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## A Brazen End Run

By Phoebe A. Wilkinson  
and Gretchen N. Werwaiss

**Where other methods have been unsuccessful, plaintiffs are increasingly using consumer protection acts to litigate claims on an aggregate basis.**

# Defending Warnings-based Claims against Manufacturers

It is no secret that plaintiffs' attorneys routinely and diligently look for opportunities to pursue litigation against corporate defendants on an aggregate basis.

Pharmaceutical and medical device manufacturers are

not strangers to this practice, having faced numerous lawsuits in which plaintiffs have sought to prosecute product liability claims through the use of the class action vehicle. The potential for aggregation of claims renders the stakes particularly high. If a class is certified, the possible exposure is enormous. If class action status is denied, the vast majority of plaintiffs drop their lawsuits, uninterested in prosecuting the case on an individual basis.

To date, pharmaceutical and medical device manufacturers have enjoyed a good measure of success in defeating plaintiffs' class certification efforts. Much of this success—reflected in numerous decisions—has been achieved because of the judicial recognition that the individual issues at play in a personal injury case involving a pharmaceutical/medical device product would render effective class treatment of such claims impossible. Perhaps in an effort to reverse the course of courts' apparent reluctance to formally aggregate these cases, plaintiffs' lawyers have increasingly

turned to consumer protection act lawsuits as a vehicle by which to prosecute warnings-based claims on a mass basis against pharmaceutical and medical device manufacturers.

All states have some form of law designed to prevent unfair and deceptive trade practices. The broad and sometimes vague language of these consumer protection acts has allowed plaintiffs increasingly to cast what would otherwise be fundamental common law failure to warn or improper warnings claims in consumer protection act terms. In doing so, plaintiffs routinely disavow any personal injury claims as a result of the use of the medicine or medical device in question. Instead, they allege that the marketing, advertising and promotion of the product was misleading, deceptive or fraudulent, that they did not "get what they paid for" as a result and, hence, they seek recovery. In essence, the industry is faced with litigating product liability suits in the abstract—cases in which the elements that provided the central hurdles to aggregation in tradi-



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tional class action cases, injury and causation, have been omitted. Apart from the relaxed pleading and proof requirements that plaintiffs assert apply, the potential recovery offered by consumer protection acts can be quite attractive to plaintiffs. Many such statutes provide for treble damages, punitive damages, attorneys' fees or statutory minimum damage awards.

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There have been a number of industry manufacturers who have recently seen the results of this trend. St. Jude, a manufacturer of heart valves, is presently facing the prospect of litigating against a nationwide class of *uninjured* heart valve recipients, who seek recovery pursuant to several Minnesota consumer protection statutes—this despite the fact that the district court did not certify a medical monitoring class or a personal injury class based upon similar allegations. *In re St. Jude Medical, Inc.*, 2006 WL 2943154, MDL No. 01-1396 (D. Minn. Oct. 13, 2006). What do the plaintiffs seek? By their own admission, they seek to find St. Jude liable for “alleged false representations and material omissions regarding the safety and efficacy of the Silzone valves through defendant’s global advertising, marketing and product labeling”—allegations remarkably similar to traditional product liability improper warnings claims.

Another example is provided by a lawsuit against Pfizer, Pharmacia Corporation and G.D. Searle, LLC, concerning the labeling and promotion of Celebrex, in which the plaintiffs allege that the defendants did not sufficiently disclose cardiovascular risk information to the Food and Drug Administration (FDA) and that they exaggerated the safety and efficacy of Celebrex. The plaintiffs claim such conduct violates the consumer protection acts of various states and further claim that the “cumulative impact” of the allegedly misleading promo-

tion led to the plaintiffs paying an inflated price for the medication. The plaintiffs assert that, had the claims about Celebrex’s efficacy not been exaggerated, the price for the drug would have been lower. They do not allege that Celebrex failed to relieve their pain or that they were injured physically in any way as a result of ingesting the medication, but they do seek to certify a class to prosecute their economic damage claims in an aggregate manner.

