Direct-to-Consumer Pharmaceutical Advertising: Catalyst for a Change in the Therapeutic Model in Psychotherapy?

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32 CONNECTICUT LAW REVIEW 209 (1999)

I realize that the drug companies, by running these commercials, are trying to make me an informed medical consumer. But I don't WANT to be an informed medical consumer. I liked it better when my only medical responsibility was to stick out my tongue. That was the health-care system I grew up under, which was called "The Dr. Mortimer Cohn Health Care System," named for my family doctor when I was growing up in Armonk, N.Y.

Under this system, if you got sick, your mom took you to see Dr. Cohn, and he looked at your throat. Then he wrote out a prescription in a Secret Medical Code that neither you nor the CIA could understand. The only person who could understand it was Mr. DiGiacinto, who ran the Armonk Pharmacy, where you went to get some mystery pills and a half-gallon of Sealtest chocolate ice cream, which was a critical element of this health-care system. I would never have dreamed of talking to Dr. Cohn about [an advertised drug] or any other topic, because the longer you stayed in his office, the greater the danger that he might suddenly decide to give you a "booster shot."

Dave Barry

The patient enters the psychiatrist’s office for a first session, with the possibility of initiating a long term relationship. In the typical first session, the patient begins to relate a

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1 Dave Barry, Z IS FOR ZOCOR, CHIC. TRIB., July 12, 1998, C30.
narrative of her feelings, her pain, and her symptoms. The classically (or Freudian) trained psychiatrist endeavors to become a “neutral, hovering” listener. The psychiatrist’s goal in this first and many treatment sessions thereafter is to “go[] along with” the patient. “The ear of the empathic listener is the organ of receptivity, gratifying and at times indulging the patient. . . . [I]t is better to be deceived going along with the patient than to reject the patient prematurely and have the door slammed shut to the patient’s inner world.”

The psychiatrist’s role is to facilitate the patient’s narrative. Allowing the patient to tell her story enables the psychiatrist to “seek and find the patient.” The psychiatrist can then separate “who the patient is” from “what the patient suffers,” properly diagnose the patient, and prescribe the appropriate course of treatment.

A leading treatise on psychiatric technique advises the psychiatrist to consider a variety of

2 PSYCHIATRY 10, table 1-4 (1997, Allan Tasman, Jerald Kay, Jeffrey A. Lieberman, eds.)

3 Id. at 12, figure 1-2. The analyst need not be a psychiatrist or any other specialty of medical doctor. Since a 1988 settlement of an antitrust claim brought by psychologists against the American Psychoanalytic Association, psychoanalytic therapists need not have graduated from medical school. See, e.g., Erica Goode, Return to the Couch: A Revival for Analysis, N.Y. TIMES, Jan. 12, 1999, F1. Indeed, in 1996, for example, “381 of the 990 candidates training in psychoanalytic institutes around the country did not have medical degrees.” Id. Nonetheless, because it addresses the impact of advertising on those who can prescribe pharmaceuticals, this article restricts its focus to “physicians” and “psychiatrists” practicing psychoanalysis.

4 PSYCHIATRY, supra note 2, at 9, citing R. R. Greenson, EXPLORATIONS IN PSYCHOANALYSIS (1978).

5 Id.

6 PSYCHIATRY, supra note 2, at 13.
the factors in conducting the interview and deciding on a course of treatment. The psychiatrist should consider the patient’s emotional distress, cognitive capacities, emotional biases, and racial, ethnic, and cultural characteristics. The treatise does not advise the psychiatrist to take into account the extent of the patient’s knowledge of symptomology or of pharmaceuticals. The patient tells her story. The psychiatrist diagnoses and determines a course of treatment, which increasingly involves a prescription of psycho pharmaceuticals.

There may now be reason to question this therapeutic model. When the model evolved, pharmaceutical companies advertised their products, if at all, only in the professional journals read by the physicians. In the early 1980s, however, the companies began advertising pharmaceuticals in media — newspapers, magazines, and on television — directed at consumers. These advertisements provide patients with a body of knowledge of symptomology and treatment which the existing therapeutic model presumes to reside exclusively with the psychiatrist. Simply put, the psychiatrist must now consider whether the patient is relating her own story or what she has read or seen in an advertisement.

Direct-to-consumer advertising, or DTC, has been controversial from its inception.

