Pharmaceutical Manufacturing

Excluding Regulatory Violations from Defect Cases

By Matthew Moriarty and Michael J. Ruttinger

If an "adulteration-equals-defect" argument reaches a jury's ears, it may cause confusion and prompt the jury or judge to apply the wrong standard.

Bargain shoppers could teach attorneys a great deal about what matters and what doesn't in pharmaceutical product liability law. These consumers who delight in the low prices of the dented and scratched "clearance" bins of their favorite stores understand the simple principle that not everything that goes "wrong" with a product makes that product dangerous. A toy with a misspelled label or a new shirt without a "cleaning instructions" tag may be a boon to a price-conscious consumer who understands that these products, despite manufacturing process mistakes, are nonetheless safe.

In mass production, mistakes are inevitable, whether from a problem with materials or the assembly process. Some finished products are bound to have "defects," some ways in which they failed to conform fully to all specifications. Such mistakes drain manufacturers economically, through waste, recalls, reputational harm and, of course, an occasional product liability lawsuit. For this reason, every industry establishes elaborate quality-control measures designed to minimize problems during the manufacturing process. Those measures usually prevent serious troubles. Sometimes, however, an equipment malfunction or lapse in a quality-control process leads to mere cosmetic problems that don't pose danger to consumers. And products that deviate cosmetically from quality standards populate the clearance bins of retail stores around the country.

But what would happen if, instead of "clearance," cast-off bins read "adulterated"? Here lies a major difference that sets the world of prescription drugs apart from the worlds of many other products. Pharmaceuticals, unlike other products, are regulated by an elaborate web of Food and Drug Administration (FDA) rules, regulations, guidances, and enforcement manuals. There aren't any scratch-and-dent bins for pharmaceutical products. The FDA prohibits manufacturers from selling drugs, even pharmaceutically perfect ones, unless they comply 100 percent with *every* relevant FDA regulation. If even a single, manufacturing process-related regulation

■ Matthew Moriarty is a partner and Michael J. Ruttinger is an associate in the Cleveland office of Tucker Ellis and West LLP. Mr. Moriarty is celebrating his 30th year as a practicing lawyer. He is board certified as a civil trial lawyer by the National Board of Trial Advocacy. Mr. Moriarty devotes the majority of his professional time to representing drug and device manufacturers in product liability cases and is a member of DRI. Mr. Ruttinger has practiced as part of the firm's appellate and legal issues group since 2009. His practice involves extensive motion practice advocacy on behalf of prescription drug and medical device manufacturers.

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unrelated to potency or stability is not satisfied, then the final product is deemed "adulterated" by statute, and a manufacturer cannot sell it.

Even though "adulterated" does not mean "defective," it is a loaded term in a lawsuit. It is bound to confuse anyone who hears it into thinking that a product with that designation had something substantively "wrong" with it in the sense that the final product deviated from its specifications. Unsurprisingly then, it has become a common trend in drug litigation for a plaintiff's attorney in a product liability case to use as evidence of a product defect official documents categorizing the product as adulterated. Yet as this article explains, evidence of adulteration is frequently irrelevant to a defect's existence; it certainly does not relieve a plaintiff of the burden to *prove* a defect existed. Defense attorneys should contest that line of thought and, when possible, keep evidence of adulteration where it belongs—strictly confined to the world of FDA regulations.

A Plaintiff's Burden of Proof in a Product Liability Case

It is a fundamental tenet of every product defect case that the plaintiff bears the burden of proving that a product was defective. How a plaintiff proves that a product was defective varies from jurisdiction to jurisdiction and may require direct evidence that a "specific defect" existed in the product, expert testimony that the product had a manufacturing defect, or circumstantial evidence that the product malfunctioned because of a manufacturing defect.

