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Stealth Celebrity Testimonials of Prescription Drugs: Placing the Consumer in Harm's Way and How the FDA has Dropped the Ball

Louis Boyarsky

STEALTH CELEBRITY TESTIMONIALS OF PRESCRIPTION DRUGS: PLACING THE CONSUMER IN HARM'S WAY AND HOW THE FDA HAS DROPPED THE BALL

I. INTRODUCTION AND OVERVIEW

This is the age of "mass-media spam."[1] As TIVO[2] and other technological advances have empowered consumers—making message avoidance easier—the advertising industry's response has been to increase output.[3] For some advertisers, the solution to breaking through to consumers who sidestep traditional advertising has been to disguise their sales message in editorial or news content.[4] Depending on the manner employed, these stealth advertisements pose unique dangers to the general public. This is the case with stealth prescription drug advertising.

Historically, pharmaceutical companies directed their advertising solely towards physicians.[5] However, with the approval of the Food and Drug Administration (FDA),[6] the prescription drug industry has begun

1. Herbert Jack Rotfield, *Understanding Advertising Clutter and the Real Solution to Declining Audience Attention to Mass Media Commercial Messages*, 23 J. OF CONSUMER MKTG. 180, 180 (2006).

2. *See* TIVO–Wikipedia, The Free Encyclopedia, http://en.wikipedia.org/wiki/TIVO (last visited Feb. 7, 2008) (explaining that TIVO is the brand-name of a popular digital video recording device that allows its users to transform television signals into captured digital files, to play back these files at their convenience, and to manipulate these files such that advertisements are bypassed entirely).

3. Rotfield, *supra* note 1, at 181.

4. *Id.*

5. *See generally* Alison J. Huang, *The Rise of Direct-to-Consumer Advertising of Prescription Drugs in the United States*, 284 MED. STUDENT J. AM. MED. ASS'N 2240 (2000).

6. The FDA is the agency tasked with the authority of monitoring pharmaceutical advertisements in the United States. The FDA generally cannot require the prescreening of prescription drug advertisements. Rather, the FDA reviews materials after their dissemination to the public, and then makes a decision as to whether enforcement is appropriate. *See FDA Regulates Prescription Drug Promotion: Hearing Before the S. Comm. On Aging*, 108th Cong. 36 (2003) [hereinafter *FDA Regulates Prescription Drug Promotion*] (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration).

advertising directly to consumers.[7] In doing so, prescription drug companies have utilized celebrity testimonials to promote their products.[8] One means of employing celebrity testimonials is to have celebrities promote prescription drugs in formats that are not clearly commercial in nature, such as television talk shows.[9] Particularly concerning are testimonials where the celebrity has failed to disclose the side effects of the promoted drug, as well as the financial consideration the celebrity has received for the promotion.[10]

These stealth testimonials exploit the unique influence celebrities have over consumers in order to promote products that, if misused, may have life threatening implications. Through celebrity stealth testimonials, the prescription drug industry flouts FDA advertising regulations requiring disclosures designed to ensure consumer safety.[11] Yet, the FDA has failed to regulate this form of Direct-to-Consumer (DTC) advertising.[12] This Article focuses on the need for immediate FDA regulation of stealth celebrity testimonials of prescription drugs.

Part II of this Article explores the development of pharmaceutical advertising and the dangers associated with DTC advertising of prescription drugs. Part III examines the statutory and regulatory framework governing advertisements of prescription drugs. Part IV asserts that the FDA must begin to regulate celebrity stealth testimonials of prescription drugs. Part V provides alternatives for how the FDA might regulate celebrity testimonials of prescription drugs. Part VI concludes that in the absence of governmental action, consumer safety remains in jeopardy.

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7. *Id.*

8. *See* CBSNews.com, *Stars Profit from Covert Pitches Unbeknownst to Viewers*, CBS NEWS, Aug. 29, 2002, http://www.cbsnews.com/stories/2002/08/29/entertainment/main520196.shtml (last visited Feb. 7, 2008).

9. *See id.*; *see also* Melody Petersen, *Heartfelt Advice Hefty Fees*, N.Y. TIMES, Aug. 11, 2002, at 1 (concerning Kathleen Turner's appearance on Good Morning America for Wyeth).

10. Petersen, *supra* note 9.

11. *See* 21 C.F.R § 202.1(e)(1) (2006) ("All advertisements for any prescription drug . . . shall present a true statement of information in brief summary relating to side effects, contraindications . . . .").

12. *See* Warning Letters and Untitled Letters to Pharmaceutical Companies 2007-1997, http://www.fda.gov/cder/warn/warn2007.htm (last visited Feb. 8, 2008).

II. BACKGROUND AND HISTORICAL DEVELOPMENT OF THE ISSUE

A. The Evolution of Prescription Drug Advertising

Pharmaceutical advertising aimed directly at the consumer is a relatively new phenomenon.[13] Prescription drug manufacturers have historically been reluctant to advertise in this manner.[14] Legislation intended to protect the public combined with the unique paternalistic relationship that physicians share with their patients had largely kept them away from such advertising.[15] Instead, the traditional focus had been on advertising solely to physicians.[16]

In the past, physicians generally played the role of sole decision maker in determining prescription medications for their patients, leaving little economic incentive for drug companies to advertise directly to consumers.[17] In fact, it was not until the 1980s that prescription drugs were first marketed directly to consumers.[18]

The initial Direct-to-Consumer (DTC) prescription drug advertisements were the result of consumers taking a larger role in the medical decision making process and a changed regulatory climate empowering them to do so.[19] Boots Pharmaceuticals issued the first American prescription drug print advertisement directed towards consumers in 1981.[20] In the same year, the pharmaceutical company Merck, Sharp, & Dohme released the second print DTC prescription drug advertisement—for a pneumonia vaccine.[21] Facing a unique method of advertising that was gaining favor among prescription drug manufacturers, the Food and Drug Administration (FDA) requested that the pharmaceutical industry temporarily abstain from producing DTC

13. Huang, *supra* note 5 ("Prior to the early 1980s, pharmaceutical companies promoted their prescription products exclusively to physicians, who were expected to act as 'learned intermediaries' interpreting drug information for the general public.").

14. *Id.*

15. *Id.*

16. Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct to Consumer Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 424 (2002).

17. Huang, *supra* note 5.

18. *FDA Regulates Prescription Drug Promotion*, *supra* note 6, at 34 (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration).

19. Huang, *supra* note 5.

20. Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 491 (1999).

21. *Id.*

advertisements.[22] During this time, the FDA assessed whether existing advertisement regulations were able to safeguard consumer health in the face of DTC advertising, and conducted a cost-benefit analysis to decide if DTC advertisements should be allowed to continue.[23]

During the moratorium, the FDA studied the effects of DTC advertisements.[24] In 1985, the FDA settled its position on the dissemination of DTC advertising for prescription drugs.[25] It concluded that the benefits of DTC advertising were not outweighed by any associated harm.[26] Additionally, the FDA determined that existing advertising regulations were sufficient to protect consumers, and lifted the DTC advertising moratorium.[27]

The moratorium's removal set the stage for the rapid adoption of DTC advertising by the pharmaceutical industry. To understand the popularity of this form of advertising in the industry, one need only look to the exponential increase in total annual expenditures on such advertising over the past decade.[28] Total annual spending on DTC advertising grew from $985 million in 1996 to over $4.2 billion in 2005, representing a 330% increase.[29]

The increased spending on DTC advertising stems from the success it has generated for the pharmaceutical industry.[30] The industry receives $4.20 for every dollar it spends on DTC advertising.[31] DTC advertising is so profitable because of its "pull effect" on consumers.[32] Evidence from consumer surveys indicates that DTC advertising encourages consumers to

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22. *FDA Regulates Prescription Drug Promotion, supra* note 6, at 34 (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration).

