

# AN ARGUMENT FOR BANNING DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS

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## INTRODUCTION

Spending by pharmaceutical companies on direct-to-consumer (DTC) advertising of prescription drugs has surged dramatically in recent years, increasing from \$17 million in 1985 to \$2.5 billion in 2000.<sup>1</sup> Spending on DTC advertising also represents an increasing percentage of total sales of pharmaceuticals, increasing from 1.2% of sales in 1996 to 2.2% in 2000, an 83% increase.<sup>2</sup> The purpose of this discussion is to propose a moratorium on DTC advertising of prescription drugs on two grounds: (1) DTC advertising may serve to undermine the physician-patient relationship and may lead to prescribing decisions being driven more by marketing forces than by rational, data-driven medical decision-making; and (2)

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<sup>1</sup> RJ Vogel, S Ramachandran , WM Zachary, *A 3-stage Model for Assessing the Probable Economic Effects of Direct-to-consumer Advertising of Pharmaceuticals*, 25 Clin. Ther. 309 (2003).

<sup>2</sup> MG Rosenthal, et al., *Promotion of Prescription Drugs to Consumers*, 346 N Engl J Med. 498 (2002). 2002.

pharmaceutical companies may face additional liability risk in failure-to-warn cases if further exceptions are carved out of the “Learned Intermediary” rule as has already occurred in New Jersey.<sup>3</sup>

Opponents of the expansion of DTC advertising argue that the practice has an adverse effect on the patient-physician relationship in that it encourages patients to pressure their physicians to prescribe specific medicines. Such pressure serves to potentially displace the physician’s professional judgment as the primary driver for prescribing decisions and could arguably impair the overall quality and efficiency of medical care for the patient. Such artificial market forces could also serve to inflate drug costs and increase overall spending on prescription drugs.

Historically, the learned intermediary rule (LIR) has shielded pharmaceutical companies from a duty to warn consumers directly about risks associated with the use of prescription drugs. Instead, drug companies have been allowed to provide information about risks and benefits of prescription drugs directly to physicians, who in turn have a duty to provide appropriate information to their patients. The LIR carries with it a presumption that the final arbiter of prescribing decisions is the physician, and that the physician will make such decisions in the context of a one-on-one relationship with his or her patients.

The relatively recent surge in DTC advertising of prescription drugs and trends in medicine

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<sup>3</sup> *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999).

toward a managed care model call into question the continuing applicability of the LIR.

Indeed, as discussed in more detail below, New Jersey has taken a first step toward abandonment of the LIR in the case of drugs advertised directly to consumers with its decision in *Perez v. Wyeth Laboratories, Inc.*<sup>4</sup> The court's analysis in this case highlights the increased liability risk for pharmaceutical companies in continuing to advertise directly to consumers.

## I. BACKGROUND [CTRL-ALT-1]

### A. History of DTC Advertising[ctrl-alt-2]

Spending on direct-to-consumer advertising of prescription drugs increased dramatically between 1996 and 2000, increasing by 212%.<sup>5</sup> This increase appears to have been driven in large part by updated guidelines for broadcast advertising that were advanced by the Food and Drug Administration (FDA) in 1997.<sup>6</sup>

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<sup>4</sup> Id.:

“(1) [the] ‘learned intermediary’ doctrine does not apply to direct marketing of prescription drugs to consumer[s]; (2) [a] rebuttable presumption exists that when [a] manufacturer complies with Food and Drug Administration (FDA) advertising, labeling, and warning requirements, [the] manufacturer has satisfied its duty to warn consumer about potentially harmful side effects of its product; and (3) when [a] drug manufacturer has advertised its drug directly to consumers, [the] role of [the] physician in prescribing drugs does not break the chain of causation for manufacturer's failure to warn patient of harmful side effects.”

<sup>5</sup> Rosenthal, supra.

<sup>6</sup> 62 FR 43171-01, *Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability* (1997).