7 Id. at 26-28.

8 Id.


Pharmaceutical companies have championed advertising as an effective method for informing consumers of health care choices.\textsuperscript{11} Physician groups such as the American Medical Association have opposed the advertisements out of fear of disruption to the physician/patient relationship.\textsuperscript{12}

From September 1983 to September 1985, at the request of the Food and Drug Administration (FDA), pharmaceutical companies agreed to a voluntary moratorium on advertising.\textsuperscript{13} During the moratorium, the FDA sponsored public meetings, invited comment, and conducted research. On September 9, 1985, the FDA withdrew the moratorium, announcing that existing advertising regulations which governed marketing directed toward physicians were also “sufficient to protect consumers.”\textsuperscript{14}

With no regulations that “pertain[ed] specifically to consumer-directed promotion,”\textsuperscript{15} DTC became increasingly popular during the 1990s.\textsuperscript{16} One restraint may have been the

\begin{itemize}
  \item See, e.g., Milt Freudenheim, \textit{Psychiatric Drugs Are Now Promoted Directly to Patients}, N.Y. TIMES, Feb. 17, 1998, A1 (citing pharmaceutical company spokespersons as stating that the ads “help[] patients overcome their problems”); Sandy Rovner, \textit{Healthtalk: The Rx for Prescription Ads}, W. POST, Aug. 24, 1984 (quoting a pharmaceutical company vice president as stating “we do know consumers need more information and we have to develop ways to get it to them.”).
  \item Stephen J. Gilbride, \textit{DTC Advertising One Year Later}, 143 DRUG TOPICS 13 (March 1, 1999) (quoting a physician: “I’ve lost patients because I refused to prescribe what was in the ad.”); \textit{Rx for Prescription Ads, supra} note 11 (Quoting an AMA policy: “none of the evidence presented to date indicates that direct advertising of prescription drugs in media intended for the public would improve the quality of medical care.”).
  \item FDA notice, August 16, 1995 60 Fed. Reg. 42581, 42582 ((1995).
  \item \textit{Id.}
  \item \textit{Id.}
\end{itemize}
requirement that all advertisements include a complete description of risks and side effects.\textsuperscript{17} Pharmaceutical companies may have worried that such disclosure, which can take up to a half page of fine print, would detract from the appeal of otherwise “sleek ads on TV or in magazines.”\textsuperscript{18}

In August 1997, the FDA removed at least part of that deterrent. The \textit{Guidance for Industry Direct-to-Consumer Rx Drug Promotion}\textsuperscript{19} affects only broadcast advertisements on television or radio. Print advertisements must contain a “brief summary” of the drug’s “side effects, contraindications, and effectiveness.”\textsuperscript{20} The Guidance authorizes broadcast advertisements to substitute for the “brief summary” an “adequate provision” “by which the majority of a potentially diverse audience can receive the advertised product’s approved labeling.” Thus, the pharmaceutical company may omit the summary of side effects by announcing that interested consumers can obtain package labeling by dialing a toll free telephone number, contacting an Internet site, or visiting a physician’s office.\textsuperscript{21}

Advertisements for psycho pharmaceuticals began appearing shortly after the FDA published its draft guidance.\textsuperscript{22} Mental health professionals have decried the ads as inappropriate

\begin{itemize}
\item \textsuperscript{17} \textit{Rx for Prescription Ads, supra} note 11.
\item \textsuperscript{18} \textit{Id.}
\item \textsuperscript{20} \textit{Id.} See text and notes - for a discussion of the “major statement” requirement.
\item \textsuperscript{21} FDA \textit{Guidance, supra} note 19.
\item \textsuperscript{22} See, Milt Freudenheim, \textit{Psychiatric Drugs Are Now Promoted Directly to Patients}, \textit{N.Y. Times}, Feb. 17, 1998.
\end{itemize}
because they are directed toward “[p]eople who are seriously mentally ill [and who] often have impaired judgment.”

The Pharmaceuticals Manufacturing Association has responded with an opposite take on the value of the marketing schemes: “This is the information age, and more information empowers patients to be able to have more meaningful conversations with their doctors about cures and treatments.”

To assist in this goal of empowerment, pharmaceutical companies have recently turned to celebrity pitch makers as “the next step to reach out to consumers.”

DTC may have reached its zenith with the formation of a home shopping television network exclusively devoted to selling pharmaceuticals. Employing “smiling nurse[s] who mix[] Hollywood charm with clinical professionalism when talking about medical conditions,” the HomeMed satellite network targets elderly and other potential purchasers “who typically can’t get out of the house.” As its chairman and president put it, “This is effectively a drugstore. We’re selling insulin. We’re selling Prozac. You name it, we’re selling it.”

This article explores the impact of DTC on the therapeutic relationship of psychiatrist and

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23 Id.

24 Id.

25 Associated Press, Drug Firms Signing Up Celebrities, CHIC. TRIB., Feb. 28, 1999, W10 (quoting a Schering-Plough spokesperson and citing to Bob Dole’s testimonials to Viagra and Joan Lunden’s testimonials to Claritin).


