA REGULATORY REQUIREMENTS AS TORT STANDARDS

*Richard Merrill\**

### INTRODUCTION

There are essentially two contexts in which laws encounter agency-produced and agency-analyzed science. One is in the context of reviewing regulatory decisions—a context governed at the federal level by the Administrative Procedure Act, at the state level by state administrative procedure acts, and sometimes by specific statutes that authorize domestic regulatory activity. Appellate judges may encounter, and federal judges surely do encounter, cases in which a party is petitioning for direct review of an agency science-based decision. Trial judges however, are much more likely to encounter agency-assessed science in a second context—private litigation in which the work of a regulatory body is claimed to be either irrelevant, or highly pertinent, to the disposition of the case. Therefore, this paper will focus on regulation of products that often give rise to claims for civil liability.

In confronting such claims, judges and juries address many complicated scientific questions bearing on whether a product is capable of causing the kind of harm that the plaintiff experienced and whether the use of or exposure to the product caused the harm that the particular plaintiff is suffering from.

Beyond causation, there are also questions about whether the manufacturer or discharger of the product took the precautions that were necessary to minimize or reduce the risk associated with its

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\* A.B., M.A., LL.B.; Daniel Caplain Professor of Law at the University of Virginia School of Law.

production or use. This is the question of breach of duty. This inquiry has two dimensions—what precautions were in fact taken, and what precautions did the responsible regulatory agency require to be taken to minimize the risks. These questions—involving knowledge about risk and measures taken to avoid risk—are as important as the questions about causation.

Most of the products that give rise to tort claims in today's America are at least *potentially* regulable by some federal agency, sometimes by both a federal and counterpart state regulatory agency. But these targets of litigation are not all subject to the same level or type of regulation, as can be seen with both the Food & Drug Administration (FDA) and Environmental Protection Agency (EPA).<sup>1</sup> These two agencies are possibly the most important public health regulatory agencies operating in Washington. The FDA has been in business for ninety-eight years.<sup>2</sup> The EPA's experience is much briefer but it is surely the most science-dependent regulatory agency in Washington. Most of the products or pollutants that give rise to civil claims today fall within the jurisdiction of one of these two agencies.

My immediate aims are quite modest. I hope, first, to get you to think about how the duty that the civil justice system might impose upon product manufacturers or pollutant dischargers should be looked at in light of the regulatory requirements the manufacturer or the discharger was subject to. Second, I want to demonstrate that regulatory systems are not all the same in their expectation for care-taking.

The horn book law in this area of civil liability is straightforward. We all remember it from our torts class. Violation of a regulatory standard is negligence (or some form of "fault") *per se* in almost every jurisdiction in the United States.<sup>3</sup> If the

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<sup>1</sup> See Michael A. Friedman, M.D., *What Is the Value of an FDA Approval in a Judicial Matter?*, 12 J.L. & POL'Y 559 (2004); Robert S. Sussman, *Science and EPA Decision-Making*, 12 J.L. & POL'Y 573 (2004).

<sup>2</sup> 21 U.S.C. §§ 1-3 (2003). The FDA was empowered by the Food and Drugs Act of 1906, which was supplanted by the Federal Food, Drug and Cosmetics Act of 1938.

<sup>3</sup> AARON D. TWERSKI, JAMES A. HENDERSON, *TORTS: CASES AND MATERIALS* (Aspen Law & Business 2003).

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defendant failed to take precautions that a regulatory agency required, this will usually end the inquiry into whether the defendant fulfilled its civil law responsibility. There is a counterpart proposition of narrower reach, namely that compliance with regulatory requirements is admissible as evidence of due care, but it is not conclusive.<sup>4</sup> These companion propositions assume, and many cases say, that regulatory standards are minimum standards, i.e., the least that the legal system is entitled to expect, but not necessarily all that the legal system is entitled to expect.