The updated guidelines were an attempt to clarify the requirements that broadcast advertisements disclose major risks of the drug involved and that “‘adequate provision’ [is] made for ‘information in brief summary relating to side effects, contraindications, and effectiveness’ that is included in package labeling.”<sup>7</sup> The “adequate provision” requirement recognizes the inability of broadcast advertisements of reasonable length to present and communicate effectively the extensive information that would be included in a brief summary; it instead specifies that presentation of the advertised product’s most important risk information as part of the “major statement,” together with “adequate provision” for the dissemination of the approved labeling, can fulfill the risk information disclosure mandated by the act. The guidelines provided that the “adequate provision” requirement could be met by referring viewers to four sources for additional information: a toll-free number, a web site, a print advertisement in a major national publication or the patient’s physician or pharmacist.<sup>8, 9</sup>

Regulation of DTC advertisement has undergone various transformations over the years, starting with passage by Congress in 1938 of the Food, Drug and Cosmetic Act (FDCA). The FDCA required for the first time that new drugs be proven safe before marketing. The Kefauver-Harris Drug Amendments in 1962 further required manufacturer’s to prove drug effectiveness before marketing. In 1970, FDA required the first patient package insert to

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<sup>7</sup> Rosenthal, supra.

<sup>8</sup> Rosenthal, supra.

<sup>9</sup> 21 CFR § 202.1 (2006).

advise patients of risks and benefits associated with the use of oral contraceptives.<sup>10</sup> In 1983, FDA initiated a voluntary moratorium in DTC advertising as a result of concerns that little was known about the effects of such advertising on the public. In September or 1985, FDA lifted the moratorium, finding that “for the time being, current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers. The agency will continue to regulate prescription drug advertising in accordance with the Federal Food, Drug, and Cosmetic Act and applicable regulations.”<sup>11</sup>

As discussed previously, an FDA guidance document was published in 1997 which relaxed requirements for communicating a comprehensive description of risks and side effects of a medicine in a consumer broadcast advertisement. Prior to 1997, the “adequate provision” requirements in the regulations were generally interpreted as preventing broadcast advertisements that mentioned both the product name and the indication.<sup>12</sup> However, the 1997 guidance provided that the “adequate provision” requirements could be met to allow broadcast ads mentioning both the drug name and indication by “includ[ing] a thorough major statement conveying the product’s most important risk information in consumer-friendly language” followed by an “approach [for meeting the ‘adequate provision’ requirement] that will allow

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<sup>10</sup> <http://vm.cfsan.fda.gov/milestone.html>.

<sup>11</sup> Direct-to-consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 FR 36677-02 (Sept. 9, 1985).

<sup>12</sup> Vogel, supra.

most of a potentially diverse audience to have reasonably convenient access to the advertised product's approved labeling" (e.g. a website URL, toll-free telephone number or reference to a major national print publication).<sup>13</sup>

***B. Economic Impact of DTC Advertising of Pharmaceuticals***

Between 1994 and 2000, spending on DTC advertising of drugs increased from \$266 million to \$2.5 billion.<sup>14</sup> The distribution of spending of advertising dollars has also changed dramatically over the same time period. In 1994, pharmaceutical companies spend 86.6% of their consumer advertising dollars on print advertising and only 13.4% on television advertising. By 2000, the distribution had changed dramatically, with 36.4% being spent on print ads and 63.6% spent on television advertising.<sup>15</sup> Total spending on advertising for 2000 (including promotions to physicians) amounted to \$15.7 billion.<sup>16</sup> According to an October, 2006 report by the Congressional Budget Office, National Science Foundation estimates indicate that pharmaceutical companies spent approximately \$15 billion on research and

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<sup>13</sup> Neal D. Fortin, Food & Drug Regulation: Law, Science, Policy, and Practice, IX-78 (2005) (electronic casebook, on file with the author and the Institute for Food Laws and Regulations, Michigan State University).

<sup>14</sup> Vogel, supra, at 316.

<sup>15</sup> Vogel, supra, at 316-7.

<sup>16</sup> Vogel, supra, at 311.

development<sup>17</sup>, meaning that DTC promotional spending represented 16.7% of research spending in 2000, with total spending on advertising for that year representing 105% of total research budgets.

There are indications that DTC advertising impacts drug pricing and consumer behavior. An economic modeling study by Vogel et al. suggests that “DTC advertising affects [both] the price and quantity demanded of pharmaceutical products indirectly via its effect on changes in consumer demand.”<sup>18</sup> While there are positive aspects to such trends, including increased patient awareness of potential medical conditions and available treatments, these observations do raise concerns about the appropriateness of prescribing decisions being more consumer-directed and less medically based and concerns about unnecessary price inflation of patented prescription drugs. These points will be discussed in more detail below.