There are several potential challenges to consumer protection act lawsuits that defense practitioners and their manufacturer clients can consider at the outset of a suit. While not an exhaustive list, the following bases are but a handful that have been advanced in recent consumer protection act lawsuits attacking allegedly deceptive marketing and promotion of pharmaceutical and medical device products. There are a number of grounds for dismissal, discussed further below, that manufacturers should consider when assessing the sufficiency of the pleadings. With respect to these, should a court agree that the pleadings are deficient, plaintiffs are likely to be given the opportunity to replead their claims in an effort to cure the deficiencies. However, in recognition of the unique role that Congress has entrusted to the FDA and related government agencies, manufacturers have additional dismissal grounds in consumer protection act lawsuits that go to the heart of the claims and cannot be cured by repleading; should these grounds be found by a court to be valid, the cases (and perhaps similar cases in other courts) are likely to be dismissed for good. These more substantive defenses are discussed first.

### **Should the Court Entertain the Claims at All?**

#### **The Doctrine of Equitable Abstention**

The doctrine of equitable abstention is an example of a possible basis for dismissal of a consumer protection act claim in its entirety. When faced with such a suit, pharmaceutical and medical device manufacturers should consider whether case law in the relevant jurisdiction supports asking a court to abstain from hearing the case. Equitable abstention is particularly appropriate where the claims raised by the lawsuit involve scientific and public policy issues. In the context of pharmaceutical

and medical device products, application of the doctrine recognizes that the judgment regarding the safety and efficacy of medications and medical devices falls squarely within the ambit of the FDA and not the court system.

Such an argument was successful in California in *Gatherer v. Purdue Pharma, L.P.*, 2002 WL 32144622, No. BC257852 (Cal. Super. Dec. 13, 2002), an action where an individual plaintiff sued the manufacturer of a prescription pain medication (OxyContin) asserting a single cause of action under California’s Business and Professions Code sections 17200 *et seq.* The plaintiff brought such claims as a “private attorney general” and sought to have the California court resolve a number of issues not only on behalf of herself, but also on behalf of “all” California patients similarly situated. Among the plaintiff’s allegations were that the product in question did not have the right “feature” or “formulation” and that the manufacturer’s “product literature and other documentation and materials” failed to provide “accurate information about [its] appropriate uses and risks.”

Purdue Pharma asked the *Gatherer* court to apply the doctrine of equitable abstention and dismiss the case. Purdue argued that it would be an abuse of discretion for a California court of equity to hear the *Gatherer* case since another branch of government—the legislature, through application of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321, *et seq.* (“FDCA”) and the Controlled Substances Act, 21 U.S.C. §801, *et seq.*—extensively regulated the conduct at issue. The *Gatherer* court agreed, stating that “[e]quitable abstention is appropriate in the instant matter as the federal government regulates” OxyContin, pharmaceutical sales representatives and industry seminars. *Gatherer*, at \*1. The court further noted that “[a]bstention applies here where the remedy, if granted, has ramifications extending throughout an industry to such a degree it would endanger the judiciary in a protracted nature of policy formulation and enforcement. Equity relief would be impossible and difficult to administer.” *Id.*

#### **The Doctrine of Primary Jurisdiction**

Manufacturers can also consider whether the allegations and relief sought in a consumer protection act lawsuit are of a nature

to warrant asking the court to dismiss the action pursuant to the doctrine of primary jurisdiction. Under that doctrine, “questions within [the FDA’s] peculiar expertise... are appropriately routed to the agency, while the Court stays its hand.” *Weinberger v. Bantex Pharms., Inc.*, 412 U.S. 645, 654 (1973); *see also Reiter v. Cooper*, 507 U.S. 258, 268–69 (1993). More specifically, “a district court may refer a matter within its original jurisdiction to the appropriate administrative agency if doing so will ‘promot[e] proper relationships between the courts and the administrative agencies charged with the particular regulatory duties.’” *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645, 00 Civ. 4042, at \*2 (S.D.N.Y. Nov. 22, 2000). Several factors are considered when assessing the propriety of applying the doctrine: (a) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise; (b) whether the question at issue is particularly within the agency’s discretion; (c) whether there exists a substantial danger of inconsistent rulings; and (d) whether a prior application to the agency has been made. *Id.* at \*2.

