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## The Psychological Manipulation of the Consumer-Patient Population through Direct-to-Consumer Prescription Drug Advertising.

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## THE PSYCHOLOGICAL MANIPULATION OF THE CONSUMER-PATIENT POPULATION THROUGH DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING

ELIZABETH C. MELBY†

*“Doctors are led to prescribe drugs that may not be necessarily worth the money, may not be better than a generic that’s already on the market and that their patients don’t need. It’s clearly contributing to the rising costs of prescription drugs and health care.”<sup>1</sup>*

—Dr. Arnold S. Relman, professor emeritus at  
Harvard Medical School and former editor  
of the *New England Journal of Medicine*<sup>2</sup>

### I. INTRODUCTION

Spending on pharmaceuticals is the fastest growing expense in the health care industry, and many in the medical community contribute this fiscal rise to the pharmaceutical industry’s emphasis on direct-to-consumer advertising.<sup>3</sup> Many physicians claim that direct-to-consumer advertising leads to inappropriate prescribing; or on the other hand, physicians are forced to spend extra time with patients explaining the information presented by the advertisers and clarifying the drug’s indications.<sup>4</sup>

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1. See Melody Petersen, *Madison Ave. Has Growing Role in the Business of Drug Research*, *N.Y. TIMES*, Nov. 22, 2002, at A1 (quoting Dr. Relman’s response to the question of whether science has been sacrificed for the success of advertisement).

2. *Id.* (commenting on the inappropriate advertising frenzy of pharmaceutical drugs).

3. See Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 *NEW ENG. J. MED.* 498, 499-501 (2002) (finding that direct-to-consumer drug advertisements increased 212% between the years 1996 to 2000, with the greatest percentage increase in television advertisements, which increased seven-fold).

4. See *id.* (discussing the potential drawbacks and costs imposed on physicians when a patient is misinformed and requests an inappropriate treatment based on a drug advertisement).

This comment addresses pharmaceutical drug direct-to-consumer advertisements, and the manipulation of the consumer public through the manufacturer's marketing practices. This comment will focus primarily on how direct-to-consumer prescription drug advertisements impact the innocent and unwitting consumer: the portrayal of a world with low-risk life-style enhancers, and the depiction of a society where a cure for any symptom or unpleasant emotion is only a prescription away.

Also addressed will be the influence that a patent life has on a manufacturer's decision to advertise the drug to consumers. Included in this discussion will be the marketing tactic of promoting one drug as superior to another, where the newly promoted drug is simply a revamped version of the older drug. It is questionable whether the lay consumer audience is conscious of this "improved" product promotion, when the newly marketed drug is simply a tweaked version of the original, either reformulated or further indicated in order to extend the drug's patent life.

Finally, this comment will focus on the changes that should be made in the world of prescription drug manufacturer liability. With an analysis of the tobacco industry's liability resulting from direct-to-consumer tobacco product advertisements, this comment will compare pharmaceutical manufacturer liability with that of tobacco manufacturers. This comment suggests that courts reassess the learned intermediary doctrine. The learned intermediary doctrine constructs an exception for drug manufacturers, allowing them to bypass the traditional products-liability rule that a manufacturer must inform purchasers of the product's potential risks; thus permitting a pharmaceutical manufacturer to omit a drug's risks when addressing consumers.<sup>5</sup> Further, this comment reasons that the use of incentive-based regulations to govern direct-to-consumer drug advertising should replace the learned intermediary doctrine. This proposition relies on the tobacco industry's success of avoiding liability in the absence of such regulation, all at the expense of the consumer.<sup>6</sup>

## II. PRESCRIPTION DRUG ADVERTISEMENTS: A BRIEF ANALYSIS

Historically, pharmaceutical companies developed and directed their entire product marketing promotion and education to physicians and health-care providers responsible for prescribing the manufacturers'

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5. Dabney J. Carr, IV & Bryony H. Bowers, *Recent Developments in Learned Intermediary Doctrine*, THE BRIEF, ABA TORT & INS. PRACTICE SECTION, 2002, at 20.

6. See Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: A Response to Market Manipulation*, 6 ROGER WILLIAMS U. L. REV. 259, 294 (2000) (asserting that the proven success of the tobacco industry at manipulating consumers is sufficient evidence in favor of forcing manufacturers who currently fall short in apprising consumers of the risks involved with a product to redirect those efforts into strengthening such awareness).

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products.<sup>7</sup> Now, though, pharmaceutical companies consider direct-to-consumer drug advertisements to be educational segments that provide consumers with health care information and choices.<sup>8</sup> Although many physicians feel that drug ads entice patients into believing that a pill can treat any symptom,<sup>9</sup> a survey by the National Medical Association found that there are some physicians who agree that drug advertisements may benefit the viewer by enlightening them about troublesome symptoms.<sup>10</sup> Yet a third group of doctors stated that they often felt pressured by patients to write a prescription for a particular brand name drug.<sup>11</sup>

A health care entity openly opposed to direct-to-consumer drug advertisements is Blue Cross and Blue Shield, which contends that highly marketed brand name drugs often work equally as well as older drugs and treatments.<sup>12</sup> For example, a clinical study found that the majority of patients with arthritis could be treated just as effectively with ibuprofen as with Vioxx, which costs a few dollars a day.<sup>13</sup> Instead, the manufacturers of Vioxx have advertised the drug tremendously, creating a demand for the pricey product in place of ibuprofen, which costs only pennies a day.<sup>14</sup>

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7. See *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1247 (N.J. 1999) (holding that pharmaceutical manufacturers who advertised the efficacy of their product directly to consumers were not relieved of liability by simply informing prescribing physicians of the risks involved).

8. See Jeff Gelles, *Prescription-Drug Ads Prompt Cheers, Fears; Onslaught of TV Commercials May Nudge People to Go See Their Doctors, or it Might Lead to Abuse*, SEATTLE TIMES, Sept. 6, 1997, at A2, available at 1997 WL 3251794; Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 166 (1999) (addressing the views of direct-to-consumer advertisement advocates).

9. See Luran Neergaard, *TV Advertising Effective for Drug Companies*, AUGUSTA CHRONICLE, May 1, 2002, available at [http://www.augustachronicle.com/stories/050102/tec\\_124-8492.shtml](http://www.augustachronicle.com/stories/050102/tec_124-8492.shtml) (last visited Mar. 12, 2003) (quoting FDA drug chief, Dr. Janet Woodcock, who questions whether the nation's barrage of drug ads has caused patients to receive inappropriate prescriptions).

10. See *id.* (citing a recent survey of the National Medical Association's African-American physician members who feel African-Americans are less likely to see a doctor for a host of diseases).

11. *Id.*

12. See Alexandra Marks, *Rise of 'Ask Your Doctor' Ads: A Public-Health Concern?*, CHRISTIAN SCI. MONITOR (Nov. 30, 2001), available at <http://www.csmonitor.com/2001/1120/p2s2-ussc.html>.

13. *Id.* (discussing anecdotal evidence of the rise in people asking their doctors for medications that they do not always need).

14. See NAT'L INST. FOR HEALTH CARE MGMT. FOUND., *PRESCRIPTION DRUGS AND MASS MEDIA ADVERTISING* (2000), available at <http://www.nihcm.org> (detailing drug manufacturers' spending on direct-to-consumer ads, finding Merck to have spent the most in 2000: \$160.8 million advertising Vioxx in 2000, with sales quadrupling between 1999 and 2000); See also Marks, *supra* note 12 (stating that Vioxx sales have increased steadily with the drug's advertisements).

In 1997, the Food and Drug Administration (FDA) initiated new guidelines for direct-to-consumer advertising with the intention of increasing “consumer access to prescription drug information.”<sup>15</sup> Unfortunately, the FDA has imparted more direct-to-consumer marketing opportunities for pharmaceutical manufacturers than it probably anticipated.<sup>16</sup> Rather than increasing consumer understanding, drug companies have increased their access to consumers.<sup>17</sup>

The FDA implemented new guidelines in response to the tremendous volume of promotion by drug manufacturers, requiring direct-to-consumer drug advertisements to include tedious fine print product warnings and indications.<sup>18</sup> To reduce the amount of intricate information required in a commercial segment, the FDA established more lenient rules for televised drug advertisements, allowing pharmaceutical companies to broadcast brand name drugs and benefits while specifying only the most prevalent side effects.<sup>19</sup> The regulation allows broadcast advertisers to side step the presentation of all the drug’s side effects and contraindications through the use of the alternative provision requirement.<sup>20</sup> This exception allows pharmaceutical companies to provide a toll-free number, refer to a printed advertisement or brochure of the drug, state the need to see a medical professional, and/or supply an internet web page address instead of furnishing complex reactionary information.<sup>21</sup>

Thinking back to the first direct-to-consumer drug advertisement, both in print and on television – Upjohn’s Rogaine hair loss treatment product<sup>22</sup> – and the onslaught of drug advertisements that followed, it is surprising that more people are not walking around with full heads of hair. Turn on the television and it will not be long before a commercial comes on displaying a person who asked his or her doctor for a particular medication: Paxil for social anxiety disorder, Viagra for erectile dysfunction,

15. Kelly N. Reeves, Note, *Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population?*, 53 *FOOD & DRUG L.J.* 661, 679 (1998).

