



Steven Meyers

WILL DIRECT TO CONSUMER ADVERTISING LEAD TO THE LOSS OF ONE OF THE PHARMACEUTICAL COMPANIES' BEST DEFENSES?

During the past decade, pharmaceutical company expenditures on direct to consumer ("DTC") advertising have increased, and so have pharmaceutical sales. These advertising budgets have drawn criticism from consumer protection groups and Congress. Some criticism has focused on the learned intermediary doctrine ("LID"). Opponents argue that the LID allows pharmaceutical companies to advertise irresponsibly without the fear of liability. Proponents maintain that DTC advertising is simply a broader means to disseminate treatment options for common health problems.

Late last year, the FDA held hearings to investigate the effects of DTC advertising, thus far with no tangible outcome. There appears to be periodic pressure from some quarters to curb such advertising. One important issue is whether the advertising practices of pharmaceutical companies will ultimately undermine one of their strongest defenses.

The Learned Intermediary Doctrine and Its Underlying Rationale

In a recent volume of this

newsletter, Daniel R. Caravan provided an excellent summary of the learned intermediary doctrine, its justification, and its most notable exceptions.¹ To briefly summarize, the learned intermediary doctrine is a well-established defense in failure to warn claims.² Although exceptions exist, the LID generally allows product manufacturers to satisfy its duty to warn the consumer by providing adequate warnings a "learned intermediary."³ In the context of pharmaceutical sales, these "learned intermediaries" are the physicians that prescribe medicine to patients.

Scholars and courts identify three primary justifications for the learned intermediary doctrine.⁴ All stem from the traditional physician-patient relationship, or what has been called the "Norman Rockwell image" of healthcare.⁵ First is the recognition that a prescribing physician is in the best position to evaluate the risks and benefits associated with a particular drug in the

context of the patient's individual medical history.⁶ Second is the observation that pharmaceutical companies often lack the means to communicate thorough warnings to patients, given their lack of direct access to the patients and the complexities of the warnings at issue.⁷ Third is the fear that imposing a legal duty upon pharmaceutical-makers might adversely affect the traditional physician-patient relationship.⁸ Each of these

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Figure 1 – Doctor and the Doll by Norman Rockwell.

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justifications certainly held true when the LID first developed and many believe they remain valid. Some argue, however, that developments in the healthcare industry have eroded each of these justifications. Most notable, perhaps, of these modern developments is the genesis of DTC advertising in the context of pharmaceutical sales.

A Brief History of Direct to Consumer Advertising

Direct to consumer advertising is a recent phenomenon. Traditionally, pharmaceutical companies focused their advertising efforts on the prescribing physicians, not the patients. Thus, in 1963, the first governmental regulation of

pharmaceutical advertising merely prevented false claims from being made to prescribing physicians.⁹ Following the first DTC advertisements in the early 1980's, the FDA imposed a "voluntary moratorium" on DTC advertising so that further investigation could be performed.¹⁰ In 1985, this moratorium was lifted.¹¹ The FDA commented at the time that existing laws adequately addressed the legal issues involving DTC advertising.¹²

The first true attempt to regulate DTC advertising arrived in 1994 pursuant to an amendment to the Federal Food, Drug and Cosmetic Act ("FDCA").¹³ This Act still governs and divides DTC advertising based upon its

particular medium. Print DTC must include a "brief summary" of product indications, contra-indications, and effectiveness for the particular drug.¹⁴ In practice, the requisite summaries have not been brief, often resulting in a full page of medical information.

Broadcast DTC advertising presented different concerns. Namely, in addition to the "brief summary" requirement, broadcast DTC ads were required to include a "major statement" of the results of clinical testing and side-effects associated with the drug.¹⁵ The "major statement" is the familiar, usually voiced-over, warnings that can be heard in all drug commercials.

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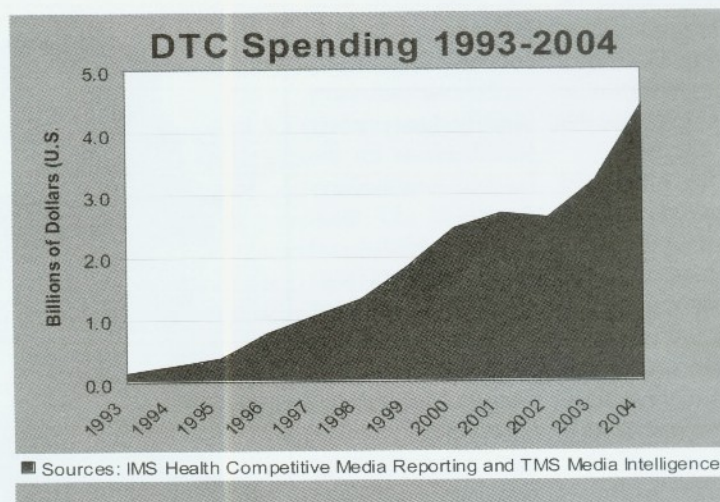


Figure 2 – DTC Spending Increases from 1993-2004.