The doctrine of primary jurisdiction acknowledges that certain matters may extend beyond the conventional experience of judges and jurors and should be referred to the administrative agency having more specialized experience and expertise. Generally, if the issue in question is of a purely legal nature, referral to an agency on the ground of primary jurisdiction is inappropriate. Hence, if plaintiffs in a consumer protection act lawsuit seek to have a court declare that FDA-approved marketing is unlawful, or that manufacturers should be enjoined from marketing pharmaceuticals or medical devices pursuant to FDA-approved labeling and advertising, the defendants should consider whether to invoke this doctrine as part of their defense to such claims.

#### **Statutory Exemptions for Manufacturers in a Highly Regulated Industry**

In addition to the legal doctrines of equitable abstention and primary jurisdiction, many state consumer protection acts contain codified exemptions that provide a

statutory basis for defendants to seek dismissal. These exemptions echo the basis pursuant to which the *Gatherer* court dismissed the consumer protection act claims at issue in that lawsuit. The relevant statutory exemptions generally provide that consumer protection acts do not apply to conduct that is “regulated” or expressly “permitted” by a state or federal regulatory body. These exemptions have particular application in the pharmaceutical and medical device industries where the FDA, Drug Enforcement Agency and/or various divisions within those bodies comprehensively and extensively regulate the formulation, design, manufacture, labeling, promotion, advertising and distribution of the products in question.

By way of example, the Ohio, Massachusetts and Illinois consumer protection act statutes contain such exemptions. *See, e.g.,* Ohio Rev. Code Ann. §1345.12; Mass. Gen. Laws ch. 93A, §3; 815 Ill. Comp. Stat. 505/10b(1). So, too, does the consumer protection act of Michigan, where an appellate court recently relied on such a provision in affirming the dismissal of consumer protection act claims against Merck in connection with its alleged misrepresentations relating to the safety and efficacy of Vioxx. *See Duronio v. Merck & Co.*, 2006 WL 1628516, Civ. No. 267003 (Mich. App. June 13, 2006).

In *Duronio*, the plaintiff, on behalf of a putative class, alleged that Merck disseminated information to the public that concealed and misrepresented the potential cardiovascular risks associated with taking Vioxx and falsely implied that Vioxx provided superior pain relief as compared to over-the-counter medications. The plaintiff also alleged that Merck’s pharmaceutical sales representatives misled physicians regarding the safety of Vioxx for their patients. The plaintiff sought a refund for the purchase price of Vioxx as well as the costs and expenses related to the medical consultation that FDA and Merck had recommended in connection with Merck’s voluntary withdrawal of Vioxx from the market. *Id.* at \*1. The appellate court affirmed the lower court’s decision to dismiss the claims against Merck on the ground that the Michigan Consumer Protection Act does not apply to a “transaction or conduct specifically authorized under laws administered by a regulatory

board... of... the United States.” *Id.* at \*6. The court referred to the FDCA, the extensive regulations implementing it, and the role of the FDA in enforcing those regulations, and held that the lower court’s decision to dismiss the consumer protection act claims against Merck was proper because “the general marketing and advertising activities underlying plaintiff’s [consumer protection act] claim are authorized and regulated under laws administered by the FDA.” *Id.* at \*7.

These explicit statutory exemptions recognize that to permit states to determine what constitutes appropriate marketing for pharmaceutical and medical device products would likely undermine the role entrusted to the FDA. Industry manufacturers should not hesitate to invoke them.

#### **Consumer Protection Act Lawsuits Should Be Dismissed in Favor of Administrative Remedies**

Plaintiffs and their counsel will no doubt react forcefully and negatively to defense motions that ask courts to abstain from hearing cases or defer to the FDA and related regulatory bodies pursuant to statutory exemptions. Plaintiffs can be expected to oppose such motions vigorously and argue that the regulators have too much to do, are overtaxed, and are without sufficient resources to discharge their tasks thoroughly and properly. Plaintiffs may also assert that they have no other recourse but to have the courts resolve their claims and provide them a remedy.