16. *Id.*

17. *Id.*

18. See Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 *Fed. Reg.* 43,171 & 43,172 (Aug., 12, 1997).

19. See 21 *C.F.R.* § 202.1(e) (1).

20. *FOOD AND DRUG ADMIN., U.S. DEPT. OF HEALTH AND HUMAN SERV., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS 2-4* (1999), <http://www.fda.gov/cber/gdlns/advrts.pdf>; William E. Holtz, *Consumer-Directed Prescription Drug Advertising: Effects on Public Health*, 13 *J.L. & HEALTH* 199, 206-08 (1999).

21. *Id.*; Holtz, *supra* note 20, at 206.

22. See Barbara J. Tyler & Robert A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 *Vt. L. Rev.* 1073, 1073 (1997).

Vioxx for orthopedic pain, Prilosec for acid reflux, Claritin for allergies, and the list goes on.<sup>23</sup>

Guaranteed results from the advertised drug's use is never the end goal of pharmaceutical advertising; the objective is to increase profits by stimulating consumer demand.<sup>24</sup> The health information supplied by drug companies in prescription drug commercials may seem helpful on its face, but "drug companies operate in a for-profit, market-driven environment."<sup>25</sup> Therefore, it is difficult for drug manufacturers to justify direct-to-consumer advertisements as a public service when the bottom line is increased market-share.<sup>26</sup>

Because increasing demand is the intention of all marketing campaigns, "a drug ad [will not] discuss other medications. . . it [will not] discuss alternative treatments; it [will not] discuss the wisdom of doing nothing for a while; and it [cannot] diagnose an illness."<sup>27</sup> Consumer advocates claim this barrage of drug advertisements has resulted in patients demanding brand name prescriptions in place of less expensive, older, but reliable, medications.<sup>28</sup>

With the goal of increasing market share through increased consumer demand,<sup>29</sup> direct-to-consumer prescription drug commercials take the consumer-viewer on a virtual tour of life-enhancing drug products. Today, pharmaceutical companies spend over an estimated one billion dollars a year on drug advertisements directed at consumers, including television commercials, periodical advertisements, internet websites, and radio spots.<sup>30</sup> This practice has resulted in an exponential increase in consumer demand for and spending on prescription drugs that the phar-

23. RICHARD FRANK, PH.D., ET AL., KAISER FAMILY FOUNDATION, *TRENDS IN DIRECT TO CONSUMER ADVERTISING OF PRESCRIPTION DRUGS* 11 (2002) (survey listing the prescription drugs with the highest spending on direct-to-consumer advertising).

24. See Tyler & Cooper, *supra* note 22, at 1073.

25. Reeves, *supra* note 15.

26. *Id.*

27. Gelles, *supra* note 8.

28. Rita Rubin, *Spotlight Falls on Drug Ads; Does Song and Dance Drive Sales, or Give Public Vital Information?*, USA TODAY, Dec. 11, 2001, at D9, available at 2001 WL 5478364.

29. See Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1451 (1999) (stating that "no force exerts a more significant influence on manufacturer behavior than the force of the market"; regardless of administrative rules and morality, advertiser manipulation of a product's risks is rooted in the market).

30. Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 98 (2002).

maceutical manufacturers could not acquire through physician-only product promotion.<sup>31</sup>

### III. IMPACT ON THE PHYSICIAN-PATIENT RELATIONSHIP

*“Dr. Bradford Pontz can always spot the patient who has seen – and been sold on – a commercial for a prescription drug.”*<sup>32</sup>

The creation by the pharmaceutical industry of a “feel good” world has the potential to burden the fiduciary physician-patient relationship. Referring to the trust and confidence seeded in the physician-patient relationship, one court has stated: “As part of this relationship, both parties envision that the patient will rely on the judgment and expertise of the physician.”<sup>33</sup> With the ever-increasing promotion of prescription drug advertisements, physicians now have to decipher whether a patient is relating subjective symptoms or regurgitating what he or she has seen in a commercial or advertisement.<sup>34</sup>

Studies have demonstrated that the warnings presented in direct-to-consumer drug commercials are only partially digested by consumers, leaving the viewer with an overall perception that the advertised ailment is safely treatable, and not with the feeling that there is the possibility that the treatment may be unsafe or inappropriate in many cases.<sup>35</sup> The

31. See Mae Joanne Rosok, *Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE U. L. REV. 629, 657, 660 (2000) (stating that the direct-to-consumer advertising result is the destruction of the patient-doctor relationship); Barry R. Furrow, *Enterprise Liability for Bad Outcomes from Drug Therapy: The Doctor, The Hospital, The Pharmacy, and the Drug Firm*, 44 DRAKE L. REV. 377, 426 (1996) (stating that direct-to-consumer advertising is motivated by drug company determinations that they can reach potential customers more rapidly than by waiting for physicians to pass the information to their patients, i.e. consumers).

32. Jackie Judd, *Truth in Advertising?*, ABCNEWS.COM, Jan. 4, 2001, available at [http://abcnews.go.com/sections/wnt/WorldNewsTonight/wnt010103\\_prescriptiondrugs\\_ads\\_feature.html](http://abcnews.go.com/sections/wnt/WorldNewsTonight/wnt010103_prescriptiondrugs_ads_feature.html) (last visited Mar. 13, 2003) (quoting Dr. Pontz, who made the statement on Jan. 3, 2001, in regard to pharmaceutical drug advertising, with the doctor further stating that he recommends to his patients that they view the drug ads with the same amount of skepticism that they would with other advertised products).

33. *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 879 (Ohio 1991).

34. See W. John Thomas, *Direct-to-Consumer Pharmaceutical Advertising: Catalyst for a Change in the Therapeutic Model in Psychotherapy?*, 32 CONN. L. REV. 209, 210-11 (1999) (addressing the issues created for a psychiatrist in the patient diagnostic experience as a result of the evolution of pharmaceutical advertising).

35. See Tyler & Cooper, *supra* note 22, at 1096 (stating consumers are more likely to interpret advice to consult a health-care professional as general reassurance that their symptoms are treatable); Prescription Drug Products; Patient Labeling Requirements, 60 Fed. Reg. 44194 (Aug. 24, 1995) (demonstrating problems with consistency in information disclosures to consumers through literature enclosed in drug packaging).

end result has been a great resistance by the medical community to direct-to-consumer drug advertisements, particularly because physicians are trained to provide for the best interest of their patients, not drug companies.<sup>36</sup>

The medical community has voiced its belief that direct-to-consumer drug advertisements “create an inappropriate demand for medications and/or a demand for inappropriate medications.”<sup>37</sup> Although some physicians see some positive effects of direct-to-consumer advertisements, many physicians have expressed great concern about the fact that drug manufacturers are inflating patients’ expectations, by circumventing the doctors responsible for prescribing the medications.<sup>38</sup> In response to the benefit-detriment effect of direct-to-consumer prescription drug advertisements, one American Medical Association delegate stated, “The big issue is medication by demand vs. [sic] medication by need. . .the more knowledge the patient gets, the better it is. On the other hand, the advertising ‘de-professionalizes’ the profession to some degree.”<sup>39</sup>

Many physicians provide drug prescriptions to patients based on the patient’s demand for the product, knowing that the patient will go elsewhere if the doctor refuses.<sup>40</sup> Many physicians would prefer to explain and demonstrate to the patient that a particular drug treatment is not necessary; or if a treatment is appropriate, that a drug that has been on the market for a longer period of time has a proven track record of being safe and effective compared to the new and highly advertised product.<sup>41</sup>

Pharmaceutical manufacturers are bombarding the consumer-patient population with the benefits of their drugs, while minimizing the risks as much as possible, and all the while leaving the physician with the title role

36. See Tyler & Cooper, *supra* note 22, at 1099-1100 (referencing an FDA moratorium on drug advertising during which time it studied opposition to direct-to-consumer advertisements).

37. *Id.* at 1098 (quoting from *Prescription Drug Advertising Direct to the Consumer*, 88 PEDIATRICS 174, 175 (1991)).

38. Robert Steyer, *Do Drug Ads Educate or Misperlead Consumers?*, ST. LOUIS POST-DISPATCH, June 20, 1999, at A9, available at 1999 WL 302399.

