PHARMACEUTICAL ADVERTISING:
“MAY YOU LIVE IN
INTERESTING TIMES”

By
Arnold I. Friede, Esq.
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INTRODUCTION

There is an ancient Chinese proverb that condemns with the following curse: “May you live in interesting times.” These are interesting times in pharmaceutical advertising and promotion. And there are at least three intersecting and overlapping spheres of activity that need to be understood and appreciated in order fully to comprehend why.

I. REGULATION AND ENFORCEMENT

This sphere of activity includes the evolving—often subjective and uncodified—standards employed by the U.S. Food and Drug Administration’s (FDA’s) Division of Drug Marketing, Advertising, and Communication (DDMAC) to evaluate truth and accuracy, deception (“misleadingness”), substantiation, and fair

1For a comprehensive criticism of FDA’s actions in regulating drug advertising and promotion, including particularly its subjectivity and extra-statutory basis, as well as, but not limited to, its serious First Amendment implications, see, for example, a Citizen Petition filed by the Washington Legal Foundation (WLF) challenging certain policies and practices of the Division of Drug Marketing, Advertising and Communications (DDMAC) in the FDA Center for Drug Evaluation and Research (CDER). See Citizen Petition of Washington Legal Foundation at 1-3 (Aug. 7, 2006), available at http://www.wlf.org/upload/0806DDMACWatch_%20Citizen%20Petition.pdf. The WLF also has challenged certain individual advertising enforcement letters issued by the DDMAC. See Washington Legal Forum, FDA/DDMAC Watch (latest posted activity Nov. 21, 2006), http://www.wlf.org/Resources/DDMAC/default.asp (posting enforcement letters by regulators and response letters by WLF).
balance in prescription drug advertising, in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), and FDA’s implementing regulations governing advertising and promotion. Likewise, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (USDHHS) is exerting increasing influence over drug advertising and promotion in areas, for example, such as “off-label” claims and promotional activity directed at physicians, as is the U.S. Department of Justice and private qui tam relators in the course of numerous


3See Federal Food, Drug, and Cosmetic Act § 502(a), 21 U.S.C. § 352(a) (stating that a “drug or device shall be deemed to be misbranded . . . [i]f its labeling is false or misleading in any particular”); id. § 502(n), 21 U.S.C. § 352(n) (stating that a “drug or device shall be deemed to be misbranded” unless “advertisements and other descriptive printed matter” about that drug include, among other things, such “information in brief summary relating to side effects, contraindications and effectiveness” as is “required in regulations which shall be issued by the Secretary”).


investigations, prosecutions, and settlements under the Federal False Claims Act, the Federal Anti-Kickback Statute, and the FFDCA itself. The industry’s response to these pressures, including the Pharmaceutical Research and Manufacturers of America’s (PhRMA’s) voluntary Code on Interactions with Health Care Professionals and PhRMA’s more-recent voluntary PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines, need to be considered in any overview of regulation and enforcement activity. While these voluntary initiatives go beyond current legal requirements, and have undoubtedly

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8See 42 U.S.C.A. § 1320a-7(b).


enhanced overall compliance, they have not, in themselves, operated as a total relief valve for the industry.\textsuperscript{12}

\section*{II. LEGISLATION AND PUBLIC POLICY}

Both Congress and State legislatures are actively considering and, in some cases have already enacted, legislation intended to regulate pharmaceutical advertising and promotion even more closely.\textsuperscript{13} Recent legislation introduced by U.S. Senators Enzi and Kennedy, for example, which was ostensibly designed to enhance new drug safety, would allow FDA to impose a two-year post-approval moratorium on direct-to-consumer ("DTC") advertising for specific drugs newly approved by FDA.\textsuperscript{14} Other suggested legislation would mandate a graphic icon in prescription drug labeling and perhaps advertising to warn about a drug’s newness