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After the amendment to the FDCA, pharmaceutical-makers found compliance with print advertising requirements to be feasible. Compliance with broadcast advertising regulations was more problematic. Ultimately, the regulations proved cost-prohibitive as a thirty-second commercial often does not offer enough time to provide the requisite "brief summary." Thus, broadcast DTC remained mostly dormant.

In 1997, however, the FDA released a new guidance document that would completely change the airwaves. Entitled "Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements," the document eased the practical problems associated with broadcast advertising compliance.¹⁶ The Draft Guidance instead allowed manufacturers to make an "adequate provision" to ensure that such information was available through means besides the "direct summary."¹⁷ The Draft Guidance explained that "adequate provision" would be satisfied if a broadcast advertisement included: (1) a toll-free number providing more specific information about the drug, (2) an internet webpage address with specific information, (3) an alternative means of dispensing package labeling to consumers not connected to the internet, or (4) a statement directing consumers to consult their pharmacists and physicians to determine if the particular drug was right for them.¹⁸

In 1999, the Draft Guidance was adopted by the FDA in substantially the same form as the 1997 version.¹⁹ These new guidelines removed some of the previous hurdles associated with broadcast DTC advertising, and DTC became more independent.

The increase in DTC spending, however, has been met with continued scrutiny. Some Congressional leaders advocate stronger regulation. Senate Majority Leader Bill Frist has commented that current DTC advertisements offer "fantasyland images" and need to be replaced.²⁰ Senator Charles Grassley offered, "It doesn't make sense to rely on drug companies to police themselves."²¹ Senators have also proposed full moratoriums – unsuccessfully – on DTC advertising for two years after the introduction of a new drug to the market.²² Even doctors have now entered the fray. Recently, two-hundred medical school professors signed an anti-DTC statement, suggesting the DTC advertising is inimical to effective healthcare.²³

Notwithstanding these incidents, the FDA has not finalized any further substantive regulation concerning DTC advertising. In 2003, the FDA held public hearings in the hopes of providing additional industry guidance, but nothing new has resulted.²⁴ Similar hearings again occurred in November 2005. The FDA did, however, issue a Final Rule on January 24, 2006 concerning prescription drug content

and labeling. With respect to DTC advertising, the FDA believes that preemption precludes "claims that a drug sponsor breached an obligation to warn by failing to include in [DTC] advertis[ing] any information the substance of which appears anywhere in the labeling . . . where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the 'brief summary' in direct-to-consumer advertising."²⁵ The FDA position on preemption embodied in the 2006 Final Rule has yet to be tested in the courts.

Perez v. Wyeth Labs: Template for a New Trend?

In 1999, in the midst of the fast-paced expansion of DTC advertising, the New Jersey Supreme Court became the first – and thus far the only – state supreme court to recognize a DTC exception to the learned intermediary doctrine.²⁶ At issue in *Perez v. Wyeth Labs* were the warnings that Wyeth provided in conjunction with its marketing of the Norplant contraceptive system. The Norplant system involved the implantation of contraceptive capsules under the skin of the patient's upper arm.²⁷ The plaintiffs alleged that Wyeth engaged in a "massive advertising campaign," beginning in 1991, which included television commercials and print advertisements in women's magazines.²⁸ The plaintiffs complained that while the ads described the benefits of the

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product, they did not warn about the side effects, which included weight gain, headaches, and a host of other difficulties.²⁹ Also asserted was that the ads neglected to mention the subsequent pain and scarring accompanying the removal of the product.³⁰

The trial court dismissed the plaintiffs' failure to warn claims, and the intermediate appellate court affirmed.³¹ The trial court cited the traditional position that the learned intermediary doctrine prevented the plaintiffs from stating a claim unless the prescribing physicians were inadequately warned — the "massive advertising campaign" notwithstanding.³² In support, the trial court observed, "a physician is not simply relegated to the role of prescribing the drug according to the woman's wishes."³³ Instead, the trial court concluded that the physician was the one ultimately responsible for weighing the risks and benefits of the drug before prescribing it to a patient.³⁴