39. See *id.* (quoting Dr. Arthur Gale, an internist, who was addressing the impact drug advertisements have on public health and the physician-patient relationship).

40. See Stephen J. Gilbride, *DTC Advertising One Year Later*, DRUG TOPICS, Mar. 1, 1999, at 13 (quoting a doctor who stated, “I’ve lost patients because I refused to prescribe what was in the ad”).

41. See Sandy Rovner, *Healthtalk: The Rx for Prescription Ads*, WASH. POST, Aug. 24, 1984, at B5, available at 1984 WL 2020342 (addressing an American Medical Association policy stating that no evidence to date existed that revealed direct-to-consumer advertisements would result in improved quality of medical care).



of “learned intermediary.”<sup>42</sup> Based on the legitimate right of a medical doctor to determine what information a patient can or will benefit from and understand, it is illogical to assume that pharmaceutical manufacturers are in the position to overstep a physician’s prescribing prerogative. Many physicians choose not to disclose all the risks involved with the use of a medication, or any treatment, reasoning that a patient’s knowledge of such information is not needed for a patient’s informed consent.<sup>43</sup>

#### IV. PSYCHOLOGICAL IMPACT OF DIRECT-TO-CONSUMER ADVERTISEMENTS ON CONSUMERS

*“[C]ritics worry that the success of drug makers and marketers in spurring big sales shortly after a drug’s approval means that millions of patients may take a drug before all of its side effects are known.”<sup>44</sup>*

Prescription drug television commercials display before-and-after scenarios of symptoms a patient may experience prior to taking the advertised drug and the dramatic improvement in life after using the product. This experience may create, whether consciously or not, a desire in the consumer to experience pre-treatment symptoms in order to require the recommended course of therapy.<sup>45</sup>

The FDA guidelines for prescription drug television advertisements require the inclusion of information about the major risks associated with the use of the drug,<sup>46</sup> and the advertisement must include a brief summary detailing the means by which the consumer can obtain the product’s labeling provisions.<sup>47</sup> During a prescription drug commercial, the state-

42. See Tyler & Cooper, *supra* note 22, at 1095-96 (addressing how direct-to-consumer drug advertisements undermine the physician-patient relationship and the learned intermediary doctrine).

43. See *Natanson v. Kline*, 350 P.2d 1093, 1106 (Kan. 1960) (holding that a physician’s duty to disclose treatment specifics is “limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances”).

44. See Petersen, *supra* note 1 (demonstrating that direct-to-consumer drug advertisements may result in billion-dollar profits, but often at the expense of the unknowing consumer).

45. Hanson & Kysar, *supra* note 29, at 1438 (hypothesizing that marketing of products directly to consumer results in the artificial creation of needs, or at the very least, direct-to-consumer marketing results in more than merely informing the consumer).

46. See Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 & 43,172 (Aug. 12, 1997) (stating prescription drug advertisements on radio, television, or telephone must include information about major risks of the advertised product). The FDA requires a statement to include information about the major side effects and contraindications of the drug; it does not require the statement to define the drug’s effectiveness. *Id.*

47. See *id.* The brief summary for obtaining the drug’s prescribing information must be the use of the following: providing a toll-free number, a reference to a printed ad or

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ment about the drug's side effects is often done against the visual backdrop of people engaged in life-affirming activities,<sup>48</sup> such as playing with a child,<sup>49</sup> exercising,<sup>50</sup> or socializing.<sup>51</sup> In spite of the repetitive positive visual graphics presented to the public, the FDA sends out approximately one hundred citation letters a year to drug manufacturers, stipulating that the companies make changes to their drug commercials and printed advertisements.<sup>52</sup> The FDA sends citation letter to drug companies when the "ads stretch the truth with overstated claims of effectiveness and understated descriptions of side effects."<sup>53</sup> The makers of the arthritis drug Celebrex, for example, were cited three times prior to the year 2001 for making false claims on direct-to-consumer advertisements.<sup>54</sup> The makers of Claritin, a drug for the treatment of allergies, were cited ten times between 1997 and 2001 for inaccurate sales pitches.<sup>55</sup>

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brochure accessible in public locations, a statement to ask a physician or pharmacist, and an internet website. *Id.*

48. See Elizabeth A. Rothermich et al., *Health-Related Quality of Life Claims in Prescription Drug Advertisements*, 53 AM. J. HEALTH SYST. PHARM. 1565, 1567 (1996) (stating that 84% of the ninety-four drug advertisements studied, 84% contained implicit health-related quality of life claims and 16% contained explicit referrals to health-related quality of life claims).

49. See, e.g., *Asthma Control That Can Help You Breathe Easier* (Merck: Singulair advertisement), at [http://www.singulair.com/montelukast\\_sodium/singulair/consumer/adult\\_asthma/tv\\_ads/watch\\_our\\_tv\\_ads.jsp](http://www.singulair.com/montelukast_sodium/singulair/consumer/adult_asthma/tv_ads/watch_our_tv_ads.jsp) (last visited Mar. 14, 2003) (promoting Singulair for the treatment of asthma).

50. See, e.g., *Dan's Story* (Merck: Zocor advertisement), at [http://www.zocor.com/simvastatin/zocor/consumer/dan\\_reeves/index.jsp](http://www.zocor.com/simvastatin/zocor/consumer/dan_reeves/index.jsp) (last visited Mar. 14, 2003) (endorsing the cholesterol lowering benefits of taking Zocor and exercising after coronary artery bypass surgery); see also *Pharmacia Pfizer: Celexa advertisement* (ABC television commercial, Aug. 2002) (promoting Celexa for the treatment of depression).

51. See e.g. *GlaxoSmithKline: Paxil advertisement* (NBC television commercial, Aug. 2002) (promoting Paxil for the treatment of depression and anxiety disorders); see generally THE GLAXOSMITHKLINE GROUP OF COMPANIES, *PAXILCR: YOUR LIFE IS WAITING* (2002) (company pamphlet sketching out the Paxil commercial for depression).

52. Judd, *supra* note 32.

53. See *id.* (quoting Tom Abrams, the FDA's watchdog for deceptive advertising, who continued to emphasize that drug advertisements are coupled with images of active people with promises of relief, leaving consumers with the belief that drugs are more effective than they really are).

54. See Letter from Spencer Salis, Pharm.D., Regulatory Review Officer Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration, to Jerome M. Prah, Associate Director of Regulatory Affairs, G.D. Searle & Co. (Nov. 14, 2000) (citing the makers of Celebrex for overstating the drug's efficacy); Judd, *supra* note 32.

55. See Letter from Joan Hankin, JD, Regulatory Review Officer, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration, to Mary Jane Nehring, Director of Worldwide Regulatory Affairs, Schering Corporation (Mar. 14, 2000) (citing the makers of Claritin for using images of loose hay flying around the actors'

A recent study done by the Kaiser Family Foundation found that forty-four percent of patients who asked their physician for a medication they had seen advertised on television received a prescription for that drug.<sup>56</sup> Another segment of the study consisted of 1,872 volunteers, three-quarters of whom were each shown one of three prescription drug commercials.<sup>57</sup> Immediately after watching the advertisements, the majority of the viewers agreed they gained knowledge about the benefits and side effects of the medications as opposed to those volunteers who did not watch the commercials.<sup>58</sup> However, the gain was not substantial – approximately sixty percent of those who viewed the advertisements said they knew little or nothing more about the medications in general, and seventy percent claimed to know little or nothing more about the conditions the medications were used to treat.<sup>59</sup> Based on the results of this study, it appears that the messages being sent by pharmaceutical companies and the messages being received by consumers are not translating appropriately.

The increase in direct-to-consumer drug advertising over the last couple of decades, including the fact that almost every pharmaceutical company has engaged in direct-to-consumer advertising,<sup>60</sup> is valid proof that significant profit gains for the drug industry result from this direct marketing practice of consumer manipulation.<sup>61</sup>

## V. DRUG PATENTS

*“There is no economic value in conferring a patent monopoly except for an invention that will have a significant impact.”*<sup>62</sup>

—John H. Barton

A drug receives a patent, granted by the United States Patent and Trademark Office, for a period of twenty years beginning when the appli-

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faces in the maker’s commercial for Claritin as a false presentation of the drug’s efficacy); Judd, *supra* note 32.

56. See HENRY J. KAISER FAMILY FOUND., UNDERSTANDING THE EFFECTS OF DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING 3, at Chart 2 (2001).

57. See *id.* at 3 (amounting to a total of 13% of there overall population).

58. See *id.* at 7.

59. See *id.*

60. Tyler & Cooper, *supra* note 22, at 1096.

61. See Hanson & Kysar, *supra* note 29, at 1455 (stating that pharmaceutical industry’s “manipulation of both consumer risk perceptions and physician prescribing behavior presents manufacturers with a significant opportunity for gain.”).