No matter how a plaintiff's attorney goes about proving that a defect existed, one requirement remains the same—proof that *the* product purchased or used by the plaintiff did not perform in the manner it was supposed to. For example, with products other than pharmaceuticals, a plaintiff may have direct evidence of a defect, such as measurements or photos related to a product's strength, size, or incorrect assembly. In other cases, if a plaintiff's attorney lacks direct evidence, he or she can establish his or her client's case by showing that an injury occurred while the client used the product in its ordinary and intended manner. As one author described the inference arising from malfunction,

> Under the Restatement Third, there is an inference that the plaintiff's harm was caused by a product defect, without proof of a specific defect, if the accident was of the type normally to be caused by a product defect and the accident was not solely the result of other causes. The plaintiff must eliminate potential causes for the accident other than the product defect.

Vicki Lawrence MacDougall, *The Impact of the Restatement (Third), Torts: Products Liability (1998) on Product Liability Law*, 62 Consumer Fin. L.Q. Rep. 105, 110 (2008). Often inferring is easy. For example, if a step stool collapses under ordinary use, a jury may infer that something was wrong with its construction. In similar cases, the common thread is that a reasonable juror can arrive at a strong inference that the plaintiff would not have been harmed unless a defect existed. But defense attorneys need to evaluate the strength of inferences that (1) harm means malfunction, and (2) malfunction means defective.

Drawing inferences about prescription drugs is different from drawing inferences about other types of products. While a plaintiff can have direct evidence of a defect from measurements or chemical testing, the concept of malfunction does not usually apply to prescription drugs for several reasons. Consumers may have idiosyncratic reactions to a medicine. For example, slight changes in a patient's condition can increase the risk of adverse reactions, especially to a drug that has a "narrow therapeutic range," meaning that the margin between a therapeutic and toxic dose for a drug is small. Moreover, a patient can have an adverse reaction when the patient takes two or more drugs that interact with one another. Adverse reactions will inevitably occur, too, in some percentage of patients even if a drug itself is pharmaceutically perfect and meets all specifications. Consequently, a jury cannot infer that a pharmaceutical manufacturing defect existed from the fact that taking a drug had a harmful consequence. Basically, harm does not mean malfunction with a prescription drug. A plaintiff's attorney who intends to prove that a defect existed in a drug with circumstantial evidence must look beyond the mere fact of injury. This is where official FDA allegations of adulterated products become important.

Understanding the Regulatory Landscape

Special problems arise when a plaintiff's attorney tries to introduce evidence that a drug has been found adulterated as circumstantial evidence that it was defective. Adulteration is a loaded term and carries a specific regulatory meaning that is different from its lay meaning. *See U.S. v. 17 Bottles, Large Size, and 65 Bottles, Small Size, of an Article of Drugs*, 55 F.2d 264, 265 (D. Md. 1932) ("It is, of course, clear enough that in the construction of language… the meaning given to the language is that ordinarily conveyed by it to purchasers. But the term 'adulterated' is given a special definition by the act, title 21, U.S. Code, Sec. 8.") (internal citations removed). For this reason, a defense attorney must be prepared to delve into the regulatory context anytime a plaintiff's attorney seeks to introduce evidence of adulteration to attempt to confuse jurors, prejudice a defendant, and obfuscate the real issue of whether a drug as used by the plaintiff was defective. Understanding how the FDA regulates the drug manufacturing process is essential for a defense counsel placed in this position.

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The primary mechanism through which the FDA regulates the drug manufacturing process is set forth in 21 C.F.R. §210 and §211, which constitute the current "good manufacturing practice" (cGMP) regulations applied to pharmaceuticals. The cGMP regulations impose a wide variety of requirements, regulating everything from personnel qualifications, 21 C.F.R. §211.25, to labeling operations, 21 C.F.R. §211.130, to laboratory testing for release and distribution, 21 C.F.R. §211.165. As one court has explained, cGMP provisions are "prophylactic measures" designed "to *prevent* the

distribution of poorly manufactured drugs and devices 'by giving the Food and Drug Administration… additional authority to require that sound methods, facilities, and controls be used in all phases of drug manufacturing and distribution." *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D. P.R. 1992). Simply, "the cGMP regulations are intended to be preventive." *Id.*

