Agency vs. Class Action in Advertising Litigation

Regulatory Compliance Defenses

By Laurie Webb Daniel

Uniform standards in regulation are at risk from piggyback litigation.

Plaintiffs' lawyers usually like to piggyback on agency action. They have been doing it for years in the securities, antitrust, and product liability arenas. Not satisfied with traditional causes of action, creative lawyers recently have blended legal theories under the general rubric of consumer protection law in an attempt to recover staggering amounts even where no injury can be shown. They have chosen a big target: prescription drug labeling and marketing practices. Ironically, however, governmental regulation of consumer communication in this industry is turning out to be an excellent platform for defense instead of the free ride expected by the plaintiffs' bar.

As plaintiffs' lawyers dip into their melting pot of theories, the industry can turn to traditional but evolving legal principles to keep consumer litigation in line with sound social policy. This article analyzes several defenses grounded in the common sense notion that it is the job of the Food and Drug Administration, not lay tribunals, to make sure that pharmaceutical information is accurate and not misleading. The article then discusses how to lay the groundwork for shaping these defenses in future appellate decisions in drug advertising cases.

The Advertising Watchdogs: Official and Self-Proclaimed

The Food and Drug Administration ("FDA") is the official advertising watchdog for the pharmaceutical industry. Although the Federal Trade Commission ("FTC") is tasked with preventing deceptive advertising for other health care products, *see* 15 U.S.C. §52, it is the FDA that must determine whether prescription drug labeling is "false or misleading." *See* 21 U.S.C. §355(b)(1); 21 C.F.R. §314.125(b)(6). Through its Center for Drug Evaluation and Research (CDER), the FDA also oversees advertising, marketing, and promotional materials relating to prescription drugs. *See* 21 U.S.C. §352(n); *see also id.*, §§321(n), 331(a), 352(a); 21 C.F.R. §§202.1(e)(4)(i)(a); 314.81(b)(3)(i). It is CDER's responsibility "to assure that prescription drug information provided by drug firms is truthful, balanced, and accurately communicated." *See* http://www.fda.gov/cder/handbook/advertis.htm (last visited 3/10/2006). CEDR accomplishes this through a comprehensive surveillance, enforcement, and education program. *Id.* CDER's "Division of Drug Marketing, Advertising, and Communications" or "DDMAC" pays particularly close attention to advertising through internet and other "direct-to-consumer" or "DTC" channels.

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See http://www.fda.gov/cder/handbook/pol_guid.htm (last visited 3/10/2006).

The FDA's supervision of drug advertising is not a rubber stamp process. There is scrutiny by various professionals, including social scientists and regulatory counsel. *See* Direct to Consumer Advertising of Prescription Drugs: Exploring the Consequences: Hearing before the Senate Special Comm. on Aging, 108th Cong. (2003), *available at* 2003 WL 56336398. The agency provides specific guidance to drug companies that submit proposed advertising. *Id.* When the FDA determines that advertising is misleading, it issues warning letters, which are posted on the FDA website. *See* http://www.fda.gov/cder/warn/ (last visited 3/10/2006). The FDA website notes that the warning letters can result in subsequent interaction between the FDA and the recipient of the letter, and the letters themselves reflect the agency's insistence on corrective action. *Id.* The public warning letters, therefore, serve to regulate the particular recipient and to provide guidance to all industry participants.

Advertising in the pharmaceutical industry also is checked by a self-regulating mechanism: the *PhRMA Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines* ("*PhRMA Guidelines*"). *Available at* http://www.phrma.org/files/DTCGuidingprinciples.pdf. "PhRMA" is the acronym for the Pharmaceutical Research and Manufacturers of America, which is a leading industry association that represents many pharmaceutical and biotechnology companies. The preamble to the *PhRMA Guidelines*, which went into effect in January 2006, articulates the industry's goal of voluntary compliance with FDA regulation in particular and with truthfulness in general.

> First and foremost, we have a responsibility to ensure that our DTC communications comply with the regulations of the Food and Drug Administration (FDA). In general, the FDA requires all DTC information:
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> - To be accurate and not misleading;
> - To make claims only when supported by substantial evidence;
> - To reflect balance between risks and benefits; and
> - To be consistent with the FDA-approved labeling.