Roughly a decade ago the American Law Institute (ALI) undertook a study of product and process injuries.<sup>5</sup> This was not a “Restatement” exercise, but the resulting report purported to be a synthesis and critique of legal developments in an arena now come to be known as product liability or toxic torts. The project was headed by some of the ablest scholars now working in the United States, including Robert Rabin of Stanford Law School, and Richard Stewart, now of New York University.<sup>6</sup> The report they produced for the ALI suggested that in some circumstances, most pertinently in suits involving FDA-approved prescription drugs, regulatory requirements should be understood as the authoritative assessment of the benefits and risks of a product and express the legal system agency’s authoritative judgment about how best to minimize those risks. If the agency had access to all of the evidence about the product’s risks that was later available in a lawsuit, a holding that the manufacturer should have taken additional precautions would create conflict between the common law tort system, on the one hand, and the regulatory system that Congress has established for guarding against and minimizing product and process injuries.<sup>7</sup>

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<sup>4</sup> *Id.*

<sup>5</sup> AM. LAW INST., REPORTERS’ STUDY ON ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY (1991) (the Project on Compensation and Liability for Product and Process Injuries, later renamed the Project on Enterprise Responsibility for Personal Injury).

<sup>6</sup> *Id.* See also Robert Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L. J. 2049 (2000); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L. J. 2167 (2000).

<sup>7</sup> AM. LAW INST., *supra* note 5.

The immediate question is: Do those observations have any relevance in the context of the work that FDA does today?

The FDA administers one basic statute: the Federal Food, Drug and Cosmetic Act, enacted in 1938.<sup>8</sup> It has been amended numerous times since then to expand the regulatory expectations for products under FDA's aegis, but these amendments have not fundamentally changed the scope of the agency's regulatory responsibilities. Those responsibilities are framed by five product categories for which the regulatory system has very different kinds of expectations.

The five product categories are cosmetics, food, therapeutic drugs, medical devices, and, finally, dietary supplements, a fifth category created by statute in 1994.<sup>9</sup> These five categories encompass many of the products that give rise to civil lawsuits in the United States today. Drugs and medical devices lead the list. We do not have many tort claims challenging the safety of food substances and relatively few involving the safety of cosmetics.

The descriptions that follow are general. They do not take account of the possibility that in a particular case the basic requirements I have ascribed to FDA may not have been omitted or might have been added to.

### *1. Cosmetics*

In regulating cosmetics, the agency functions like a highway patrolman. Its inspectors look out for products that are dangerous to health, about which it can, like a highway patrol man, do something. That something is to initiate administrative or judicial enforcement action on the premise that the product is not as safe as the law expects it to be, or that the product is not labeled as the law expects it to be labeled.<sup>10</sup>

In a nutshell, what the law says to a cosmetics manufacturer is: "Don't injure and don't mislead buyers of your products." The law

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<sup>8</sup> 21 U.S.C. §§ 1-3 (1938).

<sup>9</sup> 21 U.S.C. § 301 (1997).

<sup>10</sup> PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD & DRUG LAW: CASES & MATERIALS* (2d ed. 1991).

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FDA administers imposes no obligation on cosmetic manufacturers to do any testing of the products. Of course, manufacturers routinely do testing, but that is not because FDA demands it. Nor does the law give FDA any authority to evaluate the results of the manufacturer's testing before the product goes on the market. FDA regulation of cosmetics is entirely *ex post*.

*2. Food*

With an important exception, each of the foregoing statements about FDA's regulation of cosmetics describes its regulation of food. A seller of food may put it on the market, after whatever testing it believes it prudent to do, without ever contacting FDA. The law says that food can not harm consumers and FDA may take measures after the fact to curtail the marketing of food that it believes harmful. FDA's labeling requirements for food are more elaborate than for cosmetics, but they too can be summarized as saying: "Don't mislead and don't lie about the composition or utility of your product."

Again, in regulating foods substances, FDA functions like a highway patrol officer. The agency devoted substantial resources to this activity. Hundreds of FDA inspectors are engaged in investigating food establishments. They occasionally visit grocery stores. They follow up reports of food poisoning and the like. But FDA does not have authority to require pre-market approval for food products.