27 Id., (quoting HomeMed’s senior vice-president of operations).

28 Id., (quoting Lyman D. Eaton, II).
patient. Part I outlines the FDA’s regulatory framework for pharmaceutical advertising, presents a history of DTC, and evaluates DTC’s impact on sales. Part II examines the content of DTC advertisements, concentrating on ads for psycho pharmaceuticals. Part III examines the psycho-therapeutic relationship. It first attempts to assess the value of DTC ad copy by critiquing it in light of informed consent doctrine. Part III next provides an exposition of classical, or Freudian, psychoanalytic theory, including a discourse on transference and counter-transference in the therapeutic relationship. It concludes that, at the very least, DTC has injected an element of skepticism into therapy. The psychiatrist cannot “go along” with the patient’s story until she confirms that it is, indeed, her story. Part IV outlines a solution. It recommends the creation of an Internet site, accessible only by physicians, where pharmaceutical companies must post DTC campaigns for thirty days before presenting them to the public. Physicians can submit comments regarding the proposed campaigns and pharmaceutical companies can modify the campaigns in light of the comments. At the very least, the site will provide and efficient and inexpensive mechanism for informing psychiatrists of the ad copy which may function as a subtext to their patients’ narratives. At best, the site might serve to catalyze the formation of a therapeutic alliance among physicians, pharmaceutical companies, and Madison Avenue advertising agencies.

I. A short history of DTC and its regulation

A. The Regulatory Framework

The Food, Drug, and Cosmetic Act grants the FDA authority to regulate the labeling\textsuperscript{29}

and advertising\textsuperscript{30} of prescription pharmaceuticals. “Labeling” includes “all labels and other written, printed, or graphic matter . . . upon any article or its containers or wrappers, or accompanying such article.”\textsuperscript{31} Accompanying material includes the printed matter used by sales representatives and the information reproduced in the \textit{Physicians Desk Reference Manual},\textsuperscript{32} the guide which physicians typically consult to ascertain the risks and side effects of pharmaceuticals.\textsuperscript{33}

Neither the Act nor the FDA’s corresponding regulations define advertising. The “FDA generally interprets the term to include information (other than labeling) that is sponsored by a manufacturer and is intended to supplement or explain a product.”\textsuperscript{34} Thus, the FDA has asserted authority over promotional materials appearing in journals, magazines, and other periodicals, and on radio, television, and “telephone communication systems.”\textsuperscript{35}

The FDA recognizes three broad categories of these materials. “Help-seeking” materials present information about conditions and illnesses, recommend consultation with a physician, but

\textsuperscript{30} \textit{Id.}, § 352(n).

\textsuperscript{31} 21 U.S.C. § 321(m) (1998). This includes the label, itself, which appears on the product’s “immediate container.” § 321(k).


\textsuperscript{33} \textit{See id.}

\textsuperscript{34} FDA Notice, 60 CFR 42581, 42581 (August 16, 1995).

do not identify particular drugs or treatments. “Reminder” materials identify a drug but do
mention the conditions which those drugs treat. “Product-claim” materials make safety and
efficacy claims regarding particular drugs in treating particular conditions.\(^{36}\)

The FDA has asserted regulatory jurisdiction over only product-claim materials.\(^{37}\) Thus, only they constitute “advertisements.”\(^{38}\)

The Act and the regulations address two types of information disclosures in advertisements. Ads must contain a “brief summary” of the product’s “side effects, contraindications, and effectiveness”\(^{39}\) and a “major statement” regarding the “product’s major risks.”\(^{40}\) The FDA deems drugs to be misbranded if their advertising fails to meet these requirements.\(^{41}\)

Marketers can meet the brief summary requirement by reprinting the drug’s package insert and labeling.\(^{42}\) Print ads directed at consumers typically reproduce the labeling and insert

\(^{36}\) FDA August 1995 notice, note 34, at 4582.

\(^{37}\) Id. a42582-42583.

\(^{38}\) The FDA has also explicitly exempted three categories of “advertisements.” In addition to reminder advertisements, the agency does not assert regulatory authority over advertisements of bulk-sales of drugs for packaging or remanufacture or over advertisements of prescription-compounding drugs that sale “for use by registered pharmacists in compounding prescriptions.” 21 CFR §§ 202.1(e)(2)(I-iii).

\(^{39}\) Id.

\(^{40}\) GUIDANCE FOR INDUSTRY, supra note 19.


\(^{42}\) FDA August 16, 1995 notice supra note 34, at 42583. Broadcast ads directed to physicians can meet this requirement by citing to the product’s page number in the Physician’s Desk Reference Manual. For a description of the PDR, see supra note 32.
in fine print on the back side of the ad.\textsuperscript{43}

The FDA has pronounced this information to be “relatively inaccessible to consumers” because it is written in “technical language intended for health care professionals.”\textsuperscript{44} Thus, it has considered whether pharmaceutical companies should draft summaries “in a format and language more easily understood by consumers.”\textsuperscript{45} To date, the FDA has not required that the companies do so, but has stood by its 1983 conclusion that existing regulations which address ads to professional audiences “are sufficient to protect consumers.”\textsuperscript{46} The FDA does, however, “encourage[] sponsors to provide consumers with nonpromotional, consumer-friendly product information as well” as the package labeling.\textsuperscript{47}