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\textsuperscript{12}Some critics “assert that the voluntary industry guidelines do not go far enough in improving advertising practices.” PhRMA Guidelines May Redraw Line Between DTC, OTC Advertising, THE PINK SHEET, Aug. 22, 2005, at 7, available at http://www.thepinksheet.com/fdcreports/story/viewStory.do?targetAN=05130340005#_st0. Senator Grassley has said that the voluntary guidelines “acknowledge[] the need for greater transparency when it comes to drug safety, but [do not] deliver a single guarantee for consumers.” Id.
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\textsuperscript{14}The Enhancing Drug Safety and Innovation Act of 2006, S. 3807, 109th Cong. (2006). See id. § 101 (proposing to give FDA authority to impose temporary moratorium on direct-to-consumer advertisements of specific drugs after initial approval). There are serious First Amendment questions about the sustainability of a moratorium on DTC advertising, see, e.g., Thompson v. Western States Med. Ctr., 535 U.S. 357, 373, 122 S. Ct. 1497, 1507 (2002) (“If the First Amendment means anything, it means that regulating speech must be a last-not first-resort.”), even under a commercial speech analysis, see Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York, 447 U.S. 557, 564, 100 S. Ct. 2343, 2350 (1980).
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and the uncertain risks associated with that status. Yet other proposed legislation would impose a litany of additional disclosure requirements on pharmaceutical advertisers, many of which are at odds with FDA's own professed commitment to the concept of “less is more” in drug labeling and advertising.

State legislation regulating drug advertising and promotion is also proliferating. New Hampshire, for example, recently enacted a statute that has the

15See Institute of Medicine, The Future of Drug Safety: Action Steps for Congress at 2 (Sept. 2006) (recommending that Congress require product labels to “carry a special symbol such as the black triangle used in the UK or an equivalent symbol for new drugs, new combinations of active substances, and new systems of delivery of existing drugs”), available at http://www.iom.edu/Object.File/Master/37/331/11750_report_brief_congress.pdf.


17Section 2 of the legislation proposed by Senators Grassley and Dodd, see id., would mandate “that all promotional material with respect to the drug or biological product include certain disclosures, which shall be displayed prominently and in a manner easily understood by the general public.” Id. Those disclosures would include “a statement that describes the unreasonable risk to the health of the patients or the general public as determined by the Director of the Center,” a “statement that encourages patients to discuss potential risks and benefits with their healthcare provider,” a “statement explaining that there may be products available to treat the same disease or condition that present a more favorable benefit-to-risk profile,” a statement describing “any requirements of outstanding clinical and observational studies,” and a statement of “contact information to report a suspected adverse reaction.” Id.

18In the preamble to a recent rule, the FDA acknowledged, “In recent years, there has been an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information. . . .” Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314 & 601). The FDA changed its drug labeling rules “to enhance the ability of health care practitioners to access, read, and use prescription drug labeling.” Id. at 3923.

19Former FDA Commissioner Mark McClellan has explained how, in drug labeling, “less is more’ in terms of consumer understanding.” Comments of Pfizer Inc. at 3, In the Matter of Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements, FDA Docket No. 2004D-0042 (filed May 7, 2002) (internal quotations omitted), available at http://www.fda.gov/ohrms/dockets/dailys/04/may04/051004/04D-0042-emc00001-01.pdf. McClellan explained, “Less is more for consumers because they can actually get more out of this information.” Id. (internal quotations omitted). “The larger type, the clearer language, the focus on the more important risks that are a basis for further discussion with the health professional . . .
effect, among other things, of prohibiting pharmaceutical sales representative from using physician-identifiable prescribing information in the course of attempting to persuade a doctor to prescribe a particular drug. The specific justification for the statute the State is advancing in a constitutional challenge is the law’s utility in impeding the type of communications with physicians who are more likely to persuade doctors to prescribe brand name medicines. In other words, according to the State, the statute can survive a First Amendment challenge precisely because it has the purpose and effect of suppressing speech and thereby, supposedly, decreasing prescriptions for brand name medicines, increasing “scripts” for generic alternatives, and thereby saving the State and its citizens substantial amounts of money. If laws, like the New Hampshire statute are ultimately upheld by the U.S. Supreme Court on this basis, it will turn all of First Amendment law, not just doctrines concerning commercial speech, on its head. Yet other state legislation, like that enacted in Vermont, imposes specific reporting obligations in connection with expenditures related to pharmaceutical advertising and promotion.

[are] more beneficial to [consumers] . . . than just skipping over a brief summary section as most consumers seem to do today.” *Id.* (internal quotations omitted).