The New Jersey Supreme Court reversed. The court stated, "Our medical-legal jurisprudence is based on images of health care that no longer exist."³⁵ Citing the changes in health care, the court ultimately created a DTC exception to the LID.³⁶

Immediately following *Perez*, many believed that the New Jersey Supreme Court's decision was destined to be adopted elsewhere. Mark Hutton, attorney for many of the Norplant plaintiffs, opined that

Perez was "probably the beginning of the break in the dam."³⁷ Some legal commentators made similar assertions, explaining that *Perez* marked "the turning of the tide toward the general acceptance of the DTC exception to the LID, an exception long advocated by commentators."³⁸ In retrospect, this expansion never occurred, and in 2002, the Eastern District of Texas recognized that *Perez* continues to stand alone.³⁹

The reason that *Perez* never found further traction might be attributed to the lag between its outcome and its basis. The facts of *Perez* date to 1991, six years after the 1985 rescission of the FDA's voluntary moratorium but three years prior to the 1994 amendments to the FCDA. By the time the New Jersey Supreme Court decided the matter in 1999, however, the amended FDCA and the 1997 FDA Draft Guidance had been implemented. Thus, the environment that led to *Perez* had arguably evaporated.

Jurisprudential Evidence on the Propensity of the Courts to Create LID Exceptions

Although *Perez* remains the only instance where a state's highest court has recognized DTC advertising exception to the LID, the jurisprudence demonstrates that courts are not afraid to create exceptions to the LID when a need to do so is perceived. For instance, both the Fifth and Ninth Circuits have interpreted state laws to contain an LID exception in the

context of mass immunizations — citing the absence of a true learned intermediary.⁴⁰ Oral contraceptives and contraceptive devices also have been the subject of a LID exception in some states due to the minimal role a physician plays in the prescription of these drugs.⁴¹ In California, the "overpromotion" of new drugs is a recognized exception for reasons similar to those of *Perez*.⁴² Even the most recent Restatement suggests that exceptions to the LID should continue to develop via the case law of individual jurisdictions.⁴³

Ultimately, when courts have perceived particular circumstances to be incongruous with the justifications of the LID, there has been no hesitancy to create exceptions. Some would certainly argue that the escalation of DTC advertising creates an environment that is ripe for the jurisprudential expansion of *Perez*'s DTC exception. Thus, the pertinent question now is whether *Perez* will finally see the previously forecast expansion, whether the *status quo* will reign, or whether something else will change the current environment.

So What Does the Future Hold?

The pharmaceutical industry has taken significant steps to regulate its own DTC advertising. For instance, Bristol-Myers now has self-imposed a one-year moratorium on the DTC marketing of new drugs.⁴⁴ Pfizer also has taken a wholly new tack in its advertisements.⁴⁵ Pfizer's new

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advertising goals include providing more risk/benefit information to patients, fostering the physician-patient relationship, and motivating people to overcome potential health barriers.⁴⁶ Many new ads are geared at simply promoting greater awareness of common health conditions.⁴⁷ These sorts of initiatives by pharmaceutical companies may avert the perceived need for either the expansion of a DTC exception or Congressional action.

Industry associations also have undertaken new efforts to remain at the forefront of this issue. In August 2005, PhRMA, a coalition of pharmaceutical research and biotechnology companies, released its "Guiding Principles" concerning DTC advertisements about prescription medicines.⁴⁸ These guidelines create a focus on awareness, education, and further fostering the physician-patient relationship.⁴⁹ They also recommend a ban on the controversial "reminder advertisements," which found themselves at the center of much of the DTC debate.⁵⁰ Previously, such reminder advertisements simply identified the name of a particular drug without making any representations as to effectiveness or risk. The PhRMA guidelines also state that pharmaceutical companies should submit all new DTC television advertisements to the FDA for pre-approval.⁵¹ Ultimately, while these "Guiding Principles" are not binding on pharmaceutical companies, they reflect continuing industry sensitivity to these issues.

Conclusion

Is the stage set for broader acceptance of a DTC exception? As yet, *Perez* remains an anomaly, but the issue continues to evolve. Lawyers on both sides of the bar should stay tuned, and litigants should consult their attorneys to see if a DTC exception is right for them.

Steven Meyers is an associate at Irwin, Fritchie, Urquart & Moore LLC in New Orleans. Mr. Meyers' e-mail address is smeyers@irwinllc.com.

regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers how are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.""); James M. Beck & Anthony Vale, *Drug & Medical Device Product Liability Deskbook* §2.03[1], at pp. 2.02 -10 to -15 & nn. 21-25 (2004 & Supp. 2005) (listing precedent in 47 states and the District of Columbia accepting the learned intermediary doctrine).