23. *Id.* at 37.

24. Jane E. Henney, *Challenges in Regulating Direct-to-Consumer Advertising*, 284 MED. STUDENT J. AM. MED. ASS'N 2242 (2000).

25. *Id.*

26. JOHN E. CALFEE, PUBLIC POLICY ISSUES IN DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS 9 (2002), http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/092302/02N-0209_emc-000183-01.pdf.

27. *See* FDA, DIRECT TO CONSUMER ADVERTISING OF PRESCRIPTION DRUGS; WITHDRAWAL OF MORATORIUM, 50 Fed. Reg. 36,677 (Sept. 9, 1985).

28. *See* Julie M. Donahue et al., *A Decade of Direct to Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673 (2007).

29. *Id.* at 676.

30. *See* MEREDITH B. ROSENTHAL ET AL., HENRY J. KAISER FAMILY FOUND., DEMAND EFFECTS OF RECENT CHANGES IN PRESCRIPTION DRUG PROMOTION 16 (2003), http://www.kff.org/rxdrugs/upload/Demand-Effects-of-Recent-Changes-in-Precription-Drug-Promotion-Report.pdf.

31. *Id.*

32. *See generally* U.S. GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS (2002).

request prescriptions for specific drugs from their physicians who then provide the requested prescription.[33] The surveys asked whether consumers had seen an advertisement for a particular prescription drug and whether seeing that advertisement resulted in the consumer discussing with their physician the particular drug mentioned.[34] The respondents answered in the affirmative between sixty-five and eighty-five percent of the time.[35]

When compared to traditional advertising, the benefits of DTC advertising are clear. Prescription drugs promoted directly towards consumers quickly become bestselling drugs, and sales of DTC-advertised drugs increased faster than sales for drugs not advertised in such a manner.[36] For example, in 2000, twenty-two of the fifty drugs with the highest DTC spending were among the top fifty in sales.[37]

Today, when an individual turns on the television or reads a newspaper or magazine, their exposure to an onslaught of prescription drug advertisements is near certain.[38] The FDA and those in the health industry have characterized the explosion of DTC drug advertising as having an overall benefit to the consumer.[39] While such advertisements can provide consumers with useful information and improve their interactions with physicians—creating a better informed consumer—they can also expose the public to significant dangers.[40] These dangers can heighten when celebrities are associated with the advertising.[41]

How best to protect the public from the dangers associated with DTC prescription drug advertising is a struggle for the FDA and Congress.[42] Recent Congressional action aims to improve the regulation of DTC advertising.[43] However, the combination of Congress' failure to address

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33. *See id.* at 11.

34. *See id.* at 16.

35. *See id.*

36. *See id.* at 3.

37. *See id.*

38. *See generally* CALFEE, *supra* note 26.

39. *See generally id.*

40. *Id.* at 31.

41. *See generally Direct-to-Consumer Prescription Drug Advertising: Hearing Before U.S. Food and Drug Administration*, 109–10 (Nov. 2, 2005) (statement of Gary Ruskin, Executive Director of Commercial Alert).

42. *See generally* Arlene Weintraub, *The Drug Advertising Debate*, BUSINESSWEEK ONLINE, July 16, 2007, http://www.businessweek.com/technology/content/jul2007/tc20070715_016528.htm?chan=top+news_top+news+index_businessweek+exclusives (discussing recent Congressional attempts to limit drug marketing).

43. *See* Memorandum from Reed Smith LLP to Healthcare Clients (Oct. 24, 2007), *available at*

the dangers presented by stealth celebrity testimonials of prescription drugs and the FDA's historical leniency towards regulating such advertising continues to leave consumers in harm's way.

B. The Dangers Associated with DTC Advertising of Prescription Drugs

DTC advertising has been successful because it encourages consumers to request specific brand-name drugs from their physicians, but there are certain inherent dangers associated with this.[44] The fundamental flaw is the inability to provide consumers "complete, meaningful, and useful information."[45] A significant conflict of interest exists with a pharmaceutical company presenting complete and unbiased information about its products, because, while prescription drug companies obviously have a financial interest in seeing their products succeed, this interest can be at odds with the full disclosure of a particular drug's dangers.

A recent DTC advertising campaign promoting new treatments for HIV/AIDS illustrates this concern.[46] The advertisements—heavily laden with visual imagery—created what critics said were unrealistic expectations of treatment for patients and those at risk.[47] Supporting the criticism is a San Francisco survey which found that men who had frequently seen the advertisements were more likely to engage in unsafe sex.[48]

Another concern about DTC advertising is the impact that it has on the doctor-patient relationship.[49] Critics argue that DTC advertising encourages consumers to pressure health professionals to prescribe particular medications that are often less effective and more expensive than what they would normally prescribe.[50] A study conducted by the *Journal*

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http://www.reedsmith.com/_db/_documents/Food_and_Drug_Law_Client_Memo_1026.pdf. (discussing the Food and Drug Act Amendments of 2007, which increased fees charged to prescription drug companies in an effort to increase resources for review of television drug advertising, and gave the FDA greater authority to pre-review advertisements).

44. *See Direct-to-Consumer Prescription Drug Advertising*, *supra* note 41, at 102–14 (statement of Gary Ruskin, Executive Director of Commercial Alert).

45. *Id.* at 102–03 (quoting Allen S. Cushion, Senior Vice President for Public Affairs, Scheering Plough).

46. HEALTH ACTION INTERNATIONAL, DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING: THE EUROPEAN COMMISSION'S PROPOSAL FOR LEGISLATIVE CHANGE 6 (2001), *available at* http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf.

47. *Id.*

48. *Id.*

49. *See* MARK WAMSLEY, MEDIA EDUC. FOUND., A SOFT SELL FOR HARD DRUGS 2, http://www.mediaed.org/news/articles/SoftSellHardDrugs (last visited Feb. 23, 2008).

50. *See Impact of Direct-to-Consumer Drug Advertising on Seniors' Health and Health Care Costs: Hearing Before the S. Spec. Comm. on Aging*, 109th Cong. 88 (2005) [hereinafter

of American Medicine analyzed the impact of an advertisement campaign for a depression related drug treatment on sales of that drug.[51] It found that only ten percent of patients who had not made a specific request for an advertised drug received a prescription for that drug, while fifty-five percent of patients who specifically requested the drug received a prescription for it.[52] Further illustrating the impact of DTC advertising on the doctor-patient relationship is a recent FDA survey of 500 physicians.[53] Questioned about the problems DTC advertising creates for their practices, the majority of the physicians responded that DTC advertising confuses patients about the relative risks and benefits of advertised drugs and leads to patients unnecessarily requesting prescriptions.[54] The result is that physicians are put in a position where they have to dissuade patients from taking drugs that are wrong for the patient's particular ailments, but that advertising has led patients to believe are right for them.

Celebrity advertisements amplify the above-mentioned dangers as they hold a greater influence over the general public than traditional non-celebrity advertisements. Thus, significant potential dangers exist when drug companies use celebrities to advertise their drug products.[55] Of particular concern are several advertising incidents where celebrities have not disclosed that they are being compensated by drug manufacturers, or have failed to make material disclosures about the side effects of the drug they are promoting.[56]

C. The Celebrity Component

1. Big Pharma's Exploitation of Celebrity Star Power

Celebrities certainly have power and influence over the average

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Impact of Direct-to-Consumer Drug Advertising] (statement of Peter Lurie, Deputy Director of Public Citizens Health Research Group); WAMSLEY, *supra* note 49, at 2.

51. *Impact of Direct-to-Consumer Drug Advertising, supra* note 50, at 100 (statement of Richard L. Kravitz, M.D., MSPH, Director, Center for Health Services Research in Primary Care, University of California, Davis Medical Center).