\(^{21}\)Memorandum of State of New Hampshire Supporting Opposition to Motion by Plaintiff for Preliminary Injunction at 7-17, *IMS Health Incorporated v. Kelly A. Ayotte*, No. 1:06-cv-00280 (D.N.H. filed Sept. 01, 2006).


\(^{23}\)See Office of Attorney General, *Attorney General Requires Pharmaceutical Manufacturer To Comply With Marketing Disclosure Law* (Jan. 8, 2007) (announcing a settlement requiring a pharmaceutical manufacturing company “to file disclosures about its
Moreover, in addition to considerations about specific state and federal legislation and enforcement activities, every major pharmaceutical advertisement or promotion must now also be judged against how it will be perceived “on the Hill” and by the public at large. In other words, pharmaceutical companies need to be cognizant of the fact that their advertising and promotional activities do not take place in a public policy vacuum. As a result, anything and everything companies do in this arena must pass some sort of test of how it will fare in the so-called “court of public opinion,” where a passing grade is often difficult to determine in advance.

III. LITIGATION

In addition to the longstanding threat of competitor litigation under Section 43(a) of the Lanham Act, and despite the influence on pharmaceutical advertising and promotion from regulation and enforcement, as well as legislation and public policy, the plaintiffs’ class action bar, as well as State attorneys general, may now be the most potent “regulators” of all in this arena. This is because of the massive consumer fraud class action litigation routinely brought against all manner of pharmaceutical advertising and promotional activity. The Vioxx litigation is

marketing activities in Vermont, as required by state law”), http://www.atg.state.vt.us/display.php?smod=63&pubsec=4&curdoc=1242.

perhaps the most conspicuous example. But others abound. The claims in these cases usually involve allegations that the defendant pharmaceutical manufacturer both overpromoted the drug’s effectiveness and understated its risks. The allegations about understatement of risk typically involve assertions that the company both made affirmative misrepresentations about safety and omitted allegedly material risk information. Indeed, virtually every pharmaceutical product liability case of any magnitude involving, for example, allegations of failure to warn, is now also pleaded as a consumer fraud class action.

Consumer fraud class action litigation involving pharmaceutical advertising and promotion is spawning its own body of law across an array of procedural and substantive areas. These include questions about the certifiability of these cases as class actions under Rule 23 of the Federal Rules of Civil Procedure and analogous State rules. The cases raise serious questions, for example, about whether and to what extent traditional concepts of causation and reliance, particularly in the context of the learned intermediary doctrine, continue to provide any meaningful constraints on pharmaceutical company liability under these statutes. They also involve profound questions about such tort law concepts as proximate cause and


how remote in the chain one can be and still be entitled to maintain an action. For example, in the Vioxx Third Party Payor litigation, now pending before the New Jersey Supreme Court, insurers and other third party payors have asserted that but for the alleged overstatements of effectiveness and understatements of risk, the drug would never have been added to the payors’ drug “formulary” in the first place and, therefore, the defendant pharmaceutical manufacturer is liable for all sums paid by the third party payor for the drug. The aggregate contingent liability in the context of the Vioxx Third Party Payor cases is itself estimated to be on the order of nearly $10 billion. So, we can readily see that these are not merely academic questions of interest just to law school professors. The issues have real world, bottom-line impact.

Consumer fraud class action litigation also has an immediate nexus to the broader debate over the nature and extent to which FDA’s regulation of pharmaceutical advertising and promotion “preempts” certain state law claims. In view of FDA’s paramount regulatory role in this arena, and as a sheer matter of institutional competence, there is a strong case that consumer fraud liability rooted in State law directly conflicts with, and therefore is preempted by, FDA regulatory


and enforcement activity.\textsuperscript{29} Indeed, FDA has recognized, in a variety of contexts relating both to consumer and professional communications, that “less is more.”\textsuperscript{30} Yet state law consumer fraud liability is often predicated upon the alleged failure to provide “more,” where “more,” as FDA itself has found, is often “less.” It seems difficult, if not impossible, to reconcile these two regimes.