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Similar to other FDA-enforced preventive regulations, cGMP regulations are policed through regulatory action only and not through civil lawsuits. *See* 21 C.F.R. §210.1(b) ("[S]uch drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action."). That is, only the FDA can punish a manufacturer for violating a cGMP provision; a consumer does not have a private right of action through which he or she can sue a manufacturer for violating a cGMP regulation or any provision of the Food, Drug and Cosmetic Act. *See*, *e.g.*, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005). For this reason, unsurprisingly, plaintiffs' attorneys have turned to more creative and unorthodox means—such as offering evidence of adulteration—to advance alleged regulatory violations as evidence to juries in trials.

What Adulterated Product Means

In common usage, the word adulterated has a generally understood and accepted meaning. To laymen, a product is adulterated when it contains one or more corrupt, harmful substances. Legally, courts have defined adulterated similarly to mean "to corrupt, debase, or make impure by the additional of a foreign or baser substance." *See*, *e.g.*, *Nutritional Health Alliance v. Food and Drug Administration*, 318 F.3d 92, 99 (2nd Cir. 2003) (citing Webster's Third New International Dictionary of the English Language (14th ed. 1963)); *see also United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 89 (1964) ("The separate offense of adulteration… is concerned solely with deterioration or contamination of the commodity itself."). So it is not surprising that the hypothetical bargain shopper mentioned above would steer clear of a bin holding items marked "adulterated." This is the everyday perspective that a juror probably brings to a product liability case involving drugs.

Defense attorneys must educate jurors that under the Food Drug and Cosmetic Act (FDCA) the word adulterated has a different meaning. Under the act, a drug "shall be deemed to be adulterated" regardless of the regulation violated during the manufacturing process, whether manufacturing, packing, or holding related, or regardless of the quality of the end product:

> A drug or device shall be deemed to be adulterated…. if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administrated in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

21 U.S.C. §351(a)(2)(B). In short, the FDCA regulates the *entire* manufacturing *process*, not just the end product, and so whether a drug is adulterated depends on how it was made and not how it turns out. Consequently, to determine *in what way* a drug is adulterated, and whether the "manufacturing problem" could harm a consumer, an attorney needs to dig deeper and investigate what the cGMP provision at issue required. Only in rare cases in which the cGMP regulation bears directly on the quality of the final product should adulteration evidence reach a jury.

How a Drug Becomes Adulterated

Because cGMP regulations are preventive measures only, a final product could be safe, effective, and meet all content specifications but still earn the moniker "adulterated" because of some manufacturing-process-related violation. In fact, this counterintuitive result is probably fairly common because of the sheer scale of the pharmaceutical manufacturing industry and the omnipresence of cGMP regulations.

The cGMP regulations pertaining to manufacturing facilities offer an excellent example of how the FDA could find an otherwise safe drug "adulterated" even though nothing is wrong with the product in a conventional sense. Under 21 C.F.R. §211, subpart C, an FDA inspector could charge a manufacturer with a cGMP violation for having inadequate lighting in its facilities. *See* 21 C.F.R. §211.44 ("Adequate lighting shall be provided in all areas.") A cGMP violation could even occur if bathrooms in a manufacturing facility lack cold water. 21 C.F.R. §211.52 ("Adequate washing facilities shall be provided, *including hot and cold water.*…") (emphasis added). Both of these provisions are important preventative measures; sanitary facilities and bright lighting make it easier for employees to keep a manufacturing area clean. But a client certainly may produce a pharmaceutically perfect drug under less than these perfect conditions. Logically, the fact that a drug is considered adulterated because the manufacturing facility bathrooms lacked cold water does not mean that anything is wrong with the drug itself.

The cGMP provisions applicable to product labeling offer an even more compelling example. A drug maker could manufacture, seal, and package a pharmaceutically perfect drug yet the FDA could *still* render it adulterated because the labeling process did not comply with a cGMP regulation. For example, if a manufacturer applied the labeling on the drug bottle upside-down, the FDA would identify the drug as adulterated. *See* 21 C.F.R. §211.125 ("Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records.") Under these circumstances the drug would only have a cosmetic problem, yet the FDA nevertheless

would call that drug "adulterated" under 21 U.S.C. §351(a)(2)(B).