As outlined in this article’s introduction, in an August 1997 \textit{Guidance} announcement, the FDA recognized the futility of depicting a page or two of fine print in a television advertisement. Instead, broadcast ads can substitute for the “brief summary” a method that makes “adequate provision” for disseminating the brief summary information to interested consumers who dial a toll-free telephone number or log on to an Internet web site.\textsuperscript{48}

Freed from the requirement to air the “fine print,” drug companies found themselves able

\textsuperscript{43} See John Schwartz, \textit{FDA Relaxes Rules for On-Air Drug Ads; Changes Allow Product’s Purpose to be Stated}, N.Y. TIMES, A1 (“this summary often runs in type on the page following the ad.). Examples are in the author’s files.

\textsuperscript{44} FDA Notice, supra note 19, at 42583.

\textsuperscript{45} \textit{Id}.

\textsuperscript{46} \textit{Id.} at 4582.

\textsuperscript{47} FDA Guidance, supra note 19.

\textsuperscript{48} \textit{Id}.
to make claims about the purpose of the advertised drug without balancing those claims with
detailed information about risks. Thus, where ads once simply depicted an allergic reaction and
urged viewers to contact a physician, a newly drafted ad touts an allergy medication which
provides “non drowsy relief” and urges those with questions about side effects and risks to “ask
your doctor or pharmacist. Check out our ad in magazines like Reader’s Digest. Or call.”

Industry leaders immediately predicted that the FDA’s actions would lead to “a very
substantial increase in advertising.” As the president of a New York ad agency which
specializes in health care put it, “[w]e’re very exited for our clients that now have huge
opportunities to talk to their constituents.”

The FDA will revisit the issue in the fall of 1999, after the August 1997 Guidance has
been in effect for two years. In the meantime, the FDA is conducting studies of the impact of
DTC.

The new FDA Guidance position left unchanged the second of the FDA’s advertisement
requirements: all ads, whether in print or broadcast media, must include a “major statement” of a

49 FDA Relaxes, supra note 43.

50 Kasper Zeuthen, FDA Loosens Restriction on Drug Ads on TV, L.A. TIMES, August 9,
1997 (quoting the president of the Association of National Advertising).

51 Id.

also Unified Agenda of Federal Regulatory and Deregulatory Actions, 63 Fed. Reg. 21932,
21934 (April 27, 1998) (scheduling the notice period to end in March 1999).

53 Agency Emergency Processing Request Under OMB Review; attitudinal and
behavioral Effects of Direct-to-Consumer Advertising of Prescription Drugs, 63 FR 49582 (Sept.
drug’s risks. That statement must be an “integral part of the broadcast advertisement” and must be “communicated in language understood by consumers.”\textsuperscript{54} It must provide information relating to the “major side effects and contraindications of the advertised drug.”\textsuperscript{55}

Although it is the only remaining substantive requirement of broadcast advertising, the FDA has conceded the limited utility of the “major statement’s” general summary of risks: “the major statement is a relatively fleeting disclosure and many have questioned the ability of the consumer to comprehend and process the information.”\textsuperscript{56}

The FDA would probably give a mixed review to the advertising generated by its decision to relax restrictions. In the first twelve months after its August 1997 action, the FDA warned ten companies about possible violations of what remains of the regulations.\textsuperscript{57} It expressed concern about video cuts which distract from the presentation of warnings, a depiction of running and other activity in an ad for an asthma medication not intended for exercise-induced asthma, and a reference to burning and itching -- the potential side effects of topical ointment -- as “skin discomfort.”\textsuperscript{58} Advertisers simply do not present warnings in as memorable a fashion as they present the advertising copy. In FDA’s view, the ads must contain specific references to risks because simple references to consult a physician are not effective: “Research shows that people

\textsuperscript{54} August 16, 1995 FDA Notice, \textit{supra} note 34, at 42583.

\textsuperscript{55} 21 CFR §201.1(1)(e).

\textsuperscript{56} August 16, 1995 FDA Notice, \textit{supra} note 34, at 42583.


\textsuperscript{58} \textit{Id.}
see those [words] a couple of times and then they no longer make an impact.”

The FDA made public its concerns about DTC in September 1998. The FDA published a notice in the federal register announcing its intention to survey a random sample of 1000 adults about the effect of the risk and efficacy information presented in ads. The notice sought emergency processing of the request to conduct the survey because “the amount of prescription drug DTC advertising is growing so quickly that rapid assessment of the public is required in order to assess public response before such advertising increases further.”