62. John H. Barton, *Reforming the Patent System*, 287 SCI. 1933, 1933 (2000).

cation for the patent is filed.<sup>63</sup> This intellectual property protection allows the pharmaceutical company that owns the drug patent the right to exclude competitors from marketing and selling the same molecularly structured drug during that twenty-year period of time.<sup>64</sup> Unfortunately, pharmaceutical companies have been able to find methods of extending their dominant drugs' patent lives by fifty percent or more.<sup>65</sup> One of the most significant pitfalls of this extension of years is the continued high cost required of consumers for a brand name drug while the makers of the drug pocket the large profits.<sup>66</sup> By preventing and delaying the entry of generic competition, each lengthened patent term requires that consumers pay three times more for a brand name drug than they would for the generic equivalent.<sup>67</sup>

In general, pharmaceutical manufacturers concentrate their advertising budget on newer drugs or drugs that are young in patent years.<sup>68</sup> Pharmaceutical companies have little to gain from advertising a product whose patent is about to expire, as generic equivalents create too much price competition.<sup>69</sup> An example of a pharmaceutical company strategizing to keep its major share of the antidepressant market is Forest Laboratories' introduction of its "new" drug Lexapro.<sup>70</sup> Lexapro is not a new drug, but a reformulated version of Forest's blockbuster antidepressant Celexa.<sup>71</sup> Lexapro's introduction occurred well before Celexa was due to lose its patent.<sup>72</sup> Forest is expected to market Lexapro by encouraging physicians to switch patients on Celexa to Lexapro. As Celexa is responsible for seventy percent of Forest's total sales, it is important to establish Lexapro before generic competitors are able to acquire their share of the market with generic versions of Celexa.<sup>73</sup>

There are other exceptions to the principle that the pharmaceutical industry tends to avoid direct-to-consumer advertising of drugs with patents

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63. See NAT'L INST. FOR HEALTH CARE MGMT. FOUND., *PRESCRIPTION DRUGS AND INTELLECTUAL PROPERTY PROTECTION: FINDING THE RIGHT BALANCE BETWEEN ACCESS AND INNOVATION* 4 (2000).

64. *Id.* at 1, 4.

65. *Id.* at 1-2.

66. *Id.*

67. See GENERIC PHARMACEUTICAL ASSOCIATION, *PRESCRIPTION DRUG FACTS AND FIGURES*, available at <http://www.gphaonline.org/news/facts.phtml> (last visited Feb. 21, 2003).

68. See Rosenthal et al., *supra* note 3, at 501.

69. See *id.* at 503.

70. Petersen, *supra* note 1.

71. See *id.* (revealing that Forest was able to distinguish the therapeutic benefit of Lexapro from Celexa in only one study, a study that Forest had to pay to have published).

72. *Id.*

73. *Id.*

due to expire. One instance is when a pharmaceutical manufacturer has received approval from the FDA for a new indication for a drug already on the market.<sup>74</sup> What this means is that a drug that has been on the market for the treatment of one disease is later approved for the treatment of another disease, thus creating a new niche for the exploitation of the drug.<sup>75</sup> One example is the drug Paxil, originally indicated for the treatment of depression. Recently, Paxil was approved for the treatment of social anxiety disorder,<sup>76</sup> extending the drug's patent- and advertising-life for an additional term.

The use of heavy direct-to-consumer advertising of a drug that is nearing the end of its patent but has a new indication is likely designed to accomplish two things. One is preventing loyal users of the drug from switching to an inexpensive generic.<sup>77</sup> Another goal may be to gain a competitive edge over other drugs in the same class.<sup>78</sup> Doing so is critical, because drug companies rely on patent rights for the profits that trade name drugs bring.<sup>79</sup> It is with FDA approval and a valid patent that a drug company is allowed to "lawfully exercise its monopoly rights and reign as the sole producer of a particular drug until the patent expires and generic manufacturers enter the market."<sup>80</sup> In 1997, ninety percent of the total amount of money spent on the sale of prescription drugs in the United States was spent on brand name drugs, equaling over \$64 billion dollars.<sup>81</sup> This enormous amount of potential profit makes clear the financial incentives drug companies have to extend a brand name drug's patent life, whether it be by reformulating the drug into different versions or advertising the brand name drug to develop a barrier against generic recognition.<sup>82</sup>

Indications are the diseases or disorders that a drug has been approved to treat; for example, Paxil CR is "indicated" for the treatment of major depression and panic disorders in its prescribing information.<sup>83</sup> Indication

74. See Rosenthal et al., *supra* note 3, at 503.

75. See *id.* at 505.

76. See *id.* at 503.

77. See generally *id.*

78. See generally *id.*

79. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 231 (2001).

80. *Id.*

81. See Marcia Angell, *The Pharmaceutical Industry: To Whom Is It Accountable?*, 342 NEW ENG. J. MED. 1902, 1903 (2000).

82. See Glasgow, *supra* note 79, at 233 (listing the means by which drug companies attempt to extend drug patent lives, including legislative provisions and loopholes, suing for generic patent infringement, and merging with direct competitors in an effort to extend the monopoly).

83. GLAXOSMITHKLINE, PAXIL CR PRESCRIBING INFORMATION (2002).

add-ons extend a drug's patent life, helping a pharmaceutical company to avert the financial calamity of generic drugs replacing its one-time blockbuster product.<sup>84</sup> Because a drug's period of patent protection begins before development is completed, as many as five or more years of its protected years are essentially lost.<sup>85</sup> By the time the drug hits the market, drug companies are protected from generic competition for only about twelve years of the initial twenty.<sup>86</sup> It is this loss in profit time that leads drug companies to find ways of extending a drug's moneymaking years.<sup>87</sup>

A recent example of a class action challenge against a drug manufacturer for illegally monopolizing a sector of the antibiotic market is the lawsuit against GlaxoSmithKline, the maker's of the antibiotic Augmentin, filed on September 19, 2002.<sup>88</sup> The filing of this lawsuit came a week before GlaxoSmithKline received FDA approval for Augmentin XR, a reformulated version of the initial drug.<sup>89</sup> As one of its biggest selling products, GlaxoSmithKline developed the extended release version of Augmentin with the purpose of staving off generic competition.<sup>90</sup> GlaxoSmithKline's expectation that the reformulated version of the antibiotic would be approved by the FDA prior to the drug's patent expiration was shattered when the approval came after the drug's patent expired, which occurred in July of 2002, leaving the original version of Augmentin to face generic competition for two months prior to its reformulation hitting the market.<sup>91</sup> GlaxoSmithKline hopes to prevent generic competition by challenging a court ruling holding that Augmentin XR's patent is invalid.<sup>92</sup>

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84. See Elyse Tanouye & Robert Langreth, *Time's Up: With Patents Expiring on Big Prescriptions, Drug Industry Quakes; Top Firms Gird for Onslaught from Generics, Scramble to Develop New Products; Bet on Fewer Blockbusters*, WALL ST. J., Aug. 12, 1997, at A1.

85. *See id.*

86. *See id.*

87. *See id.* (discussing the impact that generic drugs have on the once-patent-protected drugs they now compete against, often resulting in the original drug companies' consolidation with other manufacturers due to the financial losses suffered at the expense of generic products).

88. See Press Release, Goodkind Labaton Rudoff & Sucharow LLP, Goodkind Labaton Rudoff & Sucharow LLP Announces Class Action Against Drug-Maker GlaxoSmithKline (Sept. 19, 2002), at <http://www.glr.com/index.cfm?upv=2&getGlobalID=23446> (last visited April 15, 2003).

89. See *FDA Approves Sale of New Glaxo Drug*, WALL ST. J. (LONDON), Sept. 27, 2002, at B5, available at 2002 WL-WSJ 3407218.

90. *See id.*

91. *See id.*

92. *See id.*

In addition, GlaxoSmithKline is introducing another version of Augmentin: pediatric Augmentin ES, which has a patent of its own.<sup>93</sup> If successful, the drug company will have again covered different aspects of the same antibiotic, resulting in a cycle of new patents coming to life as old patents are put to rest.<sup>94</sup> The result is that Augmentin will have a patent life nearly fifteen years beyond what patent regulations intended, originally to expire at the end of 2002<sup>95</sup> and now remaining covered until 2017.<sup>96</sup> And each new patent extension granted for Augmentin is based on research strategically done thirty years ago, not research done for an innovative and new treatment.<sup>97</sup>

The antibiotic Augmentin is marketed for the treatment of respiratory infections that have become resistant to other treatments.<sup>98</sup> It is logical to assume that consumer-patients would appreciate the choice of paying for a generic version of Augmentin, especially after having already paid for other failed treatments. In the lawsuit against GlaxoSmithKline, the complainants allege unjust competitive practices and assert that patients should be able to access appropriate drugs at the lowest cost feasible, especially if a drug has lived its brand name life and is at the point of generic competition.<sup>99</sup> Representatives of the class action contend that patients should not have to choose between paying for necessities like clothing and heat and purchasing needed prescription medications because of drug companies' persistent efforts to keep expensive drugs from exiting their monopolies.<sup>100</sup> The cost to consumers is overwhelming when one realizes the potential savings generic drugs can provide. For example, Claritin costs \$85 a month compared to a generic equivalent which will cost \$10 a month once Claritin's patent expires.<sup>101</sup>

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93. *See id.*

94. *See* Glasgow, *supra* note 79, at 231-33.