In response to these arguments—or perhaps as an affirmative argument in favor of dismissal—the defense bar should take the opportunity to dispute the validity of such arguments and point out that the proper procedure for challenging the FDA’s ongoing determinations is to (1) commence an action under section 10 of the Administrative Procedure Act for judicial review of the FDA’s orders (*see* 5 U.S.C. §§702, 706), or (2) file a citizen’s petition with the FDA, requesting that changes be made with regard to that medication (*see* 21 C.F.R. §10.30), which is then subject to subsequent judicial review. *See, e.g., Henley v. FDA*, 77 F.3d 616, 619 (2d Cir. 1996) (federal judicial review of the FDA’s denial of a citizen’s petition seeking changes in labeling for an oral contraceptive). Defend-

ants must assert that to allow the courts to encroach into the realm of the FDA without first exhausting administrative remedies already in place is not what was intended for the industry.

### **Have Plaintiffs Complied with Basic Pleading Requirements?**

Plaintiffs frequently take the position that the pleading and proof requirements in consumer protection act lawsuits are more relaxed than in traditional product liability litigations. Hence, it is rare for a plaintiff to allege that he actually saw any of the allegedly actionable marketing, that it caused him to “purchase” the medication, or that it influenced his physician’s decision to prescribe it to him. (And, indeed, in the context of a class action, plaintiffs will usually argue that such allegations are unnecessary.) Defense practitioners should take a close look at the relevant jurisdiction’s law in this respect and contest the assertion of any claims that fail to comply with the statutory requirements of a particular consumer protection act or with the sufficiency requirements of the particular allegations, given the unique characteristics of how “consumers” receive pharmaceutical and medical device products. Not only is it possible that such a challenge will lead to the dismissal of an action, but it could also serve to shift the court’s focus away from what are often sensational and torrid allegations of corporate wrongdoing and towards the more proper focus in a pharmaceutical and medical device warnings-based case—whether there is any causal link between the allegedly deceptive marketing and the decision by the physician and/or the patient to use the pharmaceutical/medical device in question.

### **Does the Relevant Consumer Protection Act Allow the Claims to Be Prosecuted as a Class Action?**

Often plaintiffs assert consumer protection act claims on behalf of a putative class of consumers. Defendants should examine the class certification issue carefully—including giving consideration to the state from which the plaintiff hails and the law that will properly govern resolution of the claims—to determine whether the action is governed by the law of a state whose consumer protection act does not permit such

claims to be prosecuted by consumers on a class-wide basis. The consumer protection acts of a number of states—for example, Alabama, Georgia, and Montana—explicitly preclude class actions.

### **Is There a Notice Requirement?**

Many states’ consumer protection acts require plaintiffs to provide pre-litigation notice to a manufacturer so as to provide that manufacturer with the opportunity to remedy the claimed defect. *See, e.g.*, Ind. Code §24-5-0.5-5. Hence, manufacturers and their counsel can hold plaintiffs to their statutory requirement in this regard. If no such notice has been provided (or plead), any suit brought by those consumers is subject to dismissal on the pleadings.

### **Is the Plaintiff a Proper Plaintiff?**

In the context of pharmaceutical products and medical devices, consumer protection act claims are frequently asserted by third party payors, organizations that have paid the healthcare costs of the consumer. Often, these organizations will seek to recover money they claim to have spent on the healthcare of these consumers. Many states, however, do not permit such organizations to avail themselves of the benefits of their consumer protection acts because such statutes require that the “consumer” be a “natural person” (Alabama) or the consumer cannot be a “business consumer that has assets of \$25 million or more” (Texas). *See, e.g.*, Ala. Code §8-19-3(2); Tex. Bus. & Com. Code Ann. §17.45(4). Without a proper plaintiff, the consumer protection act lawsuit should not be allowed to proceed.

### **Has the Plaintiff Alleged an Injury Sufficient to Confer Standing?**

Defendants should consider whether to challenge a plaintiff’s standing to sue based upon the self-proclaimed lack of personal injury that has become the hallmark of these consumer protection act suits.

As we all know, federal courts are courts of *limited* jurisdiction. They derive their authority to act from Article III of the United States Constitution, which requires that there be a “case or controversy” between parties in order to litigate actions in federal court. U.S. Const. art. III. Inherent to the “case or controversy”

requirement is that a plaintiff must establish “standing” to pursue his claims. Case law has established three elements that are required to establish standing to sue in federal court, one of which is that the plaintiff must have suffered an “injury in fact.” *See, e.g., In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133 (E.D. La. 2002), citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992). An “injury in fact” must be “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Lujan*, 504 U.S. at 560 (emphasis added).