Id.

In addition to the federal regulators and PhRMA, there are others who claim to protect the public from inaccurate medical information. These are the champions of state consumer fraud and unfair competition statutes—the state attorneys general and the plaintiffs' bar. While the attorneys general act in an official capacity as *parens patriae* for the benefit of the public, the private lawyers are self-designated prosecutors who stand to reap tremendous personal profit if they can survive the dispositive motion and class certification stages of their litigation. The highly motivated plaintiffs' bar does not suffer from a lack of creativity. When they cannot prove actual injury from pharmaceutical information, they try to imbue consumer protection statutes with presumptions from securities fraud and other areas of the law. *See*, *e.g.*, *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174,178–79 (N.J. Super. App. Div. 2003); *see also* Erin T. Welsh and Steven A. Karg, *The Recent Expansion of Traditional Products Liability—Personal Injury Claims Into More Complex Claims and Investigations*, ALI-ABA Course of Study, Products Liability: Pharmaceutical and Medical Device Issues (August 18–19, 2005), SL038 ALI-ABA 347. One fact that they cannot circumvent, however, is the pre-existing and extensive regulation of drug labeling, promotion, and advertising by the FDA. In the consumer protection context, they have no good answer to the question: Isn't regulation by the FDA enough?

Regulation by Litigation Is Bad Social Policy

If you want to shape the law through appellate decisions, you need to explain to the courts why your position makes sense. You need to show that social policy is on your side. When medical information is involved, there are compelling reasons why consumer class actions are bad from a policy standpoint.

There is no doubt that class action litigation can function as *de facto* regulation simply because the stakes are so high. "[R]egulation can be as effectively exerted through an award of damages as through some form of preventive relief." *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959). As explained by the Advisory Committee on the Federal Rules of Civil Procedure in connection with the addition of Rule 23(f) to permit discretionary appeals of class certification orders, class actions often raise the specter of undeserved "potentially ruinous liability." The high costs and risks of class action litigation can impact the availability of drugs and other medical products just as regulation by the FDA can. *See* Senate Comm. on Commerce, Sci., & Transp., Prod. Liab. Reform Act of 1997, S. Rep. No. 105-32, at 7 n. 60, 10 (1997) (noting the decline in availability of certain medical products and information due to threat of product liability costs).

The FDA has the ability to consider the views of the public at large, as well as scientists and industry participants.

Because of the highly specialized nature of this industry, however, the regulation of information relating to drugs and other medical products should be left to people who have the technical experience needed for an informed assessment of whether a statement is accurate or misleading. *See Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, 2005 WL 2993937 at *5 (D. Del. 2005). Unlike lay juries and judges, the FDA has the expertise to back up such decisions. *Id.* Further, by conducting public hearings, the FDA has the ability to consider the views of the public at large, as well as scientists and industry participants. In contrast, a court or jury can consider only admissible evidence presented by the particular litigants in the case, a restriction that increases the chances of arbitrary results.

The use of private litigation in multiple jurisdictions to regulate the flow of medical information also destroys uniformity, and thus frustrates one of the principal reasons for giving the FDA authority to establish national standards for marketing prescription drugs. The public, as well as the industry, benefits from uniform standards, consis-

tently applied. *See* Brief of United States, 2004 WL 1143720 at *25, *filed in Horn v. Thoratic Corp.*, 376 F.3d 163 (3d Cir. 2004).

Finally, allowing the plaintiffs' bar to challenge pharmaceutical communications through consumer fraud and unfair competition class actions actually can harm the consumers who are supposed to benefit from such litigation. In any industry, the costs of doing business must be covered by the price of the goods sold. This fundamental economic principle means that high defense and settlement costs will increase the prices paid by the consumers for the drugs. The risks from this type of action also could deter drug companies from DTC communications in the first place. This outcome would deprive consumers of a valuable source of information. While some people think DTC advertising is not appropriate, the agencies who have studied the issue have found otherwise.