95. *See* U.S. Patent No. 4,529,720 (issued July 16, 1985), available at WL U.S. PAT 4529720; *see also* GLAXOSMITHKLINE, AUGMENTIN ES-600, PRESCRIBING INFORMATION (2002).

96. *See* David Pilling & Richard Wolffe, *Drug Abuses: As Pharmaceutical Companies Go to Extraordinary Lengths to Protect Expiring Patents, Regulators are Starting to Pay Close Attention*, FIN. TIMES (LONDON), Apr. 20, 2000, available at <http://search.ft.com/search/articles.html> (site access requires subscription) (last visited March 15, 2003).

97. *See id.*

98. *See* FDA Approves Sale of New Glaxo Drug, *supra* note 89.

99. *See* Press Release, Goodkind Labaton Rudoff & Sucharow LLP, *supra* note 88.

100. *See id.*

101. *See* Glasgow, *supra* note 79, at 236.

The strategy of staggering patents over a period of time has enabled drug manufacturers like GlaxoSmithKline to “layer” a drug’s patents.<sup>102</sup> By patenting various aspects of a drug, manufacturers can barricade generic equivalents from entering the market by initiating patent litigation as needed.<sup>103</sup> Another line of attack is the marketing tool of using old drugs disguised as new.<sup>104</sup> Thus, if a drug manufacturer is able to time the presentation “of a new use, such as a more convenient dosing form, to coincide with the expiration of the ‘mother’ drug’s patent,” it can extend its original patent franchise in incremental steps, for a period lasting as long as eighteen additional years.<sup>105</sup>

Applied to the situation of Augmentin XR, GlaxoSmithKline was able to demonstrate to the FDA that the new version of Augmentin was equally effective as the original at treating its indicated infections, but the new version had the additional quality of preventing the drug’s enzymatic breakdown in the body.<sup>106</sup> If generic drug companies are able to prove that brand name drug companies knew of a drug’s “improved” formulation and sat on the information until the new version of the drug could be used as ammunition against generic patent infringement, the generic manufacturers may eventually provide consumers with a choice in drugs at a sooner time.<sup>107</sup>

In the realm of direct-to-consumer advertising, a drug company’s use of patent extensions allows the makers of a newer version of an old drug to extend a drug’s monopoly in marketing and advertising years. This provides pharmaceutical manufacturers with the opportunity to impress on consumers their drug’s brand name for a longer period of time, and perhaps create in the consumer-patient the resistance to switch to and believe in the efficacy of a generic equivalent when the time arises.<sup>108</sup> This resistance to change may be influenced either by the life-enhancing images portrayed in a drug’s advertisements or to a patient’s inability to

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102. See Stephen S. Hall, *The Claritin Effect; Prescription for Profit*, N.Y. TIMES MAG., Mar. 11, 2001, at 40, available at <http://query.nytimes.com> (site access requires subscription) (last visited March 20, 2003).

103. See *id.*; Glasgow, *supra* note 79, at 248.

104. See Glasgow, *supra* note 79, at 248.

105. See NAT’L INST. FOR HEALTH CARE MGMT. FOUND., *supra* note 63, at 11.

106. See Robert Langreth & Victoria Murphy, *Perennial Patents*, FORBES, Apr. 2, 2001, at 52, available at 2001 WL 2184224 (discussing Pfizer’s epilepsy drug, Neurontin, which relied on an extended released version like Augmentin to extend the drug’s patent life).

107. See *id.*

108. See Glasgow, *supra* note 79, at 252 (stating that a brand name drug’s extended coverage in the direct-to-consumer market may discourage generics from entering the market).



put a price on good health.<sup>109</sup> A consumer's resistance to switch to a generic drug is likely a combination of several factors. The bottom line, though, is that it is the brand name manufacturers who choose the price at which to sell their drugs,<sup>110</sup> and it is they who seek to prolong the drugs' profits for an excessively long period of time.

## VI. THE LEARNED INTERMEDIARY DOCTRINE

*"The conflict between the learned intermediary rule and the increased deference to the consumer's right to know leaves courts in somewhat of a quandary."*<sup>111</sup>

The learned intermediary doctrine has been a tort liability tool for nearly fifty years.<sup>112</sup> The doctrine, created by the court in *Marcus v. Specific Pharmaceuticals*,<sup>113</sup> was established with the purpose of shielding drug manufacturers from liability for failure to warn claims brought by patient-recipients of their products, because the medication was only available to the consumer through a physician's prescription.<sup>114</sup> The reasoning behind this theory is that drug manufacturers sell their goods to physicians who are responsible to the patients for whom they prescribe medications.<sup>115</sup>

Based on the principles of tort liability, pharmaceutical manufacturers have been designated as producers of "unavoidably unsafe" products.<sup>116</sup> According to the Restatement (Second) of Torts:

"There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of

109. See Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 92 (2002) (discussing the high cost of pharmaceutical drugs and the multiple factors behind drug prices).

110. See *id.*

111. James Ottavio Castagnera & Richard Ryan Gerner, *The Gradual Enfeeblement of the Learned Intermediary Rule and the Argument in Favor of Abandoning it Entirely*, 36 TORT & INS. L.J. 119, 120 (2000).

112. See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (creating the term "learned intermediary doctrine" to establish the role of the doctor between a patient and a prescription drug manufacturer).

113. 77 N.Y.S.2d 508 (N.Y. App. Div. 1948).

114. See *Marcus v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508 (N.Y. App. Div. 1948) (holding a manufacturer of suppositories not liable for the death of a child resulting from an overdose administered by prescription of physician, as the manufacturer made no claims directed at the patient).

115. Castagnera & Gerner, *supra* note 111, at 119-20.

116. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

drugs. . . Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous. . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.”<sup>117</sup>

On the same note, the FDA defines a prescription drug as one that cannot be made completely safe due to its potential for harmful side effects.<sup>118</sup> The Restatement (Second) of Torts and the Restatement (Third) of Torts: Products Liability also place responsibility on consumers and physicians, who are held to assume the potentially harmful risks associated with the use of pharmaceuticals.<sup>119</sup> This risk is usually undertaken because of the higher benefit-to-risk ratio the drug may provide a particular patient.<sup>120</sup> On the other hand, pharmaceutical manufacturers are not strictly liable for the side effects caused by their products, so long as they do not act negligently in failing to warn the prescribing physicians of the dangers about which they knew or should have known.<sup>121</sup> The general rule also holds that even though a drug manufacturer is aware that the medical community is failing to inform its patients of risks associated with the use of its product, a manufacturer should not be straddled with the responsibility either.<sup>122</sup> This rule is based on the principle that a doctor is not required to inform a patient of all a drug’s possible side effects.<sup>123</sup> It is the duty of the pharmaceutical companies to provide the prescribing physicians with adequate warnings and information about the drug prod-

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117. *Id.*

118. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b)(1)(A) (2000) (defining a prescription drug as a “drug intended for use by man which . . . because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such drug”).

119. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965); RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. m (1998).

120. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

121. *Id.*

122. *See generally* Buckner v. Allergan Pharmaceuticals Inc., 400 So.2d 820 (Fla. Dist. Ct. App. 1981) (holding that the manufacturers of prescription steroid drugs, who knew or should have known of the failure of physicians to warn patients of the drugs’ potentially harmful side effects, were under no duty to inform the patients as the ultimate consumers).

123. *Id.* at 824.

ucts so that doctors, as the learned intermediaries, can safely prescribe and inform their patients regarding risks and benefits.<sup>124</sup>

The responsibility given to the physician who prescribes a drug is not intended to remove or shield a pharmaceutical manufacturer from any or all product liability, but to shift a complex transaction to the most qualified dispenser of the product.<sup>125</sup> The court in *Reyes v. Wyeth Laboratories*<sup>126</sup> best illuminates this principle:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is a task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.<sup>127</sup>

The increase in drug advertisements directed at the consumer has created a divided stand on the issue of proposed reform of the learned intermediary rule.<sup>128</sup> Since the doctrine's inception, courts have been reluctant to impose liability on prescription drug manufacturers, realizing the potential of expanding liability to the point of invalidating its purpose.<sup>129</sup> To date, only a handful of direct-to-consumer campaigns have resulted in pharmaceutical manufacturer liability, all of which involved situations in which the physician-patient relationship was non-existent or nearly so. For example, a handful of courts have imposed pharmaceutical manufacturer liability in the harmful aftermath of the mass administra-

124. *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 142 (3d Cir. 1973) (commenting that the learned intermediary doctrine, requiring that the physician be provided with the appropriate warnings in order to relay the drug warnings to the patient, is the most effective way to keep the patient informed).