The Regulatory Paper Trail

A jury may not be impressed by cGMP violations; it may grasp that an accusation that a defendant manufactured its products in an inadequately lit facility says nothing about whether that drug was defective. But jurors are far more likely to be swayed by official FDA documents that say that the same drug was "adulterated" because it violated FDA regulations. And as with all government agencies, the FDA leaves a broad paper trail wherever it regulates. A diligent plaintiff's attorney will nearly always find *some* official statement that a manufacturer produced an adulterated product based on a violation of one cGMP provision or another, either for the specific product at issue, or another product that uses a general manufacturing or quality assurance process applicable to many of the defendant's products. To an FDA official this is only an allegation of some process-related violation that says nothing about the final product. But to a juror, an official letter from the FDA informing a manufacturer that its product was adulterated may have the appearance of something more, perhaps even compelling evidence of a product defect. At a minimum, a plaintiff's attorney may use several such official allegations pertaining to different regulations to show that a defendant has been sloppy in many general areas, hoping that a jury will infer that one specific product had a defect. If a defense attorney hopes to correct this misconception, he or she must understand the types of documents that the FDA generates detailing adulteration that an opponent may cite as evidence of a defect.

One of the first documents generated during an FDA investigation is an "Establishment Inspection Report," commonly referred to as an "EIR." These are "narrative reports stating what occurred and what was undertaken during an FDA inspection." *United States v. John D. Copanos & Sons, Inc.*, 831 F.2d 466, 468 (4th Cir. 1987). An EIR not only describes what the FDA agent inspected, but also what the inspector observed in terms of compliance or failure to comply with FDA cGMP regulations.

A "Form 483" is the first formal notice that a manufacturer receives from the FDA regarding an alleged cGMP regulation violation. The form is a "Notice of Inspectional Observations," issued by an FDA field investigator, and it contains a list of any deviations from the cGMP regulations observed by the investigator. Paul W. Goebel, Matthew D. Whalen, & Felix Khin-Maung-Gyi, *What A Form 483 Really Means*, Applied Clinical Trials Online, Sept. 1, 2001, http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/US/What-a-Form-483-Really-Means/ArticleStandard/Article/detail/92055 (last visited May 17, 2011).

A Form 483 contains the *opinion* of the FDA investigator on the scene; it is not an official FDA position. *Id.* Rather, listing alleged cGMP regulation violations in the form is the way that the FDA begins a formal dialogue with the manufacturer's representative about ways to correct manufacturing process problems. *See In re Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795, 799 (7th Cir. 2003) ("After each inspection, the FDA first sends a Form 483 to the manufacturer which notes any deviations under the cGMP, then discusses the findings with the manufacturer's representative, and requests a plan for correcting the violations.").

A "warning letter" is more significant than a Form 483 in that it communicates the FDA agency position on alleged cGMP violations, as opposed to just the observations of an FDA field investigator. Nevertheless, a warning letter is an "informal and advisory" method by which the FDA "communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action." Regulatory Procedures Manual (Mar. 2010) at 4-2, available at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf (last visited May 17, 2011).

The FDA issues warning letters "only for violations of regulatory significance," but they are *not* final agency actions. *Id.* Instead, the FDA's goal in sending a warning letter is to persuade the receiving manufacturer to voluntarily "correct violations of the statutes or regulations." *Id.*