In a detailed report supported by surveys and data, the FTC staff has advised the FDA that "empirical evidence suggests that the FDA's current approach to regulating DTC advertising generally confers benefits on consumers." *See In the Matter of Request for Comments on Consumer-Directed Promotion*, Docket No. 2003N-0344, Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission, December 1, 2003, at 5, *available at* http://www.ftc.gov/be/v040002text.pdf. "Survey evidence suggests that DTC ads have provided consumers with useful information about the drug options open to them, which, in turn, has empowered consumers to interact with their physicians more effectively. Studies of the impact of DTC advertising on demand do not support the conclusion that it has led to the increased use of inappropriate drugs or increased drug prices." *Id.*

The Senate Judiciary Committee Report on the Class Action Fairness Act stresses that "[t]he authority to decide whether consumers should have access to pharmaceuticals should remain with the FDA." S. Rep. No. 109-14 (2005), *reprinted in* 2005 U.S.C.C.A.N. 3, 2005 WL 627977, at *75. The rationale for this point applies equally to the regulation of pharmaceutical labeling, promotion, and advertising:

> [R]egulatory decisions regarding which pharmaceutical drugs are available to the American public should not be shifted away from the Food and Drug Administration into the hands of plaintiffs' lawyers, judges and juries. Many class actions against pharmaceutical manufacturers are filed in spite of the fact that the FDA has investigated an alleged problem and concluded that the drug should remain on the market. Class action lawyers borrow from the factual work undertaken by the agency and use the class action vehicle as a way to relitigate the agency's decisions. The authority to decide whether consumers should have access to pharmaceuticals should remain with the FDA. And if there are problems with FDA, the solution is to fix the agency—not to transfer its power to self-interested class action lawyers.

Id., 2005 WL at 627977, at *75.

Regulatory Compliance Defenses

The FDA's regulation of drug advertising gives rise to a number of grounds for dismissal of piggy-back class actions. Following is a summary discussion of some arguments you can make if you face a consumer challenge to regulated advertising. Keep in mind that this is not an exhaustive list, and the defenses are evolving. Although the labels given these legal theories differ based on subtle variations in analysis, these defenses have a common theme: lay tribunals should not be regulating the flow of information relating to the use and attributes of medicine.

Preemption Doctrine

The preemption doctrine is "a crazy quilt of decisions." Joseph J. Leghorn, *et al.*, *Preemption Defenses: The Latest Information and Strategies. Will It Ever Make Sense?*, ACI Drug and Medical Device Litigation (December 2005). Some courts have held that FDA regulation preempts state law actions. *See*, *e.g.*, *Dowhal v. Smith Kline Beecham Consumer Healthcare*, 12 Cal. Rptr. 3d 262 (Cal. 2004); *Dusek v. Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. 2004). Some have gone the other way. *See*, *e.g.*, *Cartwright v. Pfizer*, 369 F. Supp. 2d 876, 885–86 (E.D. Tex. 2005); *Zikis v. Pfizer Inc.*, 2005 WL 1126909 (N.D. Ill. 2005).

The conflict over preemption proves the need for preemption. The rules for drug labeling and advertising should have uniform application nationwide, which can be achieved only through federal preemption of state law. Because the FDA already has determined what warnings should be included in labeling and advertising, any other view necessarily conflicts with the agency action.

Although the preemption doctrine has not been uniformly applied, it is evolving into a sound defense in consumer protection actions challenging medical advertising. *See also Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, 2005 WL 2993937 (D. Del. 2005) (holding that the preemption doctrine bars state law actions based on statements in advertising that comply with FDA-approved labeling); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. 2003) (holding that "the wording of the ads, to the extent that it is subject to FDA oversight, *see* 21 CFR §202.1, is similarly not actionable"); *Murphy v. Playtex Family Products Corp.*, 176 F. Supp. 2d 473, 483 (D. Md. 2001) (holding that plaintiffs' consumer protection act claim is expressly preempted by the requirements of 21 C.F.R. §801.430).

Indeed, the FDA recently has embraced the preemption doctrine as official agency policy. For example, in a letter brief filed in a product liability "failure to warn" case, the FDA explained that its decision-making process is not limited to the wording of the warnings that are found on labels. It also involves a decision to limit the warnings to those that are approved. *See* Brief of United States, 2004 WL 1143720 at *29, *filed in Horn v. Thoratic Corp.*, 376 F.3d 163 (3d Cir. 2004) (affirming summary judgment on preemption grounds). The FDA provided additional facts and extensive arguments supporting preemption in the preamble to its recent final rule on prescription drug labeling. *See Requirements on Content and Format for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3933–36 (January 24, 2006). The FDA's express adoption of the preemption doctrine as agency policy in the course of its formal rule-making process is a powerful statement that should propel the preemption defense in future appellate decisions. *See Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2003) (noting deference given to federal agency's views on preemption).