125. See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (1998) (stating that medical professionals are in the best position to assess and determine the advantages and disadvantages of prescription drug therapy on an individualized patient basis).

126. 498 F.2d 1264 (5th Cir. 1974).

127. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974).

128. See Monica Renee Matter, *Emerging DTC Advertising of Prescription Drugs and the Learned Intermediary Doctrine*, 69 DEF. COUNS. J. 79, 88 (2002).

129. See Jack B. Harrison & Mina J. Jefferson, *Some Accurate Information is Better than No Information at All: Arguments Against Exceptions to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising*, 78 OR. L. REV. 605, 623-24 (1999) (asserting that the creation of exceptions to the learned intermediary doctrine would result in consumers paying the ultimate cost of such exceptions).

tion of vaccines,<sup>130</sup> and the use of oral contraceptives<sup>131</sup> and contraceptive devices.<sup>132</sup>

The Eighth Circuit has also declared the occurrence of excessive pharmaceutical direct-to-consumer advertisements to be soft ground for imposing tort liability on drug manufacturers.<sup>133</sup> In *Hill v. Searle Laboratories*,<sup>134</sup> the Court of Appeals addressed the over-promotion of an implantable intrauterine device that resulted in harm to a patient.<sup>135</sup> The court found Searle liable for the cost of the consumer's injury, finding that the drug manufacturer's mass-marketing scheme generated an aggressive impression of a high quality product, diluted the risks involved with the device's use, and diminished the physician's ability to determine the product's appropriateness for the requesting patient.<sup>136</sup>

Aside from the above exceptions, the learned intermediary doctrine continues to be upheld, insulating drug companies from liability. The judicial system's adherence to the learned intermediary doctrine is sensible, assuming that legislation is enacted to control and limit the means by which pharmaceutical manufacturers advertise to consumers. This premise is well stated by Richard C. Ausness in his article on this issue. Ausness believes "it is better to discourage unethical and dangerous marketing practices by industry self-regulation, or if necessary by government regulation, than to create new, and potentially open-ended, forms of tort liability."<sup>137</sup> Yet, critics of the learned intermediary doctrine continue to argue that pharmaceutical companies should be held to the same regulations and penalties as other sellers who advertise to the general public.<sup>138</sup>

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130. See *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 122 (9th Cir. 1968) (contracting polio from polio vaccination given during mass vaccination program); *Reyes*, 498 F.2d at 1269 (administering mass vaccination program for polio), *cert. denied*, 419 U.S. 1096 (1974); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1381 (Okla. 1975); *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) (administering mass vaccination program for swine flu).

131. See *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass. 1985) (imposing liability on a manufacturer of oral contraceptive for plaintiff's resulting stroke, as the court held that the use of birth control is often a decision not requiring ongoing physician contact).

132. See *Hill v. Searle Laboratories*, 884 F.2d 1064, 1070-71 (8th Cir. 1989) (holding that the direct-to-consumer promotion of an intrauterine device required presentation of the risks of use, distinguishable from most prescription drug products, as contraceptive practices are often not medical in nature).

133. *Id.*

134. 884 F.2d 1064 (8th Cir. 1989).

135. *Id.* at 1070.

136. *Id.* at 1070-71.

137. Ausness, *supra* note 30, at 99.

138. *Id.* at 122-23.

VII. THE TOBACCO INDUSTRY AS EVIDENCE OF SUCCESSFUL, BUT DEADLY, MARKET MANIPULATION

*“A [fact]: Science Advances New Data That May Completely Change Your Ideas of Cigarettes.”*<sup>139</sup>

An empty scientific assertion made by R.J. Reynolds Tobacco Company, aimed at deflecting consumer perceptions of health risks associated with smoking.<sup>140</sup>

In recent history, the tobacco industry has experienced an unprecedented amount of litigation on the issue of product liability related to the industry's intensive marketing, advertising, and promoting strategies, which are alleged to have left consumers inadequately informed of the dangerous side-effects of tobacco use.<sup>141</sup> Based on the lengthy research of Jon D. Hanson and Douglas A. Kysar, the legal theorists have carefully examined the tobacco industry's success at manipulating consumers through marketing strategies and the subsequent liability the industry has had to face in court.<sup>142</sup> As a result of the extensive litigation and ensuing policy changes, the discovery of a tremendous amount of documentation and evidence regarding the tobacco industry's knowledge of the risks associated with the use of tobacco has become available.<sup>143</sup> The result, according to the aforementioned legal scholars, is that the history of tobacco industry market manipulation is proof that “manufacturer manipulation not only occurs, but also succeeds.”<sup>144</sup>

Prior to legislative limits imposed on cigarette advertising, few consumer products have been the subject of such a vast array and amount of advertising as have tobacco products.<sup>145</sup> According to Allan Brandt, the cigarette is a phenomenon that would not have become so much a part of American culture as it has if not for the efforts of the industry in “corporate capitalism, technology, mass marketing, and, in particular, the impact

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139. RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* 87 (1996).

140. *Id.*

141. *See* Hanson & Kysar, *supra* note 29, at 1467-68; *but see* Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Facto Incentive-Based Regulation*, 107 *YALE L.J.* 1163, 1181-83 (1998).

142. *See generally* Hanson & Kysar, *supra* note 29 (providing an in-depth analysis of products liability and manufacturers' manipulation of consumers' product risk perceptions).

143. *Id.* at 1470.

144. *Id.* at 1469-70.

145. *Id.* at 1470-71.

of advertising.”<sup>146</sup> Cigarette advertisements reflected persons who used tobacco as being powerful and independent, thus shifting the focus away from the cigarette’s risks and toward the psychological empowerment of the viewer who purchased the product.<sup>147</sup>

Resembling pharmaceutical direct-to-consumer advertisements, cigarette advertisements portrayed desirable, life-affirming traits, such as independence and sexuality.<sup>148</sup> For example, the well-known and now-famous Marlboro Man reflected onto consumers the experience of adventure and freedom with the use of Marlboro cigarettes; consumers without the effective advertisements would most likely not have perceived these abstract emotions.<sup>149</sup> The tobacco industry’s goal of increasing market share profits was based on targeting and swaying young non-smokers, primarily with the marketing strategy of health-focused advertisements, apparently filled with deceit.<sup>150</sup> The Marlboro Man was not alone in the advertisement strategy aimed at attracting young, long-term cigarette smokers – remember the “smooth character” and “quintessential party animal” Joe Camel?<sup>151</sup> In a 1989 testimonial addressed to Congress, the model hired to portray the “Winston Man” for the manufacturer of Winston brand cigarettes stated:

I was clearly told that young people were the market that we were going after. . . . It was made clear to us that this image was important because kids like to role play, and we were to provide the attractive role models for them to follow. I was told I was a live version of the GI Joe.<sup>152</sup>

The beginning of voluminous tobacco litigations began in 1994, when Mississippi filed the first state action against big tobacco, and the state of Florida passed the Medicaid Third-Party Liability Act.<sup>153</sup> This step by the Florida legislature permitted plaintiffs to introduce and rely on market-share liability, thus stripping the tobacco industry of all its common-

146. Allan M. Brandt, *The Cigarette, Risk, and American Culture*, 119 *DAEDALUS* 155, 157 (1990).

147. *Id.*

148. *See id.* (pointing out cigarette advertising was so effective because it “pointed away from the product toward the moral and psychological power” of the consumer).

149. Hanson & Kysar, *supra* note 29, at 1471.

150. *Id.* at 1470-71.

151. KLUGER, *supra* note 139, at 701.

152. *See Hollywood Unions Sue Tobacco Companies, ACTION ON SMOKING AND HEALTH*, Nov. 27, 1997, at <http://www.no-smoking.org/nov97/11-27-97-3.html> (last visited April 14, 2003).