Increasingly, where plaintiffs have specifically disavowed any personal injury, manufacturers have challenged consumer protection act lawsuits on the ground that such plaintiffs cannot establish the requisite standing to pursue their claims. In *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002), the lead plaintiff—who had openly disavowed any physical or emotional injury—proposed to represent a nationwide class of patients who had ingested the prescription pain medication Duract. The lower court certified the class and the defendants appealed. The pharmaceutical manufacturer argued that the plaintiff lacked standing to sue in a “no-injury,” economic-theory lawsuit. The Fifth Circuit agreed and dismissed the lawsuit on the ground that the plaintiff had failed to establish an Article III “injury in fact.” The Fifth Circuit also suggested that the lower court’s Rule 23 class certification decision had been significantly flawed, but premised its dismissal—and focused all of its analysis—on the standing issue. The *Rivera* court specifically rejected the plaintiff’s argument that she had been denied “the benefit of the bargain” and denounced the attempt:

to recast their product liability claim in the language of contract law. The wrongs they allege—failure to warn and sale of a defective product—are products liability claims. Yet, the damages they assert—benefit of the bargain, out of pocket expenditures—are contract law damages. The plaintiffs apparently believe that if they keep oscillating between tort and contract law claims, they can obscure the fact that they have asserted no concrete injury. Such artful pleading, however, is not enough to create an injury in fact.

*Id.* at 320–321. *See also Williams v. Purdue Pharma Co.*, 297 F.Supp.2d 171, 178 (dismissing a consumer protection act lawsuit because “the invasion of a purely legal right without harm to the consumer—in this case, to freedom from allegedly false and misleading advertising—can be addressed through the administrative process.... Without a particularized injury, absent in this case, they do not have standing to proceed in court.”); *Prohias v. Pfizer, Inc.*, 2007 WL 1228784, No. 05-22658, at \*6 (S.D. Fla. Apr. 24, 2007) (dismissing consumer protection act claims concerning allegedly false and misleading advertising for prescription medication Lipitor on the ground that the claimed injury—alleged price inflation damages—was “too speculative to constitute an injury-in-fact under Article III.”).

The standing issue is not unique to federal courts and, generally, the outcome should not be different when consumer protection act suits are filed in state courts. A number of state courts that have considered no-injury product liability lawsuits, many of which have included claims made pursuant to consumer protection act statutes, have found such claims to be too speculative to constitute a legally cognizable injury. *See, e.g., Frank v. DaimlerChrysler Corp.*, 292 A.D.2d 118, 128, 741 N.Y.S.2d 9, 17 (N.Y.A.D. 2002) (affirming dismissal of putative class action asserting claims for, *inter alia*, unfair and deceptive trade practices based upon allegedly defective automobile seats and seeking damages for alternate transportation or expense in correcting the defect because the plaintiffs “fail[ed] to plead any actual injury.”).

#### **Are the Allegations Mere Sales Puffery?**

Manufacturers can also consider whether the allegedly deceptive marketing and promotional statements that form the basis of the consumer protection act claims are more properly characterized as sales puffery, and hence not actionable at all. Last year, a pharmaceutical manufacturer was successful in having a consumer fraud act claim dismissed for failure to state a claim on the basis that the allegedly actionable marketing statements were, at best, sales puffery that did not have the capacity to mislead. *Adamson v. Ortho-McNeil Pharmaceutical, Inc.*, 463 F.Supp.2d 496, 503–

504 (D. N.J. 2006). The *Adamson* court noted that in order to state a claim under the consumer fraud act in question—the New Jersey Consumer Fraud Act—the allegedly improper marketing piece had to have the capacity to mislead the average consumer and could not be “mere puffery” as “puffing about a product” will not support relief. *Id.* at 501, 503. The court explained that in order for a statement to be actionable under the consumer fraud act, it had to be one that was “material to the transaction and which is a statement of fact, found to be false, made to induce the buyer to make the purchase.” *Id.* (internal citations omitted). Upon examination of the allegedly actionable promotional statements concerning a prescription pharmaceutical in *Adamson*, the court concluded that none of the statements upon which the plaintiff relied were actionable under the consumer fraud statute. *Id.* at 503.