³ For a more complete discussion of many of the recognized exceptions to the LID. See Restatement (Third) § 6, cmt d, e. The Restatement, itself, did not adopt

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¹ Daniel R. Caravan, *Drug Dealer Liability: Pharmacists, Learned Intermediaries, and the Duty to Warn*, 3 Mass Tort Litigation Newsletter 2 at 9-11 (2005).

² See Restatement (Third) of Torts: Prod. Liab. § 6(d) (1998) ("A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonably instructions or warnings

any of the particular exceptions discussed in comment e, instead stating, "The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized." Restatement (Third) § 6, cmt e.

⁴ See, e.g., *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 762 (Ky. 2004); see also *Perez*

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v. *Wyeth Labs., Inc.*, 734 A.2d 1245, 1255 (N.J. 1999) (expounding four justifications for the LID that are simply different formulations of the same considerations).

⁵ See *Perez*, 734 A.2d at 1255 (“[The] Norman Rockwell image of the family doctor no longer exists.”), quoting Paul D. Rheingold, *The Expanding Liability of the Drug Manufacturer to the Consumer*, 40 Food Drug Cosm. L.J. 135, 136 (1985). Further elaborating on the meaning of the “Norman Rockwell image,” the *Perez* court explained, “At an earlier time, medical advice was received in the doctor’s office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the ‘doctor knows best.’” Pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians. In this comforting setting, the law created an exception to the traditional duty of manufacturers to warn consumers directly of risks associated with the product as long as they warned health-care providers of those risks.” *Id.* at 1246.

⁶ *Larkin*, 153 S.W.3d at 762.

⁷ *Id.* at 764.

⁸ *Id.*

⁹ See Federal Trade Commission Act, 15 U.S.C. § 55(a)(1) (1964) (“No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.”).

¹⁰ See *Perez*, 734 A.2d at 1258.

¹¹ *Id.*

¹² Michael S. Wilkes, Robert A. Bell, and Richard L. Kravitz, *Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications*, 19 Health Affairs 2 at 4 (March/April 2000) (citing Federal Register 56 (9 September 1985) 36677).

¹³ 21 U.S.C. § 352(n) (1994).

¹⁴ *Id.* at § 352(n)(3).

¹⁵ See 21 C.F.R. § 202.1 (e)(1) (2005).

¹⁶ The 1997 version of the FDA Guidance was adopted without substantial modification in 1999. See Fushman, *supra*, *Perez v. Wyeth Labs., Inc.*, 80 B.U.L. Rev. at 1174. Although the 1997 version is no longer available to review, the 1999 version is available (as of 1/22/2006) and can be found at <http://www.fda.gov/cder/guidance/1804fnl.pdf>.

¹⁷ In fact, federal regulations have long allowed for the substitution of the so-called “adequate provision” requirement for the cumbersome “brief summary,” but those same regulations never fully elaborated on what would suffice as “adequate provision.” See 21 C.F.R. §202.1 (e)(1) (2005). The FDA Guidance simply provided content to this long-standing alternative. See Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements, *supra*, p. 1-3, available at www.fda.gov/cder/guidance/1804fnl.pdf.

¹⁸ See *id.*

¹⁹ See note 16, *supra*.

²⁰ Ira Teinowitz, Rich Thomaselli, *Senate Majority Leader Endorses Two-Year DTC Ad Ban*, Adage.com (7/1/2005).

²¹ Rich Thomaselli, *Drug Industry Ad Code Seen As Negotiating Ploy*, Adage.com (8/8/2005).

²² Teinowitz, Thomaselli, *Senate Majority Leader Endorses Ban*, Adage.com (7/1/2005), *supra*.

²³ Rich Thomaselli, *200 Med School Professors Condemn DTC Advertising*, Adage.com (10/27/2005).

²⁴ Rich Thomaselli, *FDA to Hold New DTC Advertising Hearings*, Adage.com (10/5/2005).

²⁵ “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,” 71 Fed. Reg. 3922, 3936 (FDA Jan. 24, 2006) (citing “Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,” 69 Fed. Reg. 6308 (FDA Feb. 10, 2004)).

²⁶ See Christopher Q. Pham, *The Learned Intermediary Doctrine and DTC*

Advertising, 26-FEB L.A. Law. 16, 18 (2004) (citing Allen Wong, Recent Developments in Health Law: Harvard Law & Health Care Society: Products Liability: *The Fate of the Learned Intermediary Doctrine*, 30 J.L. Med. & Ethics 471 (Fall 2002)); Beck & Vale, *Drug & Medical Device Liability Handbook* §2.03[3][e].