Plaintiffs' attorneys enjoy lifting warning letters in particular from the regulatory context and placing them into the realm of tort liability. There, they hope to use these official documents as proof of product defects. But a warning letter "in no way identif[ies] a specific defect or dangerous condition" in a product used by an individual. *See King v. Danek Med., Inc.*, 37 S.W.3d 429, 442 (Tenn. Ct. App. 2000) (excluding the plaintiffs' documentary evidence, including multiple warning letters, as irrelevant to proving product defect); *Schwarz Pharma*, 2005 WL 6015068, at *1 (excluding evidence of FDA warning letters). These warning letters—which report only alleged cGMP regulation violations—amount to nothing more than a generic collection of regulatory claims that have nothing to do with manufacturing defects. *See Ilarraza v. Medtronic*, 677 F. Supp. 2d 582, 588 (citing *In re Medtronic*, 592 F.2d 1147, 1157 (D. Minn. 20009), as "referring to" cGMPs as "simply too generic, standing alone, to serve as the basis for plaintiff's manufacturing defect claims."). A warning letter—as an EIR and a Form 483 that precedes it—is not even a final agency action. *See* Regulatory Procedures Manual, *supra*, at 4-2; *see also Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 WL 3119279, at *11 (D. Wyo. July 26, 2010) ("Courts have consistently held, however, that the issuance of a warning letter by FDA does not constitute final agency action.").

"Adulteration" Is Not a Substitute for a "Defect"

Collectively, the paper trail produced by an FDA investigation frequently says nothing about—and is thus irrelevant to—whether a drug product has a defect. At most, the collection of reports, forms, and letters are circumstantial evidence that a drug was *adulterated*—that the process by which the drug was manufactured did not comply with every cGMP regulation. Defense counsel should object loud and long to a plaintiff's attorney's attempts to introduce evidence of adulteration as proof of a product defect.

Jurors, of course, do not understand that the term adulterated says nothing about the quality of a drug. To them, an adulterated drug does not meet its specifications because it is tainted with some other substance—an assumption that matches the dictionary definition of adulterated. If they hear during a trial that a drug was adulterated—for example, because the court admits FDA warning letters—jurors may

quickly leap to the conclusion that the final product did not meet its specifications. Plaintiffs' attorneys know this, and defense attorneys can count on them to use it to their advantage. After all, evidence that a product's manufacturing *process* did not meet specifications seems intuitively similar to evidence that the *product itself* did not meet specifications. Defense counsel should reject their efforts because an adulterated product is not necessarily defective and because allegations of adulteration are not relevant to product defect claims. Not only is this legally the case, but most plaintiffs' experts should admit that cGMP regulation violations do not automatically mean that drugs don't meet their specifications.

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In fact, plaintiffs' attorneys' attempts to equate adulteration with product defects represent something sinister—improper attempts to burden-shift. Plaintiffs' attorneys know that they bear the burden to prove that products have defects, and if they seek to make the case for adulteration, it is likely because they have weak proof to substantiate claims that products have defects. Unable to strengthen their own cases, they may seek to employ the language of 21 U.S.C. §351(a)(2)(B) against defendants. Specifically, because adulteration is statutorily defined as meaning that the FDA cannot "assure that such drug meets the requirements of this chapter as to safety," plaintiffs attorneys' may argue that it is *defendants*' responsibility to assure that their drugs are safe and free of manufacturing defects. This is a blatant, inappropriate attempt to manipulate their burden to prove that products have defects into a defense burden to *disprove* that defective products existed. Unfortunately, the authors have not found any case law discussing this issue.

Evidence That a Product Was Adulterated Cannot Support an Inference That a Product Was Defective

Nothing in the adulteration statute states that an adulterated drug is either outside of United States Pharmacopeia (USP) specifications or defective under state tort law. *See* 21 U.S.C. §351(a)(2)(B). Moreover, the FDA rejects attempts to equate official findings of adulteration with evidence of a manufacturing defect. The FDA has repeatedly explained that adulteration means only "that the drug was not manufactured under conditions that comply with cGMP," and "does not mean that there is necessarily something wrong with the drug." Food and Drug Administration, "Facts About Current Good Manufacturing Practices (cGMPs), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited May 17, 2011).