153. FLA. STAT. ANN. § 409.910 (West 1998 & Supp. 2003).

law affirmative defenses.<sup>154</sup> By 1997, lawsuits against tobacco manufacturers had reached more than forty states, resulting in numerous fraud, negligence, and product liability claims of multi-million dollars amounts, and plaintiffs and prosecutors armed at every level of government.<sup>155</sup>

The State of California lifted its moratorium on tobacco litigation, the outcome of which resulted in a losing streak for Philip Morris in four California jury verdicts.<sup>156</sup> The most recent of the four punitive damage awards imposed against Philip Morris by a California jury totaled \$28 billion.<sup>157</sup> Jurors determined that Philip Morris concealed the health risks associated with smoking and negligently designed its cigarettes.<sup>158</sup> Although the California courts imposed excessively high judgments against the tobacco industry, the message resulting from the verdicts suggests just how ubiquitous and unobservable market manipulation can be and the need for manufacturer liability.<sup>159</sup>

This comment is not intended to suggest that prescription drugs are as inherently dangerous as cigarettes and other tobacco products.<sup>160</sup> The purpose of addressing tobacco manufacturer liability is the correlation that the tobacco and pharmaceutical industries have used in their emphasis on direct-to-consumer advertising. Of particular significance is the impact that the marketing tactics of cigarette advertisements had on juries, including cigarette advertisements' emphasis on the improved quality of life that smoking could provide, and the minimization and camouflaging of the product's side effects.

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154. See Margaret A. Little, *A Most Dangerous Indiscretion: The Legal, Economic, and Political Legacy of the Governments' Tobacco Litigation*, 33 CONN. L. REV. 1143, 1147 (2001).

155. See *id.* at 1148-49.

156. See generally Gordon Fairclough, *Despite New Legal Tactic, Philip Morris Is Burned by Jury*, WALL ST. J., Oct. 7, 2002, at A19, available at 2002 WL-WSJ 3407987.

157. *Id.*

158. *Id.*

159. See Hanson & Kysar, *supra* note 6, at 290-91.

160. See Bryan Christopher Moody, *Prescription Medication and Consumer Protection: A Time for Reform*, 5 J. OHIO N. U. J. PHARMACY & L. 19, 19 (1995) (estimating that more than 125,000 American fatalities result annually due to the taking of prescription medications).

## VII. WHAT HAS THE LEGISLATURE DONE?

*“There’s a page of mouse tracks that I swear to God, with my eyes, I can’t read.”*<sup>161</sup>

—Rep. Pete Start, D-Cal.,  
referring to the fine print product information,  
flashed on the television screen, required of  
prescription drug commercials.<sup>162</sup>

Consumers are vulnerable to the advertising strategies of pharmaceutical manufacturers who are deemed to be experts in their field; in particular, less-educated members of society and those unsophisticated in the fields of science and medicine are especially susceptible to the exploitation of pharmaceutical advertisements.<sup>163</sup>

In 1979, the FDA proposed a regulation requiring that manufacturers of prescription drugs include a patient package insert – a consumer-directed informational about the drug.<sup>164</sup> The platform for the regulation was the FDA’s conviction that the learned intermediary doctrine had resulted in an inadequate, single-source information system that left the patient-consumer with insufficient knowledge of a drug’s use and safety profile.<sup>165</sup> The FDA provided support for the bill by demonstrating that the patient’s physician, during a doctor’s visit, normally gives the patient instructions for the administration of the prescription drug on a one-time verbal basis; the patient is often anxious, ill, and eager to leave the setting.<sup>166</sup>

161. Rubin, *supra* note 28.

162. *Id.*

163. Hanson & Kysar, *supra* note 29, at 1424-25 (arguing “because individuals exhibit systematic and persistent cognitive process that depart from axioms of rationality, they are susceptible to manipulation by those actors in position to influence the decision making context”).

164. Prescription Drug Products; Patient Labeling Requirements, 60 Fed. Reg. 44194 (Aug. 24, 1995) (basing the regulations on several considerations, including studies of the effectiveness of patient package inserts and the safe and effective use of prescription drugs).

165. See Donald Kennedy, *Remarks of the Commissioner*, 32 FOOD DRUG COSM. L.J. 384, 386-87 (1977) (commenting on patient package inserts which raise the “quality of discourse between patient and physician, eliminates unfounded apprehension, increases compliance, and draws the patient into active participation in working to solve problems”).

166. See Barbara Marticelli McGarey, *Pharmaceutical Manufacturers and Consumer-Directed Information – Enhancing the Safety of Prescription Drug Use*, 34 CATH. U. L. REV. 117, 134-35 (1984) (noting that the FDA recommended that a “written source of information that the patient can read and refer to continuously would be an effective means of reinforcing the information given by the physician and [serve] as a standing reminder to the patient of the proper purposes and use of the prescribed drug”).



Opposition to the patient package insert regulation overcame its enactment, as various pharmaceutical and medical groups argued that the patient package inserts would not serve the public's interest.<sup>167</sup> The opponents to the legislations based their argument on the package inserts interference with the physician-patient relationship; the inability of the drug manufacturer to include all of the drug's relevant safety and side-effect information; the fear caused the patient by the attention to the risks involved with the drug's use, and the resulting discontinuation of the treatment.<sup>168</sup>

Despite the FDA's loosening of its reins around the pharmaceutical industry's neck, the fact remains that the sale of prescription drugs is a highly regulated business, both in terms of research and development and advertising and distribution. The FDA, not the courts, should govern the prescription drug industry when it comes to what information is relayed to the public.

Current systems for regulating marketing, excluding the pharmaceutical industry and other manufacturers of unavoidably unsafe products, have veered away from command-and-control rules and toward incentive-based systems.<sup>169</sup> Command-and-control rules require manufacturers or enterprises to abide by regulations developed for their industry, putting most of the regulatory control in the hands of policy makers.<sup>170</sup> At the other end of the liability spectrum is the incentive-based system. Incentive-based rules force industries to internalize the costs of product-accidents, thus leaving manufacturers with the responsibility of taking precautions to adequately inform the consumer of the product's risks or else assume the costs associated with the resulting harm.<sup>171</sup> Many analysts consider the incentive-based system to be superior because it operates at the profit level of manufacturer motivation.<sup>172</sup> Further, they follow the principle that market regulation should not be placed in the hands of outside regulators who must then identify and direct efficient market outcomes.<sup>173</sup>

As for drug patent abuse and the erection of barriers to generic drugs entering the market, past legislation has done little to remove the poten-

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167. *See id.* at 135.

168. Statement of Policy Concerning Oral Contraceptive Labeling Directed to Users, 35 Fed. Reg. 9001 (June 11, 1970).

169. Hanson & Kysar, *supra* note 6, at 267.

170. *Id.* at 267-68.

171. *Id.* at 268.

172. *Id.* at 267-68, 294.

173. *Id.*

tial for abuse allowed by current patent laws.<sup>174</sup> However, steps have recently been taken by the current administration to limit the amount of patent extensions a drug maker may pursue in an effort to increase consumer access to generic drugs.<sup>175</sup> In 2003, President Bush proposed a plan to make changes in patent law protection rules by limit the number of times a brand name drug maker can extend a patent to a one time automatic 30-month stay once a generic drug application is filed.<sup>176</sup> This one time extension would allow a patent holder to challenge a generic competitor, while restricting a brand name drug maker from acquiring new patents for the existing drug based on “new packing methods, for intermediate forms of the drug, or for ‘metabolites’ – substances the drug changes into inside the body.”<sup>177</sup> In other words, the administration appears to be seeking to eliminate the use of drug fine-tuning used by many of the makers of blockbuster brand name drugs currently on the market, all with the purpose of lengthening the drug’s patent security from generic competition.

#### IX. RECOMMENDATIONS: WHAT THE LEGISLATURE CAN DO

“[A]ll the logic of economic theory tells us that manufacturers will manipulate consumer perception in the direction that benefits them most – toward the underestimation of product risks. And all the evidence of consumer product markets suggests that this manipulation has been successful and will continue to be so until policymakers take behavioralism as seriously as marketers do.”<sup>178</sup>

##### A. FDA Regulations

The financial success that direct-to-consumer drug advertising has had for the pharmaceutical industry makes fairly obvious the realization that such marketing campaigns cannot be completely reversed. The goal, therefore, must be to succeed at creating guidelines for the pharmaceuti-

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174. See James T. O’Reilly, *Prescription Pricing and Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. KY. L. REV. 413, 413-14 (2002).

175. See Randall Mikkelsen, *Bush to Seek Lower-Cost Generic Drugs*, NEWS SENTINEL (FORT WAYNE), Oct. 20, 2002, available at <http://www.fortwayne.com/mld/newssentinel/4330368.htm> (stating that President Bush, on Oct. 21, 2002, would propose new regulations aimed at limiting drug patent holders to a one-time extension to be used during a patent challenge) (author’s note: Bush did indeed introduce such regulation) (last visited April 21, 2003).