### *C. Learned Intermediary Rule*

The term “learned intermediary” first appeared in a 1966 opinion of the 8<sup>th</sup> Circuit Court of Appeals in *Sterling Drug, Inc. v. Cornish*.<sup>19</sup> The court held in *Sterling* that in the case of a prescription medication, the patient’s physician serves as a learned intermediary between the patient and the drug manufacturer, and thus that the manufacturer has a duty to warn

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<sup>17</sup> CBO Study: Research and Development in the Pharmaceutical Industry, October 2006.

<sup>18</sup> Vogel, *supra*, at 326.

<sup>19</sup> *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82,85 (8<sup>th</sup> Cir. 1966).

prescribing physicians about risks and potential side effects of the manufacturer's product. The physician would in turn be expected to advise his or her patients accordingly. The *Sterling* court found that the manufacturer's liability rested on its duty to warn the physician, "regardless of anything the doctors may or may not have done."<sup>20</sup> According to the Restatement (Third) of Torts, "[t]he rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."<sup>21</sup> In other words, the traditional view is that the physician is in a much better position to advise a particular patient of risks than is the manufacturer.

#### ARGUMENT AND ANALYSIS

##### *A. Effects of DTC Advertising on the Physician-Patient Relationship*

###### **1. Influence of patient perceptions and behavior**

Consumer-directed advertisements of prescription drugs are increasingly pervasive. One national study cited by Mello, et al. indicated that 91 % of U.S. individuals report having seen such advertisements.<sup>22</sup> Clearly, such pervasive advertisement of certain drugs or categories of drugs carries significant risk of increasing patient demands for specific brand name drugs.

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<sup>20</sup> *Id.*

<sup>21</sup> Restatement (Third) of Torts § 6 cmt. b (1998).

<sup>22</sup> JD Mello JD, *Direct-to-Consumer Advertising and Shared Liability for Pharmaceutical Manufacturers*, 289 JAMA 477 (2003).



Indeed, 25% of patients in one survey indicated that they had “initiated conversations with their doctors about a drug they saw on television.”<sup>23</sup> It is true that less than 6% of these particular survey patients actually received the requested prescription. However, patient requests clearly did influence prescribing decisions to at least a small extent. Whether the influence was appropriate or not in these individual cases is not known.<sup>24</sup> In either case, significant physician time was consumed in patient-initiated discussions about specific drugs, a substantial portion of which would have been spent (arguably wasted) dissuading patients from a particular treatment choice. Not only is this disruptive to the physician-patient relationship, it can also have a negative effect on patient satisfaction. A 1999 patient survey reported that “46% of patients would be disappointed if they failed to receive a requested prescription and 25% anticipated that they would attempt to change their physician’s mind.”<sup>25</sup>

A study by Woloshin, et al., indicated that many consumer advertisements tended to describe the benefits of the drug in “vague, qualitative terms” (e.g. “help your child out of the jungle of allergies; “naturally the response has been positive....”)<sup>26</sup> Other techniques cited

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<sup>23</sup> Rosenthal, supra, at 504.

<sup>24</sup> Rosenthal, supra.

<sup>25</sup> AR Robinson, et al., *Direct-to-consumer Pharmaceutical Advertising: Physician and Public Opinion and Potential Effects on the Physician-Patient Relationship*, 164 Arch. Intern. Med. 427, 428 (2004).

<sup>26</sup> S Woloshin S, et al., *Direct-to-consumer Advertisements for Prescription Drugs: What*

include: (1) appealing to a drug's widespread use, (2) use of vague phrases such as "clinically proven" or "proven effective" that do not reference quantitative measures, or (3) use of personal testimonials from ordinary people as opposed to experts.<sup>27</sup> 67% of the advertisements reviewed in the Woloshin study also utilized emotional appeals to consumers such as focusing on patients' desire to "get back to normal" or on a feared outcome such as cancer.<sup>28</sup>

At the same time, there appears to be significant confusion on the part of consumers about effectiveness and safety information presented in the ads and a mistaken belief by many "that only 'completely safe' drugs can be advertised".<sup>29</sup>

Clearly, the techniques described could significantly influence patients' view of advertised drugs, in downplaying relative risks, exaggerating the potential therapeutic benefit, and perhaps even in convincing a particular patient that a specific brand name drug, or any pharmacological intervention at all for that matter, is appropriate when it may not be. As the learned expert who is in the best position to understand and interpret complex information about drug indications and contraindication, the physician is an important consumer safeguard in the prescription drug realm, and one whose role is arguably usurped by DTC advertisements of prescription drugs.