B. A Short History

1. Generally

Pharmaceutical companies are spending $1 billion annually on DTC. Although that sum is substantially less than the $4 billion the companies spend on promotional efforts directed at physicians, the companies are clearly shifting more resources to consumer-directed marketing. From 1996 to 1997, drug company spending on DTC increased by forty six percent. The companies’ spending on promotions directed at physicians grew by ten percent during that

59 Id. (quoting Nancy Ostrove).


61 Id.

62 Stephen J. Gilbride, DTC advertising one year later, 143 Drug Topics 13 (March 1, 11999) (pharmaceutical companies spent more than $1 billion in the first 10 months of 1998).

63 Mary Beth Sammons, Currents; pharmaceuticals, 72 Hospitals 12, 12 (June 5, 1998).
same year.64

What some now call an “explosion” of DTC65 started quietly in the early 1980s. The first, an ad for a pneumonia vaccine, appeared in the Reader’s Digest in 1981.66 Pharmaceutical companies then initiated a discussion with the FDA, which expressed “serious reservations about pharmaceutical companies and advertisers moving into this uncharted area.”67

Few additional ads appeared before the institution of the voluntary moratorium in 1983.68 Then, in 1985, in curious fashion, the Federal Trade Commission, which has jurisdiction over only non-prescription drugs,69 entered the fray. Two members of the Commission, expressing their own views and not “necessarily [those] of the Federal Trade Commission or other members

64 Id. The companies spent $”564 million for ads in professional journals, $2.8 billion in office promotion, and $614 million in hospital promotion.” Id. More recent studies indicate that pharmaceutical company expenditures may be even greater: “Pharmaceutical companies in the United States spent $5.3 billion in the first 11 months of last year sending representatives into doctors' offices and hospitals, and $1 billion more holding marketing events for doctors. ... That translates into nearly one drug salesperson and almost $100,000 for every 11 practicing physicians in the United States, a class size and budget that might be the envy of any educational venture.” Abigail Zuger, Fever Pitch: Getting Doctors To Prescribe Is Big Business, N.Y. TIMES, January 11, 1999, A1 (citing a Scott-Levin study).


66 Id.


of its staff,” yet identifying themselves by name and the designation “Federal Trade Commission,” published an essay in *The New England Journal of Medicine*. The essay touted the public benefits of direct-to-consumer advertisements of prescription pharmaceuticals. The commission members urged wider advertising as a method for conveying information to the public about disease symptoms and available treatments and argued that the competition spurred by marketing would reduce prices.

Physician response took two forms. A spokesperson for the American Society for Clinical Pharmacology and Therapeutics aptly summarized the response of physicians who wrote to the *Journal* to castigate the essay: “the direct promotion of prescription drugs to the public . . . could harm the patient and undermine the physician-patient relationship.”

The AMA joined in this response by passing a resolution reaffirming its opposition to DTC and it added another dimension to the critique. The AMA, attacking the authors’ cloaking of their opinions in apparent FTC authority, issued a formal resolution “request[ing] the Federal Trade Commission to urge its staff to distinguish in future statements the unofficial nature of the promotion of a private study encouraging the advertisement of prescription drug products directly to the public.”


71 *Id.* at 513.

72 *Id.* at 513-15.


74 AMA RESOLUTION NO. 66 ADVERTISING OF PRESCRIPTION DRUGS (December 1985) (copy in author’s files).
Despite the immediate and sharp criticism, the FTC commissioners prevailed. The FDA withdrew the moratorium, commenting simply that existing regulations were “sufficient to protect consumers.”

The FDA’s withdrawal of the moratorium had little immediate impact. Apparently unmoved by the FTC Commissioners’ plea and wary of the public’s reaction to prescription drug advertising, most pharmaceutical companies still refrained from advertising. Indeed, in 1985 the CBS television network, in an apparent effort to lure some pharmaceutical companies to purchasing advertising time, issued its own guidelines embracing “responsible” advertising. No companies seized on the opportunity until four years later, in 1989.

Apparently not quite as reluctant to advertise in other media, pharmaceutical companies again began to purchase print advertising in 1987. The first ads, though, for an anti-allergy medication, drew the FDA’s ire, and the manufacturer withdrew them.

By the early 1990s, pharmaceutical companies had shed their twin fears of offending the public and drawing the FDA’s ire and had committed substantial resources to direct-to-consumer advertising. In 1991, pharmaceutical companies spent $91 million on advertising directly to consumers and by 1992 the expenditure more than doubled to $200 million.

75 FDA August 16, 1985 notice, supra note 34, at 42582.

76 Direct-to-the-Public Advertising, supra note 67.

77 SPENDING IT, supra note 68.


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Evidently considering the trend unstoppable and interested in launching its own consumer-directed media, the AMA reversed its opposition to DTC in 1993. Citing consumers’ “need for information” and a desire to “provide consumers with information about prescription drugs,” the AMA announced an intention to accept some portion of that $200 million and to place the consumer advertising in its own publications. The AMA continued to express some concern, however, and issued guidelines for the advertisements it would publish. It would accept only those which “enhance consumer education,” are “clear, accurate, and responsible,” and which “direct patients to their physicians for more information.”