²⁷ *Perez*, 734 A.2d at 1247.

²⁸ *Id.* at 1248 (listing Glamour, Mademoiselle, and Cosmopolitan as various women’s magazines that printed the advertisements).

²⁹ *Id.*

³⁰ *Id.*

³¹ *Perez v. Wyeth Laboratories, Inc.*, 713 A.2d 588 (N.J. Super.L. 1997), *aff’d*, 713 A.2d 520 (N.J. Super.A.D. 1998).

³² See *Perez*, 713 A.2d at 593-94.

³³ *Id.* at 594.

³⁴ *Id.*

³⁵ *Perez*, 734 A.2d at 1245.

³⁶ See *id.* at 1257. In addition, the *Perez* court also held: (1) that a physician must prescribe a prescription drug does not break the causal chain between the consumer injury and the manufacturer’s warning, *Id.* at 1262-63, and (2) that compliance with FDA regulations concerning DTC advertising would afford pharmaceutical manufacturers a rebuttable presumption that their consumer warnings were adequate, *Id.* at 1259. As to the latter, it is notable that the referenced FDA regulations were enacted subsequent to the inception of the Norplant advertising campaign. Nevertheless, some might suggest that if *Perez* were to experience an expansion that this aspect of the decision would continue to shield pharmaceutical-makers. However, the scope of such protection remains questionable because the presumption is rebuttable and because of the apparent dissatisfaction of many with current FDA regulations.

³⁷ Julie Brienza, *N.J. Court Finds Exception to Learned Intermediary Doctrine*, Trial, Nov. 1, 1999, at 94.

³⁸ Fushman, *supra*, *Perez v. Wyeth Labs., Inc.*, 80 B.U.L. Rev. at 1163-64 and citations therein.

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³⁹ *In re Norplant Contraceptive Product Litigation*, 215 F.Supp.2d 795, 827 (E.D. Tex. 2002) ("[A]s evidenced by the law in the Fifth Circuit and every other jurisdiction in the United States, apart from New Jersey, direct-to-consumer advertising does not negate the applicability of the learned intermediary doctrine."). See *Larkin*, 153 S.W.2d at 766 ("recognized only in New Jersey"); *In re Meridia Products Liability Litigation*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) ("Five years have passed In the intervening period, no other state has followed New Jersey's lead"); *Albertson v. Wyeth, Inc.*, 63 Pa. D. & C.4th 514, 539 (Pa. C.P. 2003) (adhering to learned intermediary doctrine in DTC case).

⁴⁰ See, e.g., *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 130-31 (9th Cir. 1968) (involving mass vaccination program for polio); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974) (administering mass vaccination program for polio), *cert. denied*, 419 U.S. 1096 (1974). The

Vaccine Act abolished this exception, 42 U.S.C.A. §300aa-22(c), and changes in the way vaccines are administered have largely eliminated the facts which brought it about. The last court actually to apply it was *Brazzell v. United States*, 788 F.2d 1352, 1358-60 (8th Cir. 1986).

⁴¹ See *Stephens v. G.D. Searle*, 602 F. Supp. 379, 380-81 (E.D. Mich. 1985); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878-79 (E.D. Mich. 1985); *MacDonald v. Ortho. Pharm. Corp.*, 475 N.E. 2d 65, 68 (Mass 1985), *cert. den'd*, 474 U.S. 920, 106 S.Ct. 250, 88 L.Ed. 2d 258 (1985); *Hill v. Searle Laboratories*, 884 F.2d 1064, 1070-71 (8th Cir. 1989).

⁴² *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65-66 (1973).

⁴³ See Restatement (Third): Prod. Liab. § 6(d)(2), note 2 *supra*; see also Restatement (Third) § 6, cmt e ("The Institute has left to developing case law whether other exceptions to the learned intermediary rule should be recognized.").

⁴⁴ Rich Thomaselli, *DTC Rift as Bristol Ban Breaks Ranks*, Adage.com (6/20/2005).

⁴⁵ Rich Thomaselli, *Pfizer Announces New DTC Ad Policy*, Adage.com (8/11/2005).

⁴⁶ See *id.*

⁴⁷ See *id.*

⁴⁸ PhRMA Guiding Principles: Direct to Consumer Advertising about Prescription Medicines, released August, 2005, available (as of 1/22/2006) at <http://www.phrma.org/publications/policy/admin/2005-08-02.1194.pdf>

⁴⁹ See *id.*

⁵⁰ See *id.*, PhRMA Guiding Principle 10 ("DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.").

⁵¹ See *id.*, PhRMA Guiding Principle 8.

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