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*are Americans Being Sold?*, 358 Lancet 1141 (2001).

<sup>27</sup> Woloshin, supra, at 1144.

<sup>28</sup> Woloshin, supra.

<sup>29</sup> Mello, supra, at 479.

## 2. Effects on prescribing decisions and physician perceptions

Physicians as a group tend to view DTC advertising in a negative light overall. According to Robinson, et al.<sup>30</sup>, a majority of physicians surveyed felt that DTC advertisements increase overall drug consumption (61.9%), do not provide enough information on cost (94.9%), lead to patients' request for specific drugs (80.7%), do not do a good job of informing patients of side effects (54.8%), do not provide sufficient information on alternative treatments (94.9%), increase patient visit times (55.9%), and need better regulation (68.8%). While there are positives in the physician perceptions, such as the view that DTC ads motivate patients to seek care (64.4%) and the obvious advantages that could arise from increased dialog between patient and physician and possibly even from increased visit times, the overall cost-benefit analysis from the physicians' point of view disfavors the practice of advertising drugs directly to consumers.

Physicians clearly are feeling the pressure from patients to address requests for specific name-brand drugs, requests which often stem from the omnipresent DTC advertisements. A 1997 study by Lipsky and Taylor<sup>31</sup> reported that 71% of family physicians surveyed believed that DTC advertising pressures physicians into prescribing drugs they would not ordinarily prescribe. This observation by itself suggests that the risks and drawbacks of DTC advertising

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<sup>30</sup> Robinson, *supra*, at 429.

<sup>31</sup> MS Lipsky, CA Taylor, The Opinions and Experiences of Family Physicians Regarding Direct-to-consumer Advertising, 45 J. Fam. Pract. 495 (1997).

outweigh the observed benefits (such as increased patient awareness), even if the economic implications of needless prescribing are left out of the discussion. Risk is attendant in any pharmacological intervention and arguably that risk could be higher for newer drugs, which tend to be advertised more heavily and for which less patient safety data is available than for older, established treatments that have been in the marketplace for years or even decades.

***B. Risk of Increased Liability for Pharmaceutical Companies Engaging in DTC Advertising***

**1. Restatement (Third) of Torts: Product Liability**

According the Restatement (Third) of Torts, manufacturers of prescription drug owe a duty to warn about foreseeable risks of harm to health care providers in a position to reduce risks of harm to patients, and “to the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce risks of harm in accordance with the instructions or warning.”<sup>32</sup> In comments to this Restatement section, the authors note that while this section preserves the learned intermediary rule, arguments have been advanced for “imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers...[when] manufacturers have advertised a prescription drug and its indicated use in the mass media.”<sup>33</sup> The question of whether such exceptions to the learned intermediary rule should be created is left to developing case law by the Restatement.

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<sup>32</sup> Restatement (Third) of Torts § 6(d)(2) (1998).

<sup>33</sup> Restatement (Third) of Torts § 6 cmt. e (1998).

## 2. Exceptions to the Learned Intermediary Rule

### a. New Jersey on the cutting edge: *Perez v. Wyeth Laboratories*

*Perez v. Wyeth Laboratories, Inc.* represented a significant change in the law in New Jersey, establishing an exception to the learned intermediary rule for prescription drugs advertised directly to consumers.<sup>34</sup> This case involved multiple plaintiffs who suffered significant side effects during use and/or complications upon removal of the contraceptive implant Norplant. Plaintiff's evidence showed that Wyeth advertised the product heavily in numerous national publications directed at women, such as "Glamour" and "Cosmopolitan" beginning in 1991.<sup>35</sup> Reportedly, "none of the advertisements warned of any inherent danger", nor did they warn of "side effects including pain and permanent scarring attendant to removal of the implants."<sup>36</sup>

The *Perez* court recognized that significant changes had taken place in the American health care system, changes which case law has yet to catch up with. Specifically, the court discusses the passing of the "doctor knows best" era,<sup>37</sup> and the emergence of managed care, third party payers and pharmacy departments in supermarkets as opposed to neighborhood pharmacies. As discussed previously, the learned intermediary rule came into being in just such a

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<sup>34</sup> *Perez*, 734 A.2d 1245 (N.J. 1999).

<sup>35</sup> *Id.* at 1248.

<sup>36</sup> *Id.* at 1248.