**CONCLUSION**

In reflecting on this tsunami of activity, one would suppose that a unifying theme would be readily discernible. In other words, one would think that an overarching social and policy goal, shared by all of the various protagonists, would be almost self-evident. But at least to this observer, it is not. Indeed, much of the activity seems to be at direct cross-purposes. For example, the pressure in the litigation context would seem to dictate even more disclosure in pharmaceutical advertising and promotion about anything and everything having to do with the risk or benefit of the prescription drug in question. In theory, then, the physician in the context of doctor-directed communication and the consumer in the context of DTC advertising would be fully informed by the disclosure of all potentially “material” information, thereby forestalling any possible claim of deception through omission of information that someone somewhere might regard as

\textsuperscript{29}See, e.g., In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, 2006 WL 2374742, at *10 (N.D. Cal. Aug. 16, 2006) (concluding that plaintiffs’ claims premised on Pfizer’s failure to warn consumers and physicians of cardiovascular risk are dismissed as preempted).

\textsuperscript{30}See Comments of Pfizer Inc. at 3, supra, note 19.
meaningful. At the same time, at least one actor in the drama—FDA—has quite convincingly argued that, in many contexts, “less” may well be “more.” And this notion coincides both with a good deal of the empirical evidence, and with common sense and everyday experience. There is a profound question whether a drug advertisement that, in effect, is an encyclopedia of risks and benefits achieves, say in the context of DTC advertising, its primary purpose of motivating consumers to overcome the serious barriers that we know exist to getting people to the doctor in the first place for the diagnosis and treatment of such high priority medical conditions as cardiovascular disease and depression. Indeed, there is every reason to believe that confronted with a plethora of risk and benefit information, consumers may try to “play doctor” to determine both whether they actually have the advertised condition and whether, even if they do, the risk versus benefit tradeoff is something they want to assume. This is absolutely at odds with the proposition that, in the context of prescription drugs as distinguished from those available over-the-counter, it is the learned intermediary physician who should ultimately weigh the risks and benefits of a particular therapy and advise the

31See id.

32See, e.g., id.

33See, e.g., id.; see also Citizen Petition of the Coalition for Healthcare Communication (Mar. 31, 2006) (requesting the FDA to promulgate amended regulations for prescription drug advertising to establish separate criteria for practitioner-directed and consumer-directed advertising), available at http://www.cohealthcom.org/content/FinalCHCCitizenPetition.pdf.

34See, e.g., Citizen Petition at 4-8, supra, note 33.
patient accordingly. In this respect, then, a policy that drives encyclopedic disclosure, as a consequence of the pressures in the litigation arena, seems to be in clear and present tension with a “less is more” approach that has the demonstrated benefit of driving people to the doctor in the first place.

Accordingly, as a matter of policy and law, one can make the case that we need to arrive at a meaningful and coherent scheme that both articulates and then attempts to unify the objectives we are trying to achieve. One unifying construct would be to acknowledge the paramount institutional competence that FDA possesses to regulate in this arena. Even if we acknowledge that FDA is less than perfect, it does little to solve that problem to erode FDA’s credibility and authority by inviting even more guests to the party on the theory that, with more actors, each armed with more potent weapons, we will be capable of developing and implementing a rational prescription for regulating pharmaceutical advertising and promotion while at the same time continuing to advance the public health

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35See id.; see also Proposed Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America (PhRMA) in Support of Petitioners at 9-16, Johnson & Johnson Corp. v. Hon. Mark A. Karl, No. 06-2498 (W. Va. Jan. 8, 2007) (discussing how sound public policy supports the learned intermediary doctrine) (motion to file amicus brief was denied by the Court).

36See, e.g., Comments of Pfizer Inc. at 3, supra, note 19.


38See generally, e.g., INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC (Sept. 22, 2006) (finding that the drug safety system is impaired and there “is a perception of crisis that has compromised the credibility of FDA”), available at http://www.iom.edu/CMS/3793/26341/37329.aspx.
through the power of information. FDA’s paramount institutional competence might be described, in legal terms, as FDA “preemption”39 or by some other, less legally-loaded phrase. This deserves considered discussion and analysis in its own right, and is a matter of current debate in the courts40 and elsewhere and is beyond the scope of this overview. At the same time, this overview, if it demonstrates nothing else, shows that three spheres of activity—regulation and enforcement, legislation and public policy, and litigation—are intersecting, overlapping, and perhaps even colliding with each other in ways that may not be entirely optimal for the public health.

39See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, supra, note 18, at 3967 (stating that “FDA has determined that the exercise of State authority [over certain claims] conflicts with the exercise of Federal authority under the act”).