52. *Id.*

53. *See* Kathryn J. Aikin, et al., Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results,. Jan. 23, 2003, http://www.fda.gov/cder/ddmac/globalsummit2003 (follow link "click here to start presentation").

54. *Id.*

55. Ray Moynihan, *The Intangible Magic of Celebrity Marketing*, 1 PUB. LIBR. SCI. MED. 102, 104 (2004).

56. *Id.*

American, as evidenced by our seemingly endless fascination with them.[57] Pharmaceutical companies, recognizing this power, are employing popular celebrities to attract attention to their latest drugs.[58] Examples include professional athlete Ricky Williams' contract with pharmaceutical company GSK to sell antidepressants, and politician Bob Dole's infamous campaign for pharmaceutical company Pfizer's erectile dysfunction drug Viagra.[59] The tactic of employing celebrity advertising has been so effective that firms exist solely to match celebrities with drug companies.[60]

As pharmaceutical companies continue to exploit celebrity star power, the danger is that they may do so in a surreptitious or indirect manner and that they may manipulate consumers by taking advantage of the unique influence celebrities possess over the general public. Due to the potential risks associated with the consumption of prescription drugs, stealth celebrity testimonials of a pharmaceutical product can pose a significant danger to the general public.

2. A New Tactic to Assault Consumers: Celebrity Stealth Marketing of Prescription Drugs

The increasing clutter and fragmentation of the media and the development of new technologies such as Digital Video Recording (DVR) devices that empower the consumer to bypass television advertisements impair the effectiveness of traditional forms of advertising.[61] The problem for advertisers is the consumer's desire to avoid the "cacophony of marketing messages aimed constantly toward the consuming public."[62] As wary and cynical viewers are bombarded with an increasing number of advertisements, some marketers have turned to more subtle methods of communicating their message.[63] This subset of marketing, where the consumer is unaware that they are being marketed to is often referred to as

57. *See, e.g.*, Perez Hilton, PerezHilton.com: Celebrity Juice, Not from Concentrate, http://perezhilton.com (last visited Feb. 23, 2008); PageSix.com, http://www.pagesix.com (last visited Feb. 23, 2008).

58. Moynihan, *supra* note 55, at 102–03.

59. *Id.* at 103.

60. Diedtra Henderson, *Rise of Celebrity Testimonials Spurs FDA Scrutiny*, BOSTON GLOBE, Oct. 30, 2005, at A1.

61. Andrew M. Kaikati & Jack G. Kaikati, *Stealth Marketing: How to Reach Consumers Surreptitiously*, 46 CAL. MGMT. REV. 6, 8 (2004).

62. Namita Bhatnagar, et al., *Embedding Brands Within Media Content: The Impact of Message, Media, and Consumer Characteristics on Placement Efficacy*, *in* THE PSYCHOLOGY OF ENTERTAINMENT MEDIA: BLURRING THE LINES BETWEEN ENTERTAINMENT AND PERSUASION 99 (L.J. Shrum ed., 2004) (2003).

63. *Id.*

"stealth marketing."[64]

Stealth marketing may occur in two forms.[65] The first is conventional payola marketing, where the sponsor purchases audience exposure as a form of advertising.[66] The second is embedded marketing, which occurs when promotional messages are embedded into editorial content.[67] Embedded marketing techniques can be traced to practices originally developed for publicity purposes.[68] Such publicity practices generally involve unpaid acts designed to attract public interest, as opposed to more traditional advertising, which involves the paid dissemination of messages.[69] Stealth marketing has the effect of blurring the unpaid "embedded marketing" with the "payola marketing."[70] In the context of prescription drugs, stealth marketing has taken the form of celebrities making stealth testimonials of specific drugs.[71]

Large pharmaceutical companies hire celebrities to appear on talk shows discussing various diseases and promote specific drugs during a casual chat with the host.[72] A cause for concern arises when celebrities fail to mention their financial ties to the pharmaceutical company sponsoring them or fail to make any disclosures in regards to the side effects of the drugs they are promoting.[73] Critics have characterized such stealth testimonials as essentially a commercial "masquerading as an interview."[74]

Several noteworthy examples of stealth celebrity testimonials exist. In 2002, Lauren Bacall, a prominent actress, appeared on NBC's Today Show, and discussed a friend who had lost their sight from macular degeneration.[75] Bacall then encouraged members of the audience to see their doctors for macular degeneration testing and proceeded to mention the

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64. *See generally* Undercover Marketing–Wikipedia, The Free Encyclopedia, http://en.wikipedia.org/wiki/Stealth_marketing (last visited Feb. 7, 2008).

65. *See generally* FCC Payola Rules, http://www.fcc.gov/cgb/consumerfacts/PayolaRules.html (last visited Feb. 7, 2008).

66. *See generally id.*; Rotfield, *supra* note 1.

67. Rotfield, *supra* note 1, at 181.

68. *See* Anne R. Owen & James A. Karrh, *Video News Releases: Effects on Viewer Recall and Attitudes*, 22 PUB. REL. REV. 369, 371–72 (1996).

69. *See* Bookpros.com, Publicity vs. Marketing, http://www.bookpros.com/bp2006/divpuz/publicity_vs_marketing.php (last visited Feb. 7, 2008) (distinguishing publicity and marketing).

70. Kaikati & Kaikati, *supra* note 61, at 12.

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. Petersen, *supra* note 9.

drug Visudyne, a new treatment for the disease.[76] What Bacall failed to mention was that Novartis, the manufacturer of Visudyne, compensated her for her time on the show.[77]

Another incident involves an interview with Kathleen Turner, a popular actress, on ABC's Good Morning America.[78] Turner appeared on the show to discuss her rheumatoid arthritis.[79] During the interview, she referred viewers to a website sponsored by pharmaceutical company Wyeth, saying that new medications were "'extraordinarily effective' and did not have any side effects."[80] Wyeth is not only the co-manufacturer of Enbrel, an anti-arthritis drug, but also maintains the promoted website.[81] Turner, too, failed to mention that the manufacturers compensated her for her public appearances on behalf of Enbrel.[82]

A final example comes from CBS's The Montel Williams Show. Williams, the show's host, has multiple schlerosis and featured the disease on one of his shows.[83] During the show, Williams mentioned he takes Copaxone, saying it is what has "kept [him] running."[84] Williams failed to discuss both the drug's possible side effects and his financial ties to Teva Pharmaceuticals, the manufacturer of Copaxone.[85]

The dangers associated with DTC advertising are magnified when a stealth celebrity testimonial occurs. The pharmaceutical company, relying on a celebrity's unique influence over the public, manipulates the consumer in a manner in which they are unaware. This is inherently dangerous in the realm of prescription drugs; failing to fully inform the public can have deadly effects.[86]

The events surrounding the rise and fall of pharmaceutical company Merck's pain medication, Vioxx, illustrate the dangers of failing to inform the public about the side effects of a prescription drug.[87] Clinical trials and studies conducted by Merck revealed that a potential side effect to Vioxx

76. *Id.*
77. *Id.*
78. *Id.*
79. *Id.*
80. *Id.*
81. Petersen, *supra* note 9.
82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.*
86. *See generally Direct-to-Consumer Prescription Drug Advertising: Hearing Before the S. Fin. Comm.*, 107th Cong. 1 (2004) (statement of Dr. David J. Graham, Assistant Director for Science and Medicine, Food and Drug Administration).
87. *Id.*

was an increased risk of heart attack and sudden death.[88] Tragically, Merck did not inform the public of these dangers.[89] In testimony before the Senate Finance Committee, it was estimated that Vioxx caused between 88,000 and 139,000 cases of heart attacks.[90] In 2005, a Texas jury found Merck liable for $250 million in damages in the first of several lawsuits brought against Merck for the failure to disclose Vioxx's risks.[91]

Mechanisms are in place to prevent events such as the Vioxx disaster.[92] Nearly fifty years ago the federal government began to support the idea that is necessary to disclose accurate information of prescription drug side effects to ensure the safe use of those drugs.[93] These disclosure requirements become crucial when a drug is marketed directly to the public.