176. *Id.*

177. *Id.*

178. Hanson & Kysar, *supra* note 29, at 1572.

cal industry that guarantee honest and appropriate information be portrayed in drug advertisements aimed at consumers.<sup>179</sup> Ideally, prescription drug advertisements should be in the form of public service announcements, in the framework of public education.<sup>180</sup>

The FDA must eliminate the current retrospective review process for drug commercials, which allows the consumer to be influenced by a drug commercial before the FDA and the medical community has had the opportunity to verify its accuracy.<sup>181</sup> As recommended by the American College of Physicians and the American Society of Internal Medicine, the pharmaceutical industry should be required by FDA guidelines to consult with a panel of physicians and the medical community regarding a prospective drug advertising campaign.<sup>182</sup> This will help to eliminate the negative impact on the patient-physician relationship that drug advertisements may have by allowing physicians to feel confident regarding the information their patients are receiving.<sup>183</sup>

In the field of medicine and healthcare, courts have relied on the theory of a patient's right to informed consent when it comes to a person's right to accept or reject a treatment offered to him or her.<sup>184</sup> As the information in this comment has illustrated, pharmaceutical drug commercials are not required to portray all of the advertised drug's side effects, only the most common. This lack of an accurate risk-to-benefit presentation of a drug to the consumer public appears to contradict the

179. See AMERICAN COLLEGE OF PHYSICIANS AND THE AMERICAN SOCIETY OF INTERNAL MEDICINE, DIRECT TO CONSUMER ADVERTISING FOR PRESCRIPTION DRUGS 1-2 (1998), available at <http://www.acponline.org/hpp/pospaper/dtcads.htm> (last visited on Apr. 10, 2003) (stating that although the American College of Physicians and the American Society of Internal Medicine continue to maintain that prescription drugs are not an appropriate product to be marketed directly to consumers, the fact remains that such advertisements are here to stay, and therefore require more stringent guidelines).

180. See *id.* at 2 (holding that the American College of Physicians and the American Society of Internal Medicine do not believe that product promotion has a role in prescription drug advertisements, only education).

181. *Id.* at 7-8.

182. *Id.* at 8.

183. *Id.*

184. See *Harbeson v. Parke Davis, Inc.*, 746 F.2d 517, 522 (9th Cir. 1984); *Cantebury v. Spence*, 464 F.2d 772, 780-82 (D.C. Cir. 1972); *Harrison v. United States*, 284 F.3d 293, 298-300 (1st Cir. 2002). The elements of the doctrine of informed consent are:

- (1) the existence of a material risk unknown to the patient;
- (2) the failure to disclose the risk;
- (3) that had the risk been disclosed the patient would have chosen a different course; and
- (4) resulting injury.

*Harbeson*, 746 F.2d at 522.

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“traditional principles of informed consent.”<sup>185</sup> The FDA can strive to implement regulations on the pharmaceutical industry requiring prescription drug marketing directed at consumers to protect the public by portraying accurate and complete information regarding a drug’s risks and benefits, in language that the lay public can comprehend and analyze. If a drug manufacturer is unable to comply with the required standards necessary to provide the targeted consumer with the full range of information necessary to make an informed decision whether or not to pursue a prescription for the drug, the pharmaceutical company offending the regulations must face the revocation of the right to advertise the product. As consideration for what a pharmaceutical manufacturer should be required to include in a drug commercial regarding the risks and side effects associated with the product’s use, the FDA should devise a “standard percentile [at] and above” which all side effects occurring during the research and clinical trial phase for the drug be presented to the consumer.<sup>186</sup>

### B. *Drug Patents*

The drug industry’s practice of extending a blockbuster drug’s patent life by tweaking the original drug should be tempered. The drug manufacturers’ ability to take advantage of loopholes in the patent system and solidify their drugs’ exclusive market position appears to be limitless. Legislation to increase competition in the drug market is needed. Such action will result in the moderation of prices through the introduction of generic drug equivalents. Brand name drug prices will not be lowered unless generic drugs are allowed to enter the market. However, that competition is legally barred until a brand name drug loses its monopoly.<sup>187</sup>

One potential solution: the United States Patent and Trademark Office can eliminate existing loopholes in the drug patent system. This would create a drug patent effective for twenty years, with extensions allowed for only very specific reasons. This legislation would allow patent extensions for highly select drug innovations made to drugs already under patent. At the same time, the extension clauses should clearly explain any narrow exceptions in order to prevent abuse of the system and eliminate unfair monopolization of the market. In particular, this legislation must

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185. See Holtz, *supra* note 20, at 215.

186. See *id.* at 216.

187. See FAMILIES USA, *Profiting from Pain: Where Prescription Drug Dollars Go 15* (2002), available at <http://www.familiesusa.org/ppreport.pdf> (last visited Apr. 14, 2003) (stating that it is the price of generic drugs, often sold at half of the cost of brand name equivalents, that will cause the needed moderation in prescription drug prices).

be aimed at preventing drug companies from seeking to knock-off one of their successful drugs already on the market. Drug manufacturers might then have to devote more time and resources to genuine research and development, instead of taking the easier route to increasing profits for drugs that have already cornered their fair share of the market.

C. *The Learned Intermediary Doctrine and The Pharmaceutical Industry's Duty to Assume Liability*

A final recommendation for pharmaceutical drug advertisements directed at consumers involves the evaluation of the effectiveness (or ineffectiveness) of the learned intermediary doctrine. As the above discussion of the tobacco industry's liability demonstrates, a manufacturer's liability to consumers may be based on the manufacturer's manipulation of the product's risks, which may easily be downplayed through strategic marketing tactics. The lesson that the pharmaceutical industry can learn from the tobacco industry's very successful advertising and marketing period is that there is potential for serious financial liability down the road. Courts may be able to minimize the number of future lawsuits against pharmaceutical companies related to prescription drug advertisements by replacing the learned intermediary doctrine with an incentive-based, or market-based, system of analysis. This system would require the pharmaceutical industry to internalize appropriate costs, instead of relying on regulations; thus, the pharmaceutical industry will be forced to evaluate both the positive and negative impact of their advertisements directed at consumers, all the while remaining aware of the potential for liability for their actions and failure to act.<sup>188</sup>

## X. CONCLUSION

The profits that pharmaceutical manufacturers receive as a result of direct-to-consumer marketing strategies are chilling.<sup>189</sup> Drug companies often blame the high price of prescription drugs on the high cost of research and development, asserting that a reduction in the prices charged for prescription drugs would have direct negative impact on the drug company's ability to research and develop new drug therapies.<sup>190</sup> Al-

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188. See Hanson & Kysar, *supra* note 6, at 268 (discussing the different forms of enterprise liability).

189. See FAMILIES USA, OFF THE CHARTS: PAY, PROFITS AND SPENDING BY DRUG COMPANIES 1, 3 (2001), available at <http://www.familiesusa.org/media/press/2001/drugceos.htm> (last visited April 8, 2003) (finding that the top nine pharmaceutical manufacturers made profit margins in 2000 that were nearly four times the average Fortune 500 companies).

190. *Id.* at 1.

though it takes the creation of an innovative and effectual drug to survive on the drug market, many of the leading pharmaceutical companies aggressively spend more on advertising, marketing, and administration than they do on research and development.<sup>191</sup> For example, the nine drug companies responsible for manufacturing the top fifty prescribed drugs on the market in 2001 spent nearly two-and-one-half times more money on advertising and administration than was spent on research and development.<sup>192</sup> It is this disparity – the vision of the consumer, often strapped for money, who has to make the choice between prescription drugs and food or clothing, compared to the blitz of drug advertisements displaying visuals and words of a life most consumers hope for – that makes the huge sums of money drug companies pocket each year seem exasperating.

The high tide of prescription drug advertising presented in the middle of prime time television and throughout all forms of print media will likely continue to be targeted at the unsuspecting consumer who suddenly feels symptomatic. It would be foolish to believe that pharmaceutical companies do not deserve to make a profit, as most business ventures are created with money as the primary goal and motivator. The discovery of life-saving drugs and cures, as well as the innovation of life-enhancing drugs, are the admirable social interests the general consumer population hopes the pharmaceutical industry encompasses. The making of profits by drug companies should not be used to vilify the industry, yet a capitation on or the redirection of profits to benefit the consumer-in-need appears not only necessary, but also feasible through legislation imposing stricter regulations on direct-to-consumer drug advertising and limiting drug patent extensions, as well as the reevaluation of the learned intermediary doctrine by the judicial system.

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191. *Id.* at 3.

192. FAMILIES USA, NEW 2001 DATA SHOW BIG DRUG COMPANIES SPENT ALMOST TWO-AND-ONE-HALF TIMES AS MUCH ON MARKETING, ADVERTISING, AND ADMINISTRATION AS THEY SPENT ON RESEARCH AND DEVELOPMENT 1 (2001), available at <http://www.familiesusa.org/new2001data.htm> (last visited April 8, 2003).