#### **Are the Allegations in the Complaint Sufficient to Proceed, Given the Means by Which the Consumers Obtained the Pharmaceutical and Medical Device Products in Question? Reliance and Causation**

Contrary to the assertions of many plaintiffs, a number of state consumer protection acts require a plaintiff to plead and prove reliance, not to mention that almost all require a showing of proximate causation. With respect to those statutes that do not require a showing of reliance *per se*, many do require a plaintiff to plead and prove that an injury occurred *as a result of* the dissemination of the allegedly deceptive marketing or promotional material. Holding a plaintiff to the task of properly pleading and proving these elements will often show the claims to be without merit (and may also help in the efforts to defeat class certification should the case proceed to a determination of that issue).

As with more traditional product liability claims, in the context of a consumer protection act claim that attacks the marketing or promotion of a prescription pharmaceutical or medical device product, there is also a unique figure with which the plaintiff must contend—the patient’s prescribing and treating doctor, by law, a learned intermediary. This is so because, unlike other consumer products, with respect to

which the consumer protection acts were largely written, “consumers” of prescription pharmaceuticals and medical devices can obtain such products only if prescribed to them by a physician. *See N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177–78 (N.J. Super. Ct. App. Div. 2003) (“the intervention by a physician in the decision-making process... whether or not

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to prescribe a particular medication protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products.”). Necessarily, patients rely upon their physician’s medical judgment before purchasing and ingesting a prescription medication. Hence, the physician’s judgment as to whether to prescribe that medication stands between any marketing of the medication and the patient’s purchase of the medication. As a result, this “learned intermediary” severs “the chain in terms of reliance, since the patient cannot obtain prescription drugs without the physician no matter what they believe about them.” *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 384 (D.N.J. 2004). Moreover, if the plaintiff’s physician had independent knowledge about the risks of the medication, the causal chain would likewise be broken.

Accordingly, as is true with more traditional products liability cases, at the outset of a consumer protection act litigation involving a prescription medication or medical device, manufacturers have the ability to press a plaintiff to identify (i) the particular marketing or promotional piece that is allegedly deceptive, (ii) the physician who saw the particular piece, and (iii) whether the physician relied on the marketing piece in his or her decision to prescribe the medication/medical device



to the patient/plaintiff. Even assuming that these elements can be shown, a plaintiff also has to plead and prove, as noted above, how he or she was actually injured as a result of the allegedly deceptive statement. Failure so to plead should result in the action being dismissed.

**Fraud**

With respect to allegations that a particular marketing or promotional piece was “fraudulent,” practitioners should consider whether it is in their client’s interest to assert that any such claim must be pled with particularity, as required, for example, by Federal Rule of Civil Procedure 9(b). In some instances, practitioners may determine that it is better for the client-manufacturer not to have a well-pleaded

fraud claim publicly filed, but if it appears that the plaintiff will be unable to meet the particularity requirements for fraud in a pharmaceutical/medical device case, *i.e.*, having to plead allegations that his or her physician saw the allegedly fraudulent communication, and that it caused him or her to prescribe the product to the plaintiff, then it may be strategically sound to challenge the complaint on this basis.

**Conclusion**

The significant rise of consumer protection act lawsuits against manufacturers in the pharmaceutical and medical device industry appears to be a brazen end run around the difficult obstacles the plaintiffs’ bar has previously encountered when attempting to litigate pharmaceutical and medical device

warnings-based product liability claims on an aggregate basis. Manufacturers and defense practitioners should use every weapon in their arsenal to test the validity of the consumer protection act allegations found in these lawsuits. Not only is it important to do so from the perspective of ensuring that traditional elements of prima facie product liability claims are preserved, but also because, to the degree that consumer protection act lawsuits are allowed to proceed, they will likely do so at the expense of supplanting, or at minimum encroaching upon, a federal regulatory scheme already in place regarding the safety, efficacy and appropriateness of pharmaceutical and medical device products and the means by which they are promoted to the healthcare industry. 