The notable exception is for new food ingredients, which under the law are defined as "food additives." Imagine someone who hopes to develop and market a new non-nutritive sweetener—something lower in calories than sugar, perhaps with other useful traits. The FDEC Act requires that the developer of this sweetener go to FDA and secure agency approval of its safety.<sup>11</sup> Utility is left to the marketplace, but safety is the FDA's judgment. It is a judgment made in advance of the introduction of any new food ingredient.

However, for reasons that will be obvious on a moment's

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<sup>11</sup> 21 U.S.C. § 349 (2003).

reflection, the FDA's safety judgment will not ordinarily be based on human evidence. It is generally considered unethical to conduct experiments of a new chemical in human subjects unless the chemical offers some therapeutic benefit. Thus, while we do test drugs in human subjects we do not test food additives in human beings before they enter the marketplace.

The law requires the sweetener inventor to conduct elaborate long-term animal feeding experiments designed to explore possible ways in which the substance might be harmful to human beings.<sup>12</sup> The FDA may then restrict the level or frequency of its use, extrapolating from the results in laboratory animals.

### 3. *Therapeutic Drugs*

My third category is therapeutic drugs. The law's requirements for drugs are quite different than those for cosmetics and food—and the differences should matter to judges.

All new drugs require FDA approval for safety *and* effectiveness before they may be marketed. Since all drugs have side effects—some rare, some mild, some frequent—that need to be guarded against, a central feature of FDA approval is the label, with its instructions and warnings, that the agency prescribes at the time that it approves the product.

When FDA approves a new drug for marketing, it is making a judgment about relative benefit and risk, and it mandates the instructions—conventionally directed to the physician, not to the patient—about measures necessary to minimize risks and maximize benefits. The agency's approval of a drug represents a judgment that the product, when used in accordance with the label instructions, is reasonably safe, taking into account its medical benefit.

In contrast with its approval of a food additive, FDA approval of a drug is based on randomized clinical trials in human beings. Such trials may extend over months or even years. Perhaps as many as 5,000, possibly even 10,000, patients will have been exposed to the drug and their experience analyzed before the FDA

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<sup>12</sup> *Id.*

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is prepared to judge the drug safe and effective. The results of these clinical studies are carefully reviewed by the agency, and their design and conduct are often reviewed in advance.<sup>13</sup>

FDA can revise the terms of its initial approval of a drug by requiring changes in the labeling or, less often, in the composition of the product. Manufacturers must submit to FDA information that they receive about experience with the drug that suggests the risks are greater or different than originally anticipated. The legal duty to report adverse events applies only to manufacturers, but information about post-approval experience also comes to the FDA from physicians, health care providers, and not infrequently from public health authorities in other countries. In short, FDA regulation of drugs involves a kind of ongoing oversight that is not true of cosmetics or foods, or even food additives.

Over-the-counter (OTC) drugs could be thought of as a special case. However, most of the non-prescriptions drugs that have been introduced in the last fifteen years first came onto the market through the FDA approval process for prescription drugs.<sup>14</sup>

#### *4. Medical Devices*

Medical devices, which give rise to civil claims with some frequency, are subject to a different set of regulating requirements than applies to drugs. The FDEC Act's requirements for devices were dramatically expanded in 1976.<sup>15</sup> The differences between the requirements for devices and these for drugs potentially have implications for the civil liability system.

There are two pathways by which a new medical device can come onto the marketplace. One looks very much like the process by which a new prescription drug gains FDA approval. Approval requires a finding that the device is safe and effective—or, more accurately, provides benefits that outweigh its risks. FDA approval is based on the results of clinical trials in randomized human subjects, whose data are submitted to, and closely evaluated by,

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<sup>13</sup> See Friedman, *supra* note 1.

<sup>14</sup> HUTT & MERRILL, *supra* note 10.

<sup>15</sup> 21 U.S.C. § 321(h) (2003).



FDA. For example, a new implant of almost any sort is likely to have gone through this premarket approval (PMA) process.