Today, FDA regulations prohibit prescription drug advertisements from being false or misleading, and require broadcast advertisements to contain a brief summary of a drug's side effects.[94] Yet stealth celebrity testimonials flout these requirements.[95] However, the FDA has yet to find that such activity violates prescription drug regulations. The testimonials have, in effect, allowed pharmaceutical companies to bypass FDA requirements which stipulate that advertising messages should include cautions about prescription drugs and disclose their side effects.[96] Osnat Benshoshan, an executive at pharmaceutical company Amgen, says, "the great advantage [of stealth testimonials] over [traditional] advertising . . . is there is no fair balance to worry about."[97]

Failing to provide consumers this "fair balance," or basic information regarding the side effects of a particular prescription drug, while at the same time relying on the unique influence of a celebrity, exposes the consumer to the same risks as the Vioxx tragedy. Law exists to protect the public from the harms associated with stealth celebrity testimonials, yet the FDA is failing to enforce it.[98]

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88. *Id.*

89. *Id.*

90. *Id.* at 1–2.

91. Aaron Smith, *Jury: Merck Negligent*, CNN.COM, Aug. 22, 2005, http://money.cnn.com/2005/08/19/news/fortune500/vioxx/index.htm.

92. *See* Sam Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. OF POL. ECON. 1049, 1051 (1973).

93. *Id.*

94. 21 C.F.R. § 202.1 (2006).

95. Kaikati & Kaikati, *supra* note 61, at 12.

96. *Id.*

97. Moynihan, *supra* note 55, at 113.

98. *See* Peltzman, *supra* note 92, at 1051.

III. THE REGULATION OF PRESCRIPTION DRUG ADVERTISEMENTS

A. Historical Development of Direct-to-Consumer Advertising Regulation

Upton Sinclair, a prolific American author, brought to light the nauseating conditions of the meatpacking industry and helped lead the way to the first comprehensive legislation regulating food and drugs.[99] The hazards of the meatpacking industry vividly exposed in his novel, *The Jungle*, pushed Congress to enact The Pure Food and Drugs Act of 1906.[100] The legislation, also known as the Wiley Act, primarily focused on the need for informative product labels. The Act stipulated that drugs, "defined in accordance with the standards of strength, quality, and purity in the *United States Pharmacopoeia* and the *National Formulary*, could not be sold in any other condition unless the specific variations from the applicable standards were plainly stated on the label."[101] The Act, however, did not address drug advertising because labels at the time were the primary medium for drug promotions.[102] While the 1906 Act represented landmark legislation for its era, it contained significant deficiencies.

The Wiley Act deems a drug "misbranded" only if its label contained false statements about its "curative or therapeutic effects."[103] However, it failed to prohibit false claims made off the label, which created a loophole to allow an unsafe drug to remain on the market.[104] In *FTC v. Raladam*, the Supreme Court's interpretation of the Federal Trade Commission Act of 1914 widened the loophole.[105] Although the Federal Trade Commission Act gave the Federal Trade Commission (FTC) jurisdiction over advertising practices, the Court held that the FTC did not have the authority to regulate deceptive advertisements unless it could prove that such

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99. FDA.gov, History of the FDA—The 1906 Food and Drugs Act and its Enforcement, http://www.fda.gov/oc/history/historyoffda/section1.html (last visited Oct. 28, 2007).

100. JOHN P. SWANN, HISTORY OF THE FDA, *adapted from* A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George Kuran ed., 1998), *available at* http://www.fda.gov/oc/history/historyoffda/fulltext.html (stating that Sinclair's depiction of the meat packing industry was the "final precipitating force behind both a meat inspection law and a comprehensive food and drug law").

101. *Id.*

102. HARRY A. TOULMIN, JR., A TREATISE ON THE LAW OF FOOD, DRUGS AND COSMETICS 16 (W.H. Anderson Co. 1963) (1942).

103. 21 U.S.C. § 329(a) (amending 21 U.S.C. §§ 1–15 (1934)).

104. *See id.*

105. *See generally* FTC v. Raladam, 283 U.S. 643 (1931).

advertisements injured a competitor.[106] These loopholes remained until the next significant enactment of Food and Drug legislation in 1938.[107] Gaps in the Wiley Act, changes in the pharmaceutical industry and the aggressive advertising of drugs in newspapers and magazines, necessitated this new legislation.[108] Sadly, the impetus behind the new legislation was a "therapeutic disaster" and not foresight or planning.[109]

In 1937, pharmaceutical company S.E. Massengil marketed a drug to pediatric patients containing elixir sulfanilamide.[110] The drug's chemical makeup was the equivalent of antifreeze, resulting in more than 100 deaths, the majority of whom were children.[111] The resulting public outcry led to the implementation of the Food, Drug, and Cosmetic Act of 1938.[112]

The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) repealed and replaced the Wiley Act.[113] The new law gave control of cosmetics and medical devices to the Food and Drug Administration (FDA), requiring the adequate labeling of drugs for safe use.[114] Congress decided to omit advertising restrictions from the Act and instead conferred jurisdiction over all drug advertising to the FTC.[115] It would take another thirty years before Congress would grant the FDA authority to regulate prescription drug advertisements.[116]

B. The Modern Regulatory Scheme

1. FDA Gains Power to Regulate Prescription Drug Advertisements

In 1962, the Kefauver-Harris Drug Amendments to the FDCA transferred regulatory authority over prescription drug advertising from the FTC to the FDA, by enacting Section 502(n) of the FDCA.[117] The

106. Harvard Law Review Association, *"Corrective Advertising" Orders of the Federal Trade Commission*, 85 HARV. L. REV. 470, 480 (1971).

107. *See generally* Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 (2006))

108. TOULMIN, *supra* note 102, at 16.

109. SWANN, *supra* note 100.

110. *Id.*

111. *Id.*

112. *Id.*

113. *See* Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 (2006)).

114. *See* 21 U.S.C. § 352(f) (1938).

115. *See* Wheeler-Lea Act, 52 Stat. 111 (1938).

116. *See* Drug Amendments of 1962, Pub. L. 87-781, 76 Stat. 780.

117. *See* 21 U.S.C. § 352(n) (2006).

amendments were enacted in an effort to protect the public from the dangers of potentially harmful drugs.[118] The legislation required manufacturers to provide proof of the effectiveness and safety of their drugs before approval, and required drug advertisements to disclose accurate information about side effects and efficacy of treatments.[119]

The FDCA in its present form does not actually provide an explicit definition of what constitutes an advertisement,[120] but the FDA generally interprets the term to encompass information (other than labeling) that promotes a drug product and is sponsored by a manufacturer.[121] Additionally, FDA regulations provide a list of examples of advertisements subject to regulation, including "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."[122] The manner in which the FDA regulates advertisements disseminated through these mediums depends largely on how the FDA characterizes the advertisement.

2. The Types of Advertisements that the FDA Regulates

Although there are numerous mediums through which a pharmaceutical company may communicate to consumers, the FDA only recognizes three categories of advertisements and only regulates two of them.[123] The two categories that the FDA regulates are "product-claim" advertisements and "reminder" advertisements.[124] The third category, labeled "help-seeking," is free from FDA regulation.[125]

Product-claim advertisements include the name of a prescription drug and its use, or a claim or representation about the safety or efficacy of a prescription drug.[126] Advertisements containing claims made about benefits of a particular drug must also disclose risks associated with the drug.[127] The "fair balance" requirement references the disclosure of

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118. Peltzman, *supra* note 92, at 1049–51.

119. *See id.* at 1051.

120. *See* 21 U.S.C. § 352(n) (2006).