Spending on DTC increased to half a billion dollars in 1996 and nearly $1 billion in 1997. Through the first ten months of 1998, spending exceeded $1 billion. Television advertising, spurred by the FDA’s relaxation of restrictions in broadcast advertising, represents

\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Mary Beth Sammons, \textit{Currents; pharmaceuticals}, 72 Hospitals 12, 12 (June 5, 1998).}\]
\[\text{Stephen J. Gilbride, \textit{DTC advertising one year later}, 143 Drug Topics 13 (March 1, 11999). \textit{See also DTC Spending Down Slightly in May, Business Wire, Sept. 8, 1998.}}\]
the fastest growing facet of the spending. January through May spending in 1998 on television ads totaled $263 million, a 173 percent increase over 1997 spending during those same months. Radio advertising also increased, but magazine advertising decreased from $290 million over those months in 1997 to $217 million in 1998.\(^{86}\)

The FDA’s decision to relax restrictions on direct-to-consumer broadcast advertisements\(^{87}\) represented the culmination of a two-decade long campaign by advertisers. As one analyst put it, “Advertising directly to consumers is one of the most successful movements ever in the pharmaceuticals industry. . . . It is the product of advertising executives all over America who went to sleep each night trying to figure out how to sell prescription drugs to the public without upsetting the apple cart at the F.D.A.”\(^{88}\)

The Internet may prove to be the most useful vehicle for taking advantage of this advertising triumph. A recent study revealed that 66 percent of all who use the Internet seek health information.\(^{89}\) In response, at least one Web site allows users to customize Web pages to indicate the health topics in which they are most interested. The company which maintains the Web site will notify users of new products produced by manufactures who contract for the Web site’s services.\(^{90}\) In the words of a principal in the Web site company, “[f]rom a marketing

\(^{86}\) *DTC Spending Down*, supra note 84.


\(^{88}\) *SPENDING IT*, supra note 68.

\(^{89}\) *Category Leader Claritin to be an Exclusive Sponsor of OnHealth.com*, BUSINESS WIRE, Aug. 3, 1998.

\(^{90}\) *Id.* (Referring to OnHealth.com).
standpoint, the Internet was born as a Direct to Consumer communication vehicle. As pharmaceutical companies begin these initiatives, sites like [ours] allow [them] to target their audiences more precisely. . . . Through the Internet, they can now provide the right information to the right consumer at the right time.”91

The Web site will also enable the pharmaceutical companies to identify those “right consumers” more easily. The Web site company will compile data in order to provide to pharmaceutical company clients demographic and regional preferences for pharmaceuticals.92 In the Web site company’s words, again, “the top pharmaceutical companies . . . are moving swiftly onto the Internet because it is the most measurable and targeted of all media, putting them in front of the consumer at the exact moment users are seeking information.”93

2. Psycho pharmaceuticals

Prior to the late 1990s, pharmaceutical companies and ad agencies agreed that “advertising was fine for an antihistamine,” but considered unseemly advertisements directed at those with mental illness.94 In 1997, however, apparently spurred by the FDA’s relaxation of its regulations,95 manufacturers overcame this reservation.

91 Id.
92 Id.
93 Id.
94 See Psychiatric Drugs are Now Promoted, supra note 22.
95 See supra note .
Industry officials championed the ads as “a First Amendment right”  and a mechanism to enable patients to have “more meaningful conversations with their doctors about cures and treatments.” Psychiatrists’ immediate criticism echoed the manufacturers’ original ground for reluctance in advertising: the ads prey upon a vulnerable population.

Eli Lily’s ad campaign for Zyprexa -- an antipsychotic medication -- has drawn the most strident criticism. The ads offer college scholarships to patients “diagnosed with schizophrenia” and “in treatment” with the drug.

The critical response to the Zyprexa campaign is a paradigm for the criticism leveled at all DTC of psycho pharmaceuticals. First, the critics contend that the ads promote “unrealistic expectations by both families and patients.” This is especially true of an offer of scholarships to patients who are not likely to be able to cope with the demands of higher education.

The second ground for the criticism speaks directly to the therapeutic relationship. Fueled by those expectations, patients develop incentives to convince physicians both that they suffer from the illness mentioned in the advertisements and that they would benefit from the treatment with the advertised drug. Indeed, physicians have increasingly reported “fending

96 Psychiatric Drugs Are Now Promoted, supra note 22 (quoting an official of the Pharmaceutical Research and Manufacturers Association).

97 Id. (Quoting the president of the Pharmaceuticals Manufacturing Association).

98 Id.

99 Id.

100 Id. (Quoting Dr. E. Fuller Torrey, “a psychiatrist and schizophrenia researcher”).

101 Id.

102 Id.
off” patients who demand particular drugs. In response to the criticism, Eli Lilly no longer requires that the scholarship recipients be in treatment with Zyprexa.