Federal courts, too, acknowledge that allegations of adulteration cannot establish that a product defect existed. *See*, *e.g.*, *Krueger v. Johnson & Johnson Prof'l, Inc.*, No. 4:00-cv-10032, 2002 WL 34371190, at *5 (S.D. Iowa Sept. 10, 2002) ("[T]estimony [of failure to comply with FDA regulations] does not prove that the… device implanted in Krueger was defective, or that it was a proximate cause of his injuries."); *Gellman v. United States*, 159 F.2d 881, 882 (finding that an entire shipment of medical devices was "adulterated," although "a much larger percentage of the shipment" was not defective). In fact, several courts have held that cGMP violations are not even a sufficient basis upon which to state a claim for a manufacturing defect. *See*, *e.g.*, *Myers-Armstrong v. Actavis Totowa LLC*, No. C 08-04741 WHA, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009), *aff'd*, 2010 WL 2232652 (9th Cir. June 3, 2010), No. 09-16055 ("That the [drug] was adulterated due to a lack of compliance with GMP requirements is not enough, without more, to state a claim."); *In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) (cGMPs are "too generic, standing alone, to serve as the basis for plaintiffs' manufacturing defect claims.").

Documents Containing Allegations of Adulterated Product Are Not Relevant to Product Defect Claims

Evidence that the FDA has considered a drug adulterated is, moreover, irrelevant to whether that same drug is flawed, dangerous, or defective. Courts have recognized that a drug may be "pharmaceutically perfect in content but still regarded as adulterated under the law." *United States v. Lit Drug Co.*, 333 F. Supp. 990, 998 (D. N.J. 1971). Therefore, when the FDA examines whether a product is adulterated, the issue of whether the drug is harmful or defective doesn't play a role. *See United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 486 (D. N.J. 1993) (explaining that the relevant inquiry to determine whether a drug is adulterated does not focus on the drug's pharmaceutical content); *United States v. 786 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1286 (D. P.R. 1992) ("The government need not establish that the seized devices contain any actual defects—or caused any harm—to prove that the seized articles are adulterated."); *United States v. Bel-Mar Labs., Inc.*, 284 F. Supp. 875, 881–83 (E.D.N.Y. 1968) (a drug manufactured in violation of GMPs is adulterated, whether or not it is actually deficient). The inverse is also true; juries shouldn't examine adulteration evidence when deciding whether a drug used by a plaintiff was defective.

Further, courts have cautioned against exporting regulatory conclusions such as adulteration determinations into civil tort cases for another reason: they require different burdens of proof. The FDA, charged with protecting public health, applies "a much lower [risk-utility] standard than that which is demanded by a court of law." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1249–1250 (11th Cir. 2005). This lower standard favors overestimating risks as part of "the preventive perspective that the agenc[y] adopt[s]… to reduce public exposure to harmful substances." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001); *see also McClain*, 401 F.3d at 1249–50 (the FDA takes enforcement action "upon a lesser showing of harm to the public than the preponderance-of-the-evidence or the more-like[ly]-than-not standard used to assess tort liability."). So when the FDA prevents a manufacturer

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from selling an adulterated product, to fulfill its mandate, the FDA exercises abundant caution, but *not* necessarily because it has reason to believe that the product contains defects.

Conclusion—Restoring the Focus on Proof of Defect

When plaintiffs' attorneys focus product defect claims on regulatory categorizations such as adulteration, they are putting on side shows designed to distract attention from the real issues in cases. This tactic aims to confuse jurors and shift the burden of proof by injecting an irrelevant but loaded buzzword into a case. As explained above, cGMP violations do not necessarily have anything to do with the actual content of a drug.

FDA rules and regulations are difficult enough for most attorneys to wade through without having plaintiffs' attorneys muddle the issues by equating regulatory manufacturing-process-oriented violations with proof of product defects. If an adulteration-equals-defect argument reaches a juror's ears, it will cause confusion, and it may well prompt a jury, or even a misled judge, to apply the wrong standard. Defense counsel thus inherit the burden of keeping evidence of FDA regulatory violations where they belong—in the world of agency enforcement actions, outside the civil trial. By doing so, they best serve their clients, preserve the integrity of the courts, and assure that judges and juries soundly apply well-established law regarding proof of defect.