Safe Harbor Provisions

Although not technically preemption, there is a comparable defense incorporated into many state consumer protection statutes. These "safe harbor" provisions defer, as a matter of state law, to federal regulation. For example, Delaware's Consumer Fraud Act expressly does not apply "[t]o any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission." 6 Del. C. §2513(b)(2). Recognizing that the FTC and the FDA share jurisdiction over the regulation of drug marketing, with primary responsibility going to the FDA, the court in *Penn. Employee Benefit Trust Fund* recently held that advertising is not actionable under the Delaware consumer statute if it is consistent with FDA-approved labeling. 2005 WL 2993937 at *2.

An appellate decision reversing a $10 billion award involving the tobacco industry recently made clear that formal agency regulation is not a prerequisite to the safe harbor defense under Illinois law. *See Price v. Philip Morris, Inc.*, ___ N.E.2d ___, 2005 WL 3434368 (Ill. App. 2005). Significantly, the court based its decision on precedent from the pharmaceutical industry and on evidence regarding voluntary compliance mechanisms.

The Illinois Consumer Fraud Act does not reach actions that are "specifically authorized by laws administered by" the regulatory body. 815 ILCS 505/10b(1). Although the lower court in *Price* made a finding that the FTC did not specifically authorize the use of the disputed terms, the appellate court held that it was entitled to *de novo* review because the facts were undisputed. *Id.* at *29. The court then agreed with the defendant that, as a matter of law, the agency authorization need not be express to be specific. *Id.* at *38.

The *Price* court carefully noted the evidence that an agency does not regulate solely by formal action. "In lieu of formal rule-making, the FTC can withdraw proposed rules if those affected voluntarily agree to comply. In addition, the FTC can issue advisory opinions upon request by an industry actor or other interested party." *Id.* at 20. The court observed that "[t]he United States Court of Appeals for the District of Columbia Circuit long ago noted the FTC's tendency to regulate by obtaining voluntary compliance with its policies, rather than engaging in formal rulemaking." *Id.* at 43. The court, therefore, had ample support for its conclusion "that the FTC's informal regulatory activity, including the use of consent orders, comes within the scope of section 10b(1)'s requirement that the specific authorization be made 'by laws administered by' a state or federal regulatory body." *Id.* at 41.

A pharmaceutical case from the Seventh Circuit also played a prominent role in the *Price* opinion. *Id.*, *citing Bober v. Glaxo Wellcome PLC*, 246 F.3d 934 (7th Cir. 2001). The *Bober* court pointed out that statements designed to comply with the technical requirements of the highly regulated pharmaceutical industry could very well be confusing or even misleading to a consumer. 246 F.3d at 942–43. Following the *Bober* analysis, the *Price* court held that "even if those statements may tend to be confusing or misleading and even if there is no express authorization for the making of such statements in the applicable federal regulations," the statements were entitled to protection if they "fall within the boundaries established by federal law." *Price*, 2005 WL 3434368 at *43.

The *Price* decision has many interesting facets. It used a *de novo* standard of review to reverse what appeared to be a finding of fact. It stressed that a layperson's perception of "misleading" material should not invoke liability with respect to statements made in compliance with technical requirements imposed by the FDA. Perhaps most significantly, it indicates that voluntary compliance—even through consent orders—can constitute regulatory activity deserving of safe harbor protection. Under the *Price* analysis, the fact that the FDA challenged conduct at some point in time might not support liability if the problem was voluntarily corrected through subsequent dealings with the agency. Thus, evidence of a transgression can at the same time possibly establish a preemption or safe-harbor defense—if it is accompanied by corrective behavior.