But the law requires another pathway to the market for devices that represent modest advances on the existing technology. For such devices the law affords a less rigorous path to the market, known as the 510K or pre-market notification process. To follow this pathway the maker must give the FDA advance notice of its plan to market the product and demonstrate, not that the product is safe and effective based on clinical studies, but that it is “substantially equivalent” to an existing device. This is a significantly less rigorous burden than required by the PMA process.

Several years ago, in *Medtronic, Inc. v. Lohr*, Justice Stevens provided a lucid description of these two statutory pathways and emphasized how they differ with respect to the question of whether compliance with FDA’s requirements should afford a defense to tort liability.<sup>16</sup> The *Medtronic* case arose because the medical device law, uniquely, contains a feature of special relevance to our inquiry: Congress included a pre-emption provision in 1976 device amendments.<sup>17</sup> The provision states that no state may impose requirements that are different from or in addition to the requirements FDA has imposed to assure the safety of a device.<sup>18</sup> The possibility that a tort verdict could be viewed as a “requirement” that adds to FDA requirements has been the focus of several dozen cases, mainly in the federal courts.<sup>19</sup> Because most medical devices have entered the market through the 510k “substantially equivalent” pathway, they have received less scrutiny from FDA than most therapeutic drugs.

### 5. Dietary Supplements

Dietary supplements are products that appeal to consumers who desire their promised physical effects, but typically avoid

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<sup>16</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>17</sup> *Id.* at 470; 21 U.S.C. § 360k(a) (2003).

<sup>18</sup> 21 U.S.C. § 360k(a).

<sup>19</sup> *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001).

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overt claims about their health benefits. They are not promoted as medicines. In 1994 Congress, for only the second time in the agency's history, amended the law to *relax* FDA's regulatory oversight category of products, which it called "dietary supplements."<sup>20</sup>

As a result of this legislation FDA has no authority to require evidence of safety for any dietary supplement. Whatever testing of these products is done, is done voluntarily by the manufacturer. Like manufacturers of cosmetics and ordinary foods, the maker of a dietary supplement cannot lie about the product. The FDA must be notified if the manufacturer intends to market a dietary ingredient that has never before been used in the United States. However, this is simply a mechanism for alerting the agency so it can invoke its *ex post* authority to punish misleading labeling or harmful products. It does not provide FDA an opportunity to exert *ex ante* controls.

## CONCLUSION

The primary message of this short essay is easily summarized. In deciding what, if any, weight to accord, in a tort suit, evidence that a product manufacturer has complied with a regulatory agency's safety requirements for the product, a judge should understand precisely what the agency has required and why. This is sound advice in general and especially important in the context of suits to recover for injuries caused by products regulated by FDA. FDA-regulated products account for roughly one quarter of the consumer economy, but they are subject to very different types and levels of safety regulation. Some products—notably therapeutic drugs—are carefully assessed for safety before they are marketed and must comply with detailed requirements for design, manufacture, labeling, and marketing, which reflect FDA's considered judgment about what precautions are appropriate and consistent with the health benefits they provide. And drug

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<sup>20</sup> The drug combination Phen-fen is not a "dietary supplement." It may be promoted for its effects related to diet, e.g., as a weight-reducing agent, but it was marketed with claims that made it, under the law, a drug. Phen-fen therefore required the kind of FDA approval used for drugs.

manufacturers are under a continuing duty to share with FDA all of the information they learn about the effects of their products in use.

The case for allowing tort recovery—and for imposing an additional level of deterrence—is much stronger for cosmetics and most foods, which are not required to undergo premarket review for safety and thus carry no implication that FDA has assessed and attempted to control their risks. Dietary supplements are similarly subject only to *ex post* regulation for safety. The regulatory scheme for medical devices is more complicated and a judge should be attentive to the different levels of safety review required for new devices and for variations of familiar devices.

FDA-regulated products are frequently the target of liability suits because they are universally consumed and because many medical products have the capacity to injure as well as the ability to cure or prevent injury. The latter are subject to unusual levels of regulatory control, a reality that should elicit careful and informed judicial assessment.