The very reason for the controversy -- the vulnerability of the targeted market segment -- has also limited the debate. For example, at its annual meeting in June 1998, the AMA, fearing the creation of a “‘demand based,’ rather than ‘need based’ pharmaceutical market,” passed a resolution urging the FDA to study the effect that DTC has on physicians. The AMA delegates, however, had originally planned to request a study of only advertising for psychiatric drugs. But, fearing that such a request would inappropriately single out the mentally ill, the delegates broadened the request to include a study of all DTC. Apparently, the AMA delegates fear that criticizing the ads would duplicate the transgression which the drug companies and advertisers commit in their advertising: it would stigmatize the mentally ill.

Although perhaps stung by the criticism of its scholarship program, the Eli Lilly Company has not been deterred from its role as a leader in DTC of psycho pharmaceuticals. On September 14, 1998, the company became the first to run a television ad for a psychiatric drug.

103 John Hendren, Drug Ads Make Patients Pickier Doctors Are Hearing More Demands for name-Brand Medications, ROCKY MTN. NEWS, January 8, 1998 (“In Dallas, psychiatrist Mudhukar is fending off depressed patients who ‘need’ Prozac); Erik Parens, The Problem With Mixing Drugs and Ads, W. POST, October 26, 1997, C2 (“Advertising increases the pressure to “say no” to requests for particular drugs). Section, infra addresses the extent to which physicians “fend off” these patients.

104 Psychiatric Drugs Are Now Promoted, supra note 22.


106 Id.

107 Psychiatric Drugs Are Now Promoted, supra note 22.
The ad mentioned depression, provided a voice over statement that “treatment that has worked for millions is available from your doctor,” and urged viewers to call their doctors for more information on depression and its treatment. The ad did not mention the advertised product -- Prozac.

C. Impact on sales

1. The data

As one pharmaceutical industry analyst has stated, it is difficult to determine the relationship between DTC and sales “because there’s no direct measure of why . . . a doctor prescribes a particular medicine.” At the very least, however, DTC and pharmaceutical sales are correlated with the FDA’s relaxation of advertising restrictions. Sales in 1998 have increased by a record 17.6 percent over 1997 sales. From 1997 to 1998, all direct-to-consumer spending increased by nearly 50 percent, and television spending increased by nearly 175 percent. Moreover, during that same time period, patient requests to physicians for specific, brand-name drugs rose by 59 percent.

Initial data support the inference of a causal link between the advertising and the sales


109 Id. (Quoting Dennis Moore, Nightly Business Report Correspondent).

110 See supra text at note 58.

112 See supra text at note .

increase. *Prevention Magazine* commissioned the largest study. 114 Developed with technical assistance from the FDA’s Division of Drug Marketing and conducted by Princeton Survey Research Associates, the study consisted of a telephone survey of 1,200 U.S. adults from March 28 through April 20, 1998. 115 The study attempted to measure consumer awareness of DTC and assess its impact on the use of prescription medicines. 116 *Prevention* presented the results to a meeting of two hundred advertisers and pharmaceutical company executives in New York in June 1998. 117

Seventy percent of those surveyed had seen a DTC advertisement. 118 In 1997, prior to the FDA’s relaxation of advertising standards, only 63 percent reported having seen the ads. The 1998 results estimate, based on the 1996 U.S. census, that over 127 million Americans have seen the ads. 119 Most who reported seeing DTC advertisements – 77 percent – had seen the ads on television. Sixty four percent had seen them in magazines, 30 percent had seen them in newspapers, and 23 percent had heard ads on radio. 120

The study also produced an early picture of the relationship between advertising, patients,
and physicians. One third of those who had seen the ads talked with their physicians about the advertised medication.\textsuperscript{121} Twenty eight percent had asked for the advertised medication.\textsuperscript{122} Of those who asked, 80 percent, or an estimated 12 million patients, received a prescription.\textsuperscript{123} In the language of the study, “DTC is more than a means of opening up a dialog between consumers and their doctors.”\textsuperscript{124} It may well facilitate sales.

Whatever its impact, DTC seems most effective for psycho pharmaceuticals. As summarized above, 70 percent of the respondents reported seeing “advertisements for specific medications that you can get only with a doctor’s prescription.”\textsuperscript{125} When asked whether they had seen advertisements for specific “prescription medications,” 90 percent, representing approximately 163 million Americans, responded positively.\textsuperscript{126} Prozac, with 73 percent recognition rate, was the most recognized drug.\textsuperscript{127} At the time, Prozac had only been advertised for the few months since the FDA’s relaxation of advertising restrictions.\textsuperscript{128} Moreover, more respondents recognized Prozac than some products which received even more advertising. For example, the Prozac 1998 advertising budget was $25.2 million. The next-most-recognized

\begin{footnotesize}
\begin{enumerate}
\item Id. at 18, table J.
\item Id. at 22, table O.
\item Id., table P.
\item Id. at 22.
\item Id. at 9, table C.
\item Id. at 11 table D.
\item Id.
\item See Psychiatric Drugs Are Now Promoted, supra note 22.
\end{enumerate}
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pharmaceuticals -- the allergy medications Claritin and Allegra -- had greater advertising budgets ($51.3 million and $30.9 million, respectively), but were recognized by fewer respondents (63 percent and 47 percent, respectively). As Prevention recognized, the high Prozac awareness level may reflect the impact of media coverage of the controversy of advertising psychiatric medications.