Consumer Expectation Test

Defendants have successfully relied on the "consumer expectation test" to defeat liability based on challenges to labeling. The gist of the argument is that a plaintiff cannot satisfy the "consumer expectation test" as a matter of law where the label complies with FDA requirements. The significance of this defense is that it can apply to labeling claims even when there is no federal preemption. Thus, if you find yourself in a jurisdiction that has rejected the preemption doctrine in medical advertising cases, you nonetheless can argue that regulatory compliance compels dismissal under this common law principle. Although the "consumer expectation" defense arose in the context of products liability, its rationale also applies to consumer protection actions.

An illustrative case is *Murphy v. Playtex Family Products Corp.*, *supra*. The court in *Murphy* addressed claims based on allegedly improper tampon labeling. *See Murphy*, 176 F. Supp. 2d at 473. After dismissing the consumer protection claims under the preemption doctrine, the *Murphy* court agreed with the plaintiffs that there was no federal preemption of the product liability claim. *Id.* at 488. The court then agreed with the defendant, however, that the plaintiffs could not prove a case under the consumer expectation product liability test. *Id.* at 489. Under the consumer expectation test, liability attaches where a product is more dangerous than an ordinary consumer would expect. *Id.* at 485. Following precedents from the Ninth and Seventh Circuits, the *Murphy* court reasoned that an ordinary consumer is not entitled to expect a product to perform more safely than its government mandated warnings indicate. *Id.* at 488 (*citing Haddix v. Playtex Family Products Corp.*, 138 F.3d 681 (7th Cir. 1998) and *Papike v. Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997)).

Risk/Utility Analysis

The Restatement's "risk-utility" doctrine also shows that the regulatory compliance defense is rooted in established common law principles. Comment k to the Restatement (Second) of Torts §402A provides a famous example of the risk-utility doctrine in the medical context:

> [T]he vaccine for the Pasteur treatment of rabies… not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both marketing and the use of the vaccine are fully justified, notwithstanding the

unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Section 6 of the Restatement (Third) of Torts applies an evolved version of the risk-utility concept to prescription drug companies. In a nutshell, before a drug can be marketed, its benefits must be weighed against its risks, and reasonable warnings of foreseeable risks must be provided. *See* Restatement (Third) of Torts: Products Liability §(b)–(d). If these steps are taken, then a drug company has a defense to liability.

Advertising that complies with FDA regulation should not be actionable because the required risk-utility analysis and development of reasonable warnings of foreseeable risk is an essential aspect of the FDA approval process. *See Murphy*, 176 F. Supp. 2d at 492–93 (granting summary judgment based, in part, on FDA risk/utility findings); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991) (holding that risk/benefit analysis performed by the FDA was sufficient). Significantly, this is not a preemption argument. Rather, it is based on the established common-law principle that a drug company that acts reasonably to weigh and convey both the benefits and the risks should not be liable.

Learned Intermediary Doctrine

The "learned intermediary doctrine" can be a good vehicle for presenting a regulatory compliance defense. The learned intermediary doctrine recognizes that the prescribing physician is the proper party to inform a patient of the risks of medicine. The duty of the drug company, therefore, is satisfied when the company reasonably discloses risks to physicians. *See*, *e.g.*, *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). The relationship between the drug company and the patient is too remote to support liability.

Even with DTC advertising, the regulated nature of the pharmaceutical industry requires a "learned intermediary" before a patient can have access to prescription drugs. "In this context, that is, within a highly regulated industry in which the ultimate consumer is not in fact free to act on claims made in advertising in any event, the relationship between words used in the advertising and purchase of the product is at best an attenuated one." *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d at 178. The learned intermediary doctrine, therefore, should bar consumer protection actions based on prescription drug advertising. *See Wyeth-Ayerst Labs. v. Medrano*, 28 S.W.3d 87, 93–94 (Tex. App. 2000) (reversing denial of learned intermediary defense to claim under Deceptive Trade Practices Act).

First Amendment Protection

Truthful pharmaceutical advertising is commercial speech entitled to protection under the First Amendment. *Thompson v. Western States Medical Center*, 535 U.S. 1497 (2002). While state law can impose restrictions on commercial speech that is false or "inherently misleading," state law cannot regulate speech that is only "potentially misleading" without satisfying at least the intermediate scrutiny test described in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). Whether the speech is "inherently misleading" is a question of law. *See Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 100 (1990).