121. The FDCA defines labeling as any "written, printed, or graphic matter" upon or accompanying the drug. 21 U.S.C. § 321(k) (2006).

122. 21 C.F.R. § 202.1(k)(l)(1) (2006).

123. 60 Fed. Reg. 42,581, 42,583 (Aug 16 1995).

124. *FDA Regulates Prescription Drug Promotion*, *supra* note 6, at 34 (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration).

125. *Id.*

126. 60 Fed Reg. 42,581 (Aug. 16, 1995).

127. *Id.*

benefits and risks of the drug.[128]

Reminder advertisements, also regulated by the FDA, are advertisements that contain the product's name and certain descriptive information, such as correct dosage or price. However, unlike the product claim advertisements, they do not make any specific claims or representations about the drug.[129] Additionally, the FDA regulations exempt reminder advertisements from the risk disclosure requirements.[130] This is because historically, reminder advertisements were directed towards health care professionals and not the general public.[131]

Finally, "Help Seeking" advertisements, unregulated by the FDA, discuss a disease or condition and advise the audience to see a doctor for possible treatments.[132] The FDA does not regulate this type of advertisement because it does not consider a help-seeking advertisement as a drug advertisement, because these advertisements do not mention a specific drug.[133]

3. The FDA's Statutory Authority to Regulate Advertisements

The FDCA requires manufacturers, packers and distributors who advertise prescription human and animal drugs, including biological products for humans, to disclose certain information about the advertised product's use and risks.[134] Section 502(n) of the FDCA provides the FDA with the authority to regulate prescription drug advertisements and the implementing regulations provide specifics about the content of such advertisements.[135] It is important to note that neither the statute nor the implementing regulations prohibit pharmaceutical companies from advertising directly to consumers in any form.[136]

For prescription drugs, the FDCA requires advertisements to give a brief summary of the drug's "side effects, contraindications and

128. *Id.*

129. *Id.*

130. *Id.*

131. *FDA Regulates Prescription Drug Promotion, supra* note 6, at 34 (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration); *see also* 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

132. 60 Fed. Reg. 42,581, 42,582 (Aug. 16, 1995).

133. *Id.*

134. 21 U.S.C. § 352(n) (2006).

135. 21 C.F.R. § 202.1 (2006); *see also* 21 U.S.C. § 502(n) (2000).

136. *FDA Regulates Prescription Drug Promotion, supra* note 6, at 35 (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration).

effectiveness."[137] The Act's implementing regulations further specify that prescription drug advertisements be free from false and misleading statements and must not omit material facts.[138] These regulations additionally require advertisements to contain a "fair balance" between information pertaining to the benefits and risks of a particular drug.[139]

The prescription drug advertising regulations also distinguish between requirements necessary for print and broadcast advertisements.[140] The regulations specify that print advertisements must include a brief summary of risks on the approved package label.[141] Advertisements that are broadcast through media such as television or radio must disclose a drug's major side effects in either the audio or visual parts of the presentation.[142] Sponsors of broadcast advertisements must also present a brief summary or alternatively make "adequate provision . . . for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."[143]

In addition to the regulations published in the Federal Register, the FDA has on occasion issued "Draft Guidance" to clarify its interpretation of its own regulations.[144] For example, in recognition that the brief summary requirement is not easily satisfied in a thirty-second television commercial, FDA regulations allow sponsors of broadcast advertisements on both television and radio to make "adequate provision" of approved product labeling rather than providing the entire brief summary in the advertisement.[145] To clarify how the adequate provision requirement may be satisfied, the FDA issued a draft guidance in August 1999 entitled "Guidance for Industry: Consumer-Directed Broadcast Advertisements" (Guidance).[146] The Guidance details an approach for ensuring that audiences exposed to prescription drug advertisements on television and radio have convenient access to the advertised drug's labeling.[147]

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137. 21 U.S.C. § 352(n) (2006).

138. *See* 21 C.F.R. § 202.1(e)(5) (2006).

139. *Id.* § 202.1(e)(5)(ii).

140. *See id.* § 202.1(e)(4).

141. *Id.*

142. *See id.* § 202.1(e)(1); *see also* Food and Drug Administration, et al., Guidance for Industry, Consumer-Directed Broadcast Advertisements (Aug. 1999), *available at* http://www.fda.gov/cder/guidance/1804fnl.pdf [hereinafter Guidance for Industry].

143. 21 C.F.R. § 202.1(e)(1) (2006); *see also* Guidance for Industry, *supra* note 142.

144. *See* Guidance for Industry, *supra* note 142; *see also* 64 Fed. Reg. 43,197 (Aug. 9, 1999).

145. 21 C.F.R. § 202.1(e)(1) (2006).

146. Guidance for Industry, *supra* note 142.

147. *Id.*

Essentially this informs the pharmaceutical industry that a broadcast advertisement will not violate the regulations if it complies with the Guidance.[148] Although the Guidance is technically not legally enforceable, when a broadcast advertisement conflicts with the Guidance or with the implementing advertising regulations, the FDA has several tools at its disposal to ensure compliance with both its regulations and the law.[149]

C. The FDA's Failure to Enforce its Own Regulations

The FDA generally cannot require the prescreening of prescription drug advertisements.[150] Instead, it reviews materials after their dissemination to the public and then makes a decision as to whether an enforcement action is necessary.[151] Within the FDA, the Division of Drug Marketing, Advertising, and Communications (DDMAC) performs this task.[152] To ensure compliance with both prescription drug advertising laws and regulations in general, DDMAC employs a program that monitors advertisements.[153] Concerned citizens, healthcare practitioners, and competitor pharmaceutical companies also alert the FDA to questionable advertisements.[154]

If DDMAC finds that an advertisement violates the law, it issues one of two letters to the company in violation.[155] The first type of letter, a Notice of Violation letter (NOV or "untitled letter"), the DDMAC sends for minor violations.[156] The second type, a warning letter, DDMAC sends for more serious violations and essentially is an indication that the FDA will proceed against the manufacturer if it does not initiate corrective action.[157] If an advertiser fails to take corrective action, the FDA has other available methods of enforcement including seeking an injunction against the manufacturer or pursuing criminal prosecution.[158] To date, the FDA has not employed any of these more serious enforcement measures for DTC

148. *FDA Regulates Prescription Drug Promotion*, *supra* note 6, at 33.

149. *Id.* at 42.

150. *Id.* at 36 (statement of Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration).

151. *Id.* at 33.

152. *Id.*; *see also* FDA.gov, Division of Drug Marketing, Advertising, and Communications, http://www.fda.gov/cder/ddmac/ (last visited Feb. 23, 2008).

153. *FDA Regulates Prescription Drug Promotion*, *supra* note 6, at 40.

154. *Id.*

155. *Id.* at 42.

156. *Id.* at 34.

157. *Id.*

158. *See, e.g.*, 21 U.S.C. §§ 331–37 (2006).

advertising violations. In fact, the FDA's overall enforcement of its advertising regulations has been—as one commentator puts it—rather "lackadaisical."[159]

Between 1998 and 2004 there was an eighty-five percent decline in enforcement of questionable DTC advertisements on the part of the FDA, in spite of dramatically increased DTC advertising spending during the same time-period.[160] Only forty-five warning letters requesting promotion be stopped immediately were sent during these seven years. In 2002 alone, there were approximately 6,000 DTC ads.[161] Lack of enforcement has become such a problem that Louis Morris, the former head of the FDA's drug-marketing division was quoted as saying, "FDA enforcement has waxed and waned . . . I watch TV and say to myself, 'Isn't that illegal?'"[162]

Even when an enforcement action occurs, the average time between the initial placement of the drug advertisement and the enforcement action was 177 days.[163] In a 2002 report, the General Accounting Office concluded that, "reviews of draft regulatory letters from FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before FDA issued the letters."[164]

This lack of vigorous enforcement has placed the American consumer in harm's way for all types of drug advertising. The FDA's "lackadaisical" enforcement should cause much concern, particularly since the FDA has never taken enforcement action in response to a celebrity stealth testimonial.[165]

IV. THE FOOD AND DRUG ADMINISTRATION CAN REGULATE STEALTH CELEBRITY TESTIMONIALS UNDER CURRENT REGULATIONS

Although the Food and Drug Administration (FDA) has failed to regulate stealth celebrity testimonials of prescription drugs, the FDA does

159. *Impact of Direct-to-Consumer Drug Advertising*, *supra* note 50 (statement of Peter Lurie, Deputy Director of Public Citizens Health Research Group).