<sup>37</sup> *Id.* at 1247 (citing *Logan v. Greenwich Hosp. Ass'n*, 465 A.2d 294,299 (Conn. 1983)).

paternalistic, “doctor knows best” environment, an environment in which “pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians.”<sup>38</sup> Arguably, the very rule that pharmaceutical companies hide behind as a liability shield, the learned intermediary rule, is itself the best argument for disallowing DTC advertisements or at a minimum for creating an exception to the learned intermediary rule for prescription drugs advertised directly to consumers. The rule itself is premised on the very notion that physicians and other health care providers are in the best position to understand and assess risks and convey those risks effectively to the patient. That being said, it seems difficult for companies to argue that they should continue to be shielded from liability for a failure to warn, while simultaneously continuing to heavily (and successfully) promote prescription drugs directly to consumers.

The court stated its belief that “when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.”<sup>39</sup> While the New Jersey decision is not binding on other courts, and certainly the majority have to date demonstrated a reluctance to carve out such an exception to the learned intermediary rule, the court’s reasoning is certainly persuasive and could be predictive of legal trends to come.

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<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

In arriving at its decision, the *Perez* court also relied to some extent on previous exceptions carved out of the learned intermediary rule, such as an exception for mass-administered drugs like vaccines, which are not normally delivered to patients in a typical physician's office setting.<sup>40</sup> The 9<sup>th</sup> Circuit held in *Davis v. Wyeth Laboratories, Inc.* that "the manufacturer of a polio vaccine....[has] an independent duty to warn the consumer [of risks associated with the vaccine] because in mass immunization clinics such as where the plaintiff received a polio vaccine, there was 'no physician present to weigh the risks and benefits of the drug therapy for each patient'." <sup>41</sup>

Certainly, direct-to-consumer advertisements of prescription drugs present a similar problem to some extent, since drugs are being directly promoted to consumers who may be reaching conclusions about requesting specific drugs without adequate advance input from a physician. By its very nature, a conflict of interest exists when manufacturers are promoting products to patients in a commercial way via the same medium by which information about risks is to be conveyed. Or as stated quite eloquently by Mello, et al., "[a]dvertisements are....inherently biased; their purpose is to promote a product. Inclusion of detailed risk information may lead consumers to view these advertisements as objective and balanced, when in fact they never will be."<sup>42</sup> Content analyses cited by Mello "suggest that DTC

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<sup>40</sup> *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9<sup>th</sup> Cir. 1968).

<sup>41</sup> *See Perez*, 734 A.2d at 1250.

<sup>42</sup> Mello, *supra*, at 479.

advertisements tend to allot more space to the positive features of the product, relegating information about risks and adverse effects to the small print.”<sup>43</sup> While this problem can be somewhat addressed by statutory requirements for DTC advertising, there will always be an inherent conflict of interest for manufacturers who have an understandable duty to their shareholders to sell as much of a product as possible.

**b. Applicability of the Court’s reasoning to a broader expansion of exceptions to the LIR**

In the *Perez* decision, the court outlined four premises for the learned intermediary rule: “(1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of “doctor knows best” of [a] need for the patient’s informed consent; (3) inability of drug manufacturer[s] to communicate with patients; and (4) complexity of the subject.”<sup>44</sup> The court goes on to explain that with the possible exception of the last point, “all [of the above are] absent in the direct-to-consumer advertising of prescription drugs.”<sup>45</sup> In other words, by definition, the doctor patient relationship is undermined to some extent by direct-to-consumer advertising since it leads to patient requests for specific drugs and to the possibility that the information communicated by the physician may differ from that the patient is exposed to in advertising media. In the era of managed care and other economic pressures on physicians to minimize visit times, the “doctor knows best” defense to drug company liability for drugs

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<sup>43</sup> *Id.*

<sup>44</sup> *Perez*, 734 A.2d at 1255.

<sup>45</sup> *Id.*



advertised to consumers is difficult to defend.

Further, the very nature of direct-to-consumer advertising is such that it is preposterous to assert that manufacturers have an inability to communicate with patients. By design, drug companies are paying large sums of money for advertising campaigns that have proven very effective in getting the consumer's attention and increasing sales. Thus, the drug companies have themselves demonstrated their superior ability to communicate with patients.

Arguably, the last point on the court's list (complexity of the subject matter) may contribute significant weight to the best argument of all for a ban on direct-to consumer advertisements of prescription drugs as opposed to a mere abandonment of the learned intermediary rule for DTC advertised drugs. Safety and risk information is inherently complex and somewhat individualized and as such, may be best filtered and appropriately communicated through a learned intermediary, the physician.