Significantly, commercial speech is only "inherently misleading" if it would be misleading in all circumstances." *Bioganic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1168, 1180 (D. Colo. 2001). Thus, advertising that is found by the FDA to be not misleading cannot be "inherently misleading," and is protected by the First Amendment from state law restrictions. *See Bioganic Safety*, 174 F. Supp. 2d at 1180–82) (holding as a matter of law that statements contained in product's advertisements and EPA-approved label were "not inherently misleading").

Future Strategy: Begin with the End in Mind

Shaping the law through appellate opinions requires a good record to support a reasoned legal analysis. The groundwork must begin early—even before litigation has commenced. In other words, you should "Begin with the End in Mind." *See* Stephen R. Covey, *The 7 Habits of Highly Effective People* (Simon & Schuster 1989). Following are some pointers on what you can do to advance regulatory compliance defenses through case law.

Develop a Good Record

Take a good look at the *Price* case. Its underlying theme is that agency regulation is not just about formal rulemaking. This means that you can build a record to support regulatory compliance defenses by documenting voluntary compliance activities. Signing onto the PhRMA guidelines would demonstrate intentional submission to the regulatory process. Pro-active dialogue with the FDA can yield evidence of agency action to support an express preemption defense. Request advisory opinions. Raise your issue at multiple levels, talking to scientific as well as enforcement personnel at the FDA. If you receive a warning letter from the FDA, do a good job of documenting corrective action. If a lawsuit is filed later, you will have the facts at hand to show that your dealings with the FDA are an integral part of the regulatory process that preempts or otherwise protects the advertising at issue from challenge under state law.

Create a Legal "Road Map"

Before you start a trip, it usually is a good idea to have a road map handy. Even if you think you know the way, you might encounter a detour. A map can show you alternate routes to your destination. The same is true for a case. As soon as you get the complaint, take the time to conduct a thorough legal analysis of the regulatory compliance defenses and put it down in writing. The memorandum can serve as the basis for your dispositive motions and eventual appeal. These defenses are building momentum, so be sure to update your analysis regularly.

You might be able to keep your litigation trip short with a motion to dismiss, as occurred in *Pennsylvania Employee Benefit Trust v. Zeneca, Inc.* and in *New Jersey Citizen Action v. Schering-Plough Corp.* The motion to dismiss should be as thorough as possible to make sure that you do not waive any arguments that you might want to make on appeal.

If a successful motion to dismiss is unlikely because you are in a jurisdiction that is hostile to the preemption defense or you need to point to evidence of agency approval, then consider asking for bifurcation of the regulatory compliance issue. Many courts will permit limited discovery and summary judgment motions on this

type of threshold issue, which will save everyone time and expense. This procedure also is useful for framing up an interlocutory appeal if you are not successful with your motion.

Be Ready for an Interlocutory Appeal

If you put together a great dispositive motion, in your heart of hearts you think you are going to win it. If the motion fails, however, you need to be able to act quickly to preserve possible avenues for an interlocutory appeal.

Interlocutory orders are not appealable as a matter of right. It is possible, however, to petition for discretionary review of the denial of a motion to dismiss or motion for summary judgment in federal court pursuant to 28 U.S.C. §1292(b). This procedure requires a controlling issue that involves developing and significant legal principles that justify early intervention by the higher court. A number of appellate courts have accepted discretionary review of preemption issues under this procedure. *See*, *e.g.*, *Philip Morris, Inc. v. Harshbarger*, 122 F.3d 58 (1st Cir. 1997). The other regulatory compliance defenses discussed earlier in this article are equally worthy of interim appellate review. *See Perkins v. F.I.E. Corp.*, 762 F.2d 1250 (5th Cir. 1985).

Because appeals under §1292(b) are not routinely granted, it is important to convince the courts that your issue is special. Be sure to include the social policy arguments that favor your cause. Also, a little help from your friends never hurts. So, while your dispositive motion is pending in the trial court, you should be lining up potential *amici curiae* who can add weight to the significance of your issue if you have to file a petition under §1292(b).

Conclusion

There are many reasons "regulation by litigation" is not appropriate when it comes to prescription drug advertising. The regulatory compliance defenses discussed above, while still evolving, honor both social policy and established principles of law. If these defenses are presented to courts across the country in well developed and fully supported analyses, a cohesive body of law should emerge that will end piggyback litigation in this arena.