160. *See* Warning Letters and Untitled Letters to Pharmaceutical Companies 1998–2004, http://www.fda.gov/cder/warn/ (last visited Feb. 8, 2008).

161. *See id.*; *see also FDA Regulates Prescription Drug Promotion*, *supra* note 6, at 41.

162. Julie Schmidt, *FDA Races to Keep up with Drug Ads That Go Too Far*, USA TODAY, May 30, 2005, *available at* http://www.usatoday.com/money/industries/health/drugs/2005-05-30-drug-ads-usat_x.htm?POE=MONISVA.

163. *Impact of Direct-to-Consumer Drug Advertising*, *supra* note 50, at 93.

164. U.S. GENERAL ACCOUNTING OFFICE, *supra* note 32, at 23.

165. *See* Warning Letters and Untitled Letters to Pharmaceutical Companies 1998–2004, *supra* note 160.

have the authority to do so,[166] and the testimonials are characteristically similar to the advertisements that they have regulated in the past.[167] A stealth testimonial is essentially a more subtle form of a traditional advertisement. Therefore, just as the FDA regulates traditional advertisements, it should also regulate stealth testimonials. Not doing so leaves the public at risk. For the following reasons, the FDA should regulate stealth celebrity testimonials.

A. Celebrity Stealth Testimonials Constitute Advertising under the Federal Food, Drug, and Cosmetic Act of 1938

The Federal Food, Drug, and Cosmetic Act (FDCA) does not define what constitutes "advertising."[168] The only guidance in the area are FDA regulations that illustrate the various mediums through which advertisements are subject to regulation.[169] However, the list is not exhaustive. In the past, methods of advertising outside of those enumerated in the regulations have been subject to FDA supervision.[170] For example, in addition to those mediums listed, the FDA regulates advertising conducted through sales representatives, computer programs, fax machines, and online message boards.[171] This demonstrates the FDA's willingness to expansively interpret its regulatory authority over the various channels through which businesses disseminate their advertisements. The FDA should apply a similar approach to regulating newly emerging forms of advertising not yet listed in FDA regulations.

Black's Law Dictionary defines advertising as "the action of drawing

166. *See* 21 U.S.C. §§ 331(a)–(b), 352(a), (f), (n) (2006) (statutory authority for prohibition against misbranding and requirement of fair balance in advertising); *see also* 21 C.F.R. § 202.1 (2006) (FDA interpretive regulations).

167. *See* Letter from Thomas W. Abrams, Director, Division of Drug Marketing, Advertising and Communications, FDA, to Raymond V. Gilmartin, President and CEO, Merck & Co., Inc. (Sept. 17, 2001), *available at* http://www.fda.gov/cder/warn/warn2001.htm (finding Merck had engaged in a promotional campaign that minimized the potential risks and misrepresented the safety profile for Vioxx.); *see also* Letter from Barbara S. Chong, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, FDA, to Susan P. Rinne, Vice President, Regulatory Affairs, Alza Corp. (Jul. 12, 2001), *available at* http://www.fda.gov/cder/warn/warn2001/10196.pdf (finding Alva Corp. DTC Advertisements for Ditrospan XL were false and misleading by suggesting the drug was more effective than it was and failing to disclose important facts about its limitations).

168. *See generally* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 331, 352 (2000).

169. *See* 21 C.F.R. § 202.1(k)(l)(1) (2006).

170. SWARBRICK & BROLIN, ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY 48 (Michael Drekker, Inc. Informa Health Care 2d ed. 2002) (1992).

171. Id.

the public's attention to something to promote its sale."[172] Similarly, in his book *Promotion and Integrated Marketing Communications*, Richard Semenik defines advertisements as a "specific message an organization has placed to persuade an audience."[173] These definitions, combined with the FDA's interpretation of its powers to regulate advertising, are sufficiently broad for the FDA to assert authority over stealth celebrity testimonials.

When a pharmaceutical company compensates a celebrity to appear on a talk show, as was the case in Lauren Bacall's appearance on *The Today Show*, it does so in an attempt to persuade the consumer.[174] As the court in *Lugosi v. Universal Pictures* explains, the company is commercially using a celebrity's persona in a manner "intended to increase the value or sales of the product by fusing the celebrity's identity with the product and thereby siphoning some of the publicity value . . . in the celebrity's persona into the product."[175] Bacall's compensation for mentioning the drug Visodyne on *The Today Show*, and Kathleen Turner's remuneration for directing *Good Morning America* viewers to a website operated by Wyeth, both constitute a form of advertising. These examples of stealth celebrity testimonials are not only advertisements as defined by the FDCA, but are also of the character that the FDA traditionally regulates.[176]

B. Celebrity Stealth Testimonials are of the Type of Ads that the FDA Traditionally Regulates

As previously mentioned, the FDA regulates two classifications of advertisements, "Reminder Ads" and "Product Claim Ads."[177] Both categories involve the identification of specific drugs, but the product claim category deals with those ads that contain assertions of a drug's benefits, safety, and effectiveness.[178] This latter category is arguably more dangerous to the consumer due to the potential for the advertisement to include false or misleading statements. The FDA should classify many stealth celebrity testimonials as product claim advertisements.

A stealth celebrity testimonial constitutes a product claim

172. BLACK'S LAW DICTIONARY 55 (7th. ed. 1999).

173. RICHARD SEMENIK, PROMOTION & INTEGRATED MARKETING COMMUNICATIONS 555 (South-Western 2002).

174. Petersen, *supra* note 9.

175. Lugosi v. Universal Pictures, 623 P.2d 425, 438 (Cal. 1979).

176. *FDA Regulates Prescription Drug Promotion*, *supra* note 6, at 34 (statement of Janet Woodcock, Director Center for Drug Evaluation and Research, Food and Drug Administration).

177. *Id.*

178. *Id.*

advertisement when a pharmaceutical company provides financial remuneration to a celebrity who has appeared on television and that celebrity has made assertions in regards to a specific drug's benefits, safety, or effectiveness. Lauren Bacall's appearance on *The Today Show* to encourage viewers to see their doctors about macular degeneration, during which she mentioned Novartis' prescription drug Visodyne, was unmistakably a claim about the use of the drug.[179] Likewise, by featuring the drug Copaxone on his show and stating it that was what has "kept him running," Montel Williams was making an assertion about the effectiveness of the drug.[180] The specific claims made during these testimonials, and others like them, should subject these advertisements to FDA regulations such as those requiring specific disclosures of the benefits and risks of a particular drug.

The FDA requires prescription advertisements to include a "true statement of information in brief summary relating to side effects, contradictions and effectiveness" of the drug advertised.[181] A manufacturer fails to meet this true statement requirement if an advertisement is "false or misleading, does not present fair balance between side effects and contraindications information or effectiveness information, or fails to reveal material facts."[182] The FDA realizes that requiring a complete listing of side effects and other balance information is impracticable for broadcast advertising. Instead, the FDA requires such advertising only to include statements concerning major risks of the drug advertised, "provided that the manufacturer makes adequate provision for the dissemination of the approved package labeling."[183] In determining whether a violation has occurred the regulations call for the FDA to go beyond supervising the "veracity in advertising statements to examine how the information is presented."[184] Information regarding side effects must be presented prominently and regulations require several factors to be considered in determining whether an advertisement has run afoul of this requirement.[185]

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179. *Id.*

180. Petersen, *supra* note 9.

181. 21 C.F.R. § 202.1(e) (2006).

182. RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 76–77 (Jones and Bartlett Publishers 2005).

183. *Id.* at 77.

184. Pa. Emps. Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 245 n.8 (3d Cir. 2007).

185. 21 C.F.R. § 202.1(e)(7)(viii) (2006) (stating some of the factors are whether the advertisement fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug . . . and whether the advertisement fails to provide sufficient emphasis for the information relating to side effects and contraindications, when such information is

If an advertisement fails to meet these standards then it is deemed false and misleading.[186]

The incidents involving Mr. Williams and Ms. Bacall demonstrate how stealth celebrity ads will usually fail to meet the FDA's standards. While both celebrities made claims about the benefits of a particular drug, neither sought to balance these claims with information regarding the side effects or effectiveness of these drugs. Additionally, both incidents failed to make adequate provision for the dissemination of the package labeling of the drugs mentioned. Applying the FDA's own standards, these testimonials are misleading and false. They fail to meet FDA regulations regarding presentation and more importantly ignore the FDA's fair balance requirement. Yet the FDA has taken no action. Its failure to enforce its regulations on celebrity stealth testimonials has exposed the public to unnecessary danger and runs counter to congressional intent in enacting the FDCA.

C. The Congressional Intent of Enacting the FDCA

The FDA's failure to regulate celebrity stealth testimonials thwarts Congress' intent in enacting the FDCA. Congress enacted the FDCA to protect the public's health and welfare.[187] Because the FDCA sought to protect consumers against fraud, the Supreme Court has construed it liberally.[188] The Court in *United States v. Dotterweich* noted that "[b]alancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."[189] Accordingly, the Court has interpreted the FDCA in favor of protecting consumers even though this may result in hardships for the product manufacturers or advertisers.[190]

In enacting the FDCA, Congress sought to protect the consumer by "ensuring that drugs sold in the marketplace are safe, effective, and not

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contained in a distinct part of an advertisement, because of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.).

186. *Id.* § 202.1(e)(7)(viii).

187. *See* C.C. Co. v. United States, 147 F.2d 820, 824 (5th Cir. 1944); *see also* United States v. Sullivan, 332 U.S. 689, 696 (1948) (stating "the Act as a whole was designed primarily to protect consumers from dangerous products.").

188. United States v. Kordel 164 F.2d 913 (7th Cir. 1947), *aff'd* 335 U.S. 345 (1948); *see also* United States v. Lee 131 F.2d 464, 466 (7th Cir. 1942).

189. United States v. Dotterweich, 320 U.S. 277, 285 (1943).

190. *Id.*

misbranded."[191] To effectuate these goals Congress included the fair balance requirements. Under the Act, an advertisement is "false, lacking in fair balance, or otherwise misleading if it [f]ails to present information relating to side effects and contraindications."[192] Unbalanced celebrity prescription drug testimonials clearly contravene the Act. This is exactly what Congress sought to prevent with the enactment of the FDCA.

Celebrity stealth testimonials place consumers at a greater risk of harm than more traditional forms of advertising. Consumers see celebrities as trustworthy and knowledgeable spokespersons for the products they endorse.[193] Celebrity advertisements offer the pharmaceutical companies a "premium" because they are more effective at reaching consumers than general advertising, thus generating higher consumer awareness and retention levels.[194] "When a celebrity talks about something everyone stands up and takes notice," states Dr. Jonathan Sackier, founder of the company Spotlight Health, which develops celebrity medical education campaigns for health care concerns.[195] Indeed, a celebrity testimonial of a particular prescription drug creates what one industry insider has called an "intangible sort of magic."[196]

Celebrity drug testimonials are especially dangerous because they usually fail to disclose the adverse effects of prescription drugs. Because stealth testimonials "fly under the radar, tucked away in places where consumers expect non-commercial reality,"[197] a testimonial that does not address a drug's major side effects endangers consumers who are less likely to appreciate that the testimonial is a paid advertisement. In light of the FDCA's consumer protection and anti-fraud goals, these highly surreptitious testimonials contravene Congress' expressed intent. Congress has not yet responded to this problem, but if the FDA continues to neglect its statutory duties, they may have to enact further legislation.

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191. Mut. Pharm. Co. v. Ivax Pharms., Inc., 459 F. Supp. 2d 925, 933 (2006).

192. Pa. Emps. Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 245 n.8 (3d Cir. 2007)

193. Moynihan, *supra* note 55, at 103.

194. *See generally Celebrities in Advertising: What are they likely or not likely to Do?: Public Hearing on Direct to Consumer Promotion of Medical Products Before the Food and Drug Administration* 4 (2005) (presentation of Abhilasha Metha, Director of Research, Robinson & Gallup, Inc.).

195. Petersen, *supra* note 9.

196. Moynihan, *supra* note 55.

197. Michael McCarthy, *Ads Show up in Unexpected Places*, USA TODAY, Mar. 23, 2001, at 1B (speaking generally about Stealth Advertising).

D. Recent Amendments to the FDCA Fail to Address Stealth Celebrity Testimonials

On September 27, 2007, Congress reauthorized the FDCA with the Food and Drug Administration Amendments Act of 2007.[198] The amendments give the FDA the authority to require post-approval labeling changes of prescription drugs, collect larger fees to fund oversight operations of Direct-to-Consumer (DTC) advertisements and impose new civil penalties for violations of the FDCA.[199] Some contend that the reauthorization is "the most comprehensive overhaul of food and drug law since 1997."[200] While this may be true, these amendments fail to meaningfully address DTC advertising.[201] Congress' failure is a victory for the pharmaceutical advertising industry.[202]

Speaking about the reauthorization, Mike Rutstein, Executive Vice President of Consumer Health Care at Interpublic Group stated, "[t]he upside is the fact that it's not changing significantly, because it could have been an ugly picture."[203] Originally, the House and Senate bills contained provisions that, if approved, would have required a moratorium on DTC advertising for new drugs,[204] pre-clearance of ads by the FDA, and new mandatory warning requirements for advertising.[205] However, the combined efforts of the drug and advertising industries eviscerated any language in the reauthorizing legislation that would have significantly changed drug advertising regulation.[206] Accordingly, it is not surprising that no provision of the new legislation specifically addresses celebrity stealth testimonials, and very little in the law substantially affects DTC advertising.[207]

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198. Food and Drug Administration Amendments Act of 2007, Pub.L. 110–85, 121 Stat. 823.

199. Memorandum from Reed Smith LLP, *supra* note 43.

200. *Id.*

201. *See, e.g.*, Anna W. Matthews & Stephanie King, *Media Industry Helped Drug Firms Fight Ad Restraints*, WALL ST. J., Sept. 21, 2007, at B1.

202. Press Release, American Association of National Advertisers, Inc., Ad, Media Groups Help Derail Drug Ad Restrictions—Commercial Alert, (Sept. 21, 2007) *available at* http://www.ana.net/news/content/835.

203. Matthews & King, *supra* note 202.

204. Enhancing Drug Safety and Innovation Act of 2007, H.R. 1561, 110th Cong. § 101(H) (1st Sess. 2007).

205. Matthews & King, *supra* note 202.

206. *Id.*

207. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. 110–85, 121 Stat. 823 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.).

Congressional inaction regarding celebrity stealth testimonials[208] combined with the FDA's dereliction of its law enforcement duties[209] leaves consumers in precarious positions. As it stands now, stealth celebrity prescription drug testimonials are too dangerous for the status quo to continue.