It is true that the 2002 Supreme Court decision in *Thompson v. Western States Medical Center*<sup>46</sup>, held that provisions under the Food and Drug Administration Modernization Act (FDAMA) which restricted advertising and promotion of particular compounded drugs are unconstitutional restrictions of commercial speech. However, the promotion addressed in this particular case related to a small subset of drugs, those that are individually compounded for patients who are unable to use existing commercial products. The restrictions that were held unconstitutional barred specialty pharmacists from advertising, even to physicians with special

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<sup>46</sup> *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

needs patients, their specialized compounding capabilities.<sup>47</sup> The situation addressed in *Thompson* is clearly distinguishable from a proposed ban on direct-to-consumer advertisements of FDA approved prescription drugs. If direct-to-consumer advertisements of approved drugs were banned, companies would still have at their disposal all of the classic drug promotion tools: advertising in professional journals, personal visits to physicians, physician samples, presentations at professional meetings, investigator study grants, etc. Furthermore, the “playing field” would be level since all competing drug companies would face the same restrictions on advertisement. One might also further argue that public policy goals such as the safety and efficacy of prescription drugs, would be furthered in an environment where promotional materials could only be directed at medical experts. Since the target audience would be the learned professionals, it would be necessary to use a more data-oriented approach to selling the safety and efficacy advantages of new drugs in a class. Thus, a natural incentive would exist to develop compounds for which a great deal of solid medical evidence could be generated. This could result in an overall increase in the quality of new medicines submitted for FDA approval.

#### CONCLUSION

Overall, it would be in the best interests of the public and the pharmaceutical companies to institute a ban on the practice of advertising prescription drugs directly to consumers.

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<sup>47</sup> *Id.* at 359.

Direct-to-consumer advertising has significant potential to disrupt the doctor-patient relationship for a number of reasons, including: (1) a decrease in patient confidence in the physician when individualized information presented is in conflict with that gleaned from advertising, (2) denial of patient requests for specific drugs can lead to tension between the physician and the patient, and (3) physicians are continually forced to spend the precious resource of time “talking patients out of” inappropriate drug choices and explaining why such choices are inappropriate. As the expert in medicine and in the details of a particular patient’s medical condition, the physician is in the best place to choose the right drug treatment when drug treatment is appropriate to a particular case. Further, the physician is also best-suited to review safety and efficacy data generated by drug companies for new medicines and to make educated prescribing decisions based on that information.

Pharmaceutical companies face significantly increased liability risk with continuing the practice of direct-to-consumer advertisements in the “post-*Perez*” world. There is certainly some risk of a wider expansion of an exception to the learned intermediary rule for prescription drugs advertised directly to consumers. Further, the “LIR shield” itself is perhaps the best argument of all that the physician (not the patient) is the appropriate target for promotional material from the pharmaceutical companies. As a “learned intermediary” the physician can best interpret the technically challenging information on efficacy and risks and provide that information to the patient in a manner appropriate for a given person’s ability to understand it.

An across-the-board ban on DTC advertising would eliminate risks of one company having

unfair advantage over another in the marketing of competing drugs. All companies in this scenario would be forced to “sell” only to physician experts. Thus, they would need good products with good supporting data to convince the experts of a product’s worth. Such a model can only improve the safety and quality of new drugs entering the marketplace, since physicians by nature would represent a “harder sell” than the average consumer watching a 30-second television advertisement. Even in the current world where direct-to-consumer advertisements are pervasive, drug companies spent ~20% of their advertising dollars on DTC ads, with the remainder being spent on promotion to physicians.<sup>48</sup> Thus, this proposal would not represent a sea change in promotional spending. It is true that the elimination of DTC advertising does have the potential to reduce sales of a drug. However, it can be argued that when a drug is appropriate for a particular patient’s condition, physicians who have been apprised of a drug’s benefit will prescribe it. Certainly no one will seriously argue that a reduction in inappropriate prescribing is harmful to the social good.

One additional benefit of “freeing up” dollars currently being spent on direct-to-consumer advertising is an increase in the pool of potential monies which pharmaceutical companies can use to fund additional research that could lead to effective new medicines and to treatment breakthroughs benefiting all of mankind.

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<sup>48</sup> Vogel, supra, at 311.