V. A PRAGMATIC SOLUTION

Not only do celebrity stealth prescription drug testimonials violate the Federal Food, Drug and Cosmetics Act of 1938 (FDCA),[210] they also place the consumer's health at risk.[211] Even though the current law provides a framework that is sufficient to regulate these testimonials,[212] the Food and Drug Administration (FDA) does not adequately enforce it.[213]

The FDA could take a more proactive approach in policing stealth celebrity prescription drug testimonials. First, the FDA could apply the current regulatory framework and completely ban celebrity testimonials of prescription drugs.[214] This option may eliminate the potential dangers associated with stealth testimonials,[215] but it also obliterates their benefits.[216] Among these benefits is improved consumer awareness of certain ailments and their treatments, which can induce consumers to seek information from physicians about certain prescription drugs.[217] Moreover, this option raises serious First Amendment issues.[218] The negative aspects

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208. *Id.*

209. *See, e.g., Impact of Direct-to-Consumer Drug Advertising*, *supra* note 50, at 90–99 (statement of Peter Lurie, Deputy Director of Public Citizens Health Research Group).

210. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 352 (2000).

211. Petersen, *supra* note 9.

212. *See* FDCA 21 §§ U.S.C. 331(a),(b), 352(a),(f),(n) (2006) (statutory authority for prohibition against misbranding and requirement of fair balance in advertising); *see also* 21 C.F.R. §§ 202.1 et. seq. (FDA implementing regulations).

213. *Impact of Direct-to-Consumer Drug Advertising*, *supra* note 50, at 90–99 (statement of Peter Lurie, Deputy Director of Public Citizens Health Research Group).

214. Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85, 121 Stat. 823 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.).

215. *See, e.g.*, Petersen, *supra* note 9.

216. *See* Alison Masson & Paul H. Rubin, *Matching Prescription Drugs and Consumers: The Benefits of Direct Advertising*, 313 NEW. ENG. J. MED. 513, 513–15 (2002) (noting that DTC advertising results in a more informed consumer.).

217. John E. Calfee, *Public Policy Issues in Direct to Consumer Advertising of Prescription Drugs*, 19 J.L. & ECON. 174, 225 (2002).

218. *See* Bd. of Trs. v. Fox, 492 U.S. 469, 477 (1989) (discussing how although commercial speech receives a lesser degree of protection than traditional First Amendment issues, in recent years there has been a shift towards greater protection for commercial speech); *see also* 44 Liquor Mart v. Rhode Island, 517 U.S. 484, 516 (1996) (invalidating unjustifiably broad statutes curbing speech); Cincinnati v. Discovery Network, 507 U.S. 410, 429–31 (1993) (striking down a city

associated with a complete proscription of all celebrity testimonials undermine the viability of this options' implementation.

Alternatively, the FDA could issue a draft guidance to the pharmaceutical industry asserting that celebrity stealth testimonials are subject to its Direct-to-Consumer advertisement regulations. This guidance would stipulate that the general restrictions governing traditional broadcast television advertisements apply where a celebrity receives compensation to promote a particular prescription drug in a setting that is not clearly commercial in nature, such as a talk show.[219] This would require any paid celebrity testimonial stating the benefits of a prescription drug to: (1) disclose the drugs' sponsor; (2) include a brief statement summarizing the major side effects of the drug; and (3) provide adequate provision for the consumer to gain access to further details about the drug.[220] Satisfying the adequate provision requirement would also require advertisers to mention a toll-free telephone number, website, or other comparable form of information dissemination where consumers could access more details about the promoted drug.[221]

This option would put the industry on notice as to what the FDA would consider proscribed behavior, and would remove the stealth aspects of celebrity testimonials without raising the same First Amendment concerns as a complete prohibition. In addition, this option would minimize the pharmaceutical industry's burden because the proposed standard is the same one that applies to traditional broadcast television commercials.

Thus, if this guidance had been in place when Lauren Bacall appeared on NBC's *The Today Show* to promote Visudyne or when Montel Williams highlighted Copaxone, there would have been specific disclosures alerting unassuming consumers to the commercial nature of the testimonials. This would have given consumers a better way of informing themselves about the risks of the promoted drugs. Under this approach, celebrity testimonials would no longer contain the deceptive element that one critic

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ordinance banning news racks of advertising brochures for aesthetic and safety reasons).

219. The guidance suggested would address only those incidents where celebrities receive compensation for promoting a prescription drug. A broader application of FDA regulations to non-compensated celebrity testimonials seems beyond the authority conferred to the FDA under the FDCA. Additionally, the feasibility of enforcing a broader application combined with certain speech infringement issues that would arise from its enforcement make such an approach not viable.

220. Food and Drug Administration, Guidance for Industry, Consumer-Directed Broadcast Advertisements (Aug. 1999), *available at* http://www.fda.gov/cder/guidance/1804fnl.htm.

221. *Id.*

claims differentiates stealth marketing from traditional advertising.[222] Therefore, a draft guidance that specifically covers celebrity stealth testimonials is a simple solution to a problem that jeopardizes the public's health and safety. However, given Congress' recent failure to address the issue and the FDA's historical apathy towards enforcing its own regulations, the likelihood of governmental action on the issue is questionable.[223]

In the absence of FDA action or new legislation on the matter, the only way to solve this problem is for celebrities to refrain from giving stealth drug testimonials. It is in celebrities' best interest to avoid surreptitiously promoting prescription drugs because stealth testimonials may cause a consumer backlash. "Instead of delighting or surprising consumers, the surreptitious campaign could negatively impact the brand because consumers feel they have been duped."[224] A recent press release from Bob Brody, a media specialist at Ogilvy, discusses this possible backlash and suggests that media outlets are keenly aware of the dangers of celebrity testimonials.[225] The press release states that *The Today Show*, which Mr. Brody calls the "Holy Grail" of celebrity health campaigns, has severely restricted any such promotions on its program and the Associated Press will not lend its name to any celebrity promotion of a pharmaceutical that it deems "unduly commercial."[226]

However, the effectiveness of these measures is potentially limited. Markets generally have mixed reactions to questionable advertising and some media outlets "still love celebrity health campaigns."[227] In addition, there are inherent deficiencies in relying solely on consumer backlash to defend against stealth celebrity testimonials. For example, any lag time between the consumer backlash and corrective action by the prescription drug industry represents a time period of potential harm to consumers. Therefore, there is no perfect solution to these public health and safety dangers.

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222. Undercover Marketing Uncovered: Hidden Cameras Capture Salespeople Secretly Pitching Products, CBSNEWS, July 25, 2004, *available at* http://www.cbsnews.com/stories/2003/10/23/60minutes/main579657.shtml.

223. *See* Matthews & King, *supra* note 202; *see also Impact of Direct-to-Consumer Drug Advertising*, *supra* note 50, at 90 (statement of Peter Lurie, Deputy Director of Public Citizens Health Research Group).

224. Kaikati & Kaikati, *supra* note 61, at 18.

225. Bob Brody, Ogilvy Public Relations Worldwide, Celebrity Health Campaign: The Next Generation, at 1, *available at* http://www.ogilvypr.com/pdf/celebrity-health-campaigns.pdf.

226. *Id.*

227. *Id.*

VI. CONCLUSION

The fragmentation of the media has impaired the effectiveness of traditional forms of advertising, forcing those who wish to promote their brands to develop novel methods to reach the consumer. One means of doing so has been the stealth advertisement. The stealth advertisement, although efficient in cutting through the clutter, poses unique dangers to the consumer, especially in the context of prescription drugs. These dangers heighten when pharmaceutical companies employ celebrities to promote their products. Yet this practice remains unregulated and, in the absence of regulation, the marketplace has provided an incomplete solution to the problem. To ensure consumer safety, government action is necessary. The Food and Drug Administration must begin to regulate stealth celebrity testimonials of prescription drugs.

Louis Boyarsky[*]

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