If, for whatever reason, ads for psycho pharmaceuticals are more memorable than ads for other pharmaceuticals, one might expect them to be more effective in spurring sales. Or at least the ads should be more likely to lead to a conversation with and request for a prescription from a physician.

The Prevention study did not address the issue of the effectiveness of ads for specific pharmaceuticals, including Prozac. At least one study, however, provides a basis for conjecture. A 1997 survey by the Pennsylvania-based consulting firm Scott-Levin revealed that 92 percent of patients who requested Prozac received a prescription.

Scott-Levin’s more recent research on other pharmaceuticals provides additional support for inferring a causal relationship between advertising and sales. Patient visits to physicians from January 1998 through September 1998 increased by 2 percent over visits during those same


\[130\] PREVENTION MAGAZINE SURVEY, supra note 114 at 11, table D.

\[131\] Id. at 11, table D.

\[132\] Problem with Mixing Drugs, supra note 103.
months in 1997. Visits for allergy treatments, however, increased by 10 percent. Allergy medications have received the highest advertising budgets of any pharmaceuticals.

2. The actors

If the data are inconclusive, the conduct of the principal actors who stand to gain or lose from DTC unequivocally signals a belief in a causal relationship between the advertising and sales. Pharmaceutical companies have clearly decided to risk their economic futures on the benefits of advertising. Although full-year figures are not yet available, analysts have estimated that pharmaceutical companies spent $1.6 billion on direct-to-consumer marketing in 1998. “That would mean outspending cereals, beer and hotels and resorts.” And, of course, advertising agencies cannot be anything but ecstatic about a phenomenon which appears to be transforming the industry: “[M]edical advertising used to be this sleepy little, almost insular industry. We did our thing and minded our own business. The arrival of DTC was like the Berlin Wall coming down.”

Pharmaceutical companies and ad agencies, then, are anticipating a financial windfall.


134 Id. (Reporting a and increase “five times as fast” as the 2% increase for other treatments).

135 Id. See also text and notes Supra.

136 Seminar, supra note 117 (quoting Maureen C. Regan, chief executive of a New York advertising firm).

The managed care organizations who will pay for a substantial portion of the sales which DTC may generate, however, appear to be preparing for an assault on their economic bottom lines. The vice president of pharmacy for California’s Blue Cross characterized DTC as conceived to reverse the cost-saving methods which are the hallmark of managed care: “This appears to be primarily a tool of the pharmaceutical manufacturers to bypass some of the managed care interventions that we have.”138 In the words of a Kaiser Permanente physician, “The advertising is purposely directed at driving patients to demand medication – irrespective of whether those medications are medically necessary.”139

The problem, according to managed care organizations, is that “[y]ou don’t see many ads for generic drugs. What you often see are ads for the very newest [and more costly] drugs.”140 The ads, in the view of managed care organizations, create a patient demand for expensive and unnecessary drug treatments. This runs contrary to managed care organizations’ attempts to employ less expensive drugs through the use of restrictive formularies or simply refusing reimbursement for specific drugs.141 Some managed care organizations have responded by paying only 60 percent of the cost of advertised drugs if cheaper, equally effective alternatives


139 Id. (quoting Francis Crosson).


On occasion, pharmaceutical and managed care organizations have waged explicit battles. For example, in 1997 a Colorado HMO classified the allergy medication Claritin as a "non-preferred brand name." Thus, members had to pay a higher copay to purchase Claritin than to purchase the HMO’s “preferred,” and presumably less expensive medication. In response, Schering Plough, the drug’s manufacturer, placed ads in a local newspaper which stated in bold type, “Claritin is covered by over 93% of the managed care plans in the country. Is your plan one of the 93%?”

Schering Plough’s efforts may have been unnecessary. HMO members appear to be more loyal to pharmaceutical brand names than to managed care organizations. A study published in September 1998 by CareData examined “consumerism in managed care pharmacy.” The study, like the Prevention Magazine study, found that only 20 percent of those who requested prescriptions from their physicians failed to receive them. And, those who did not receive the prescriptions that they requested were more than twice as likely as those who did to express dissatisfaction with their HMOs and to switch to another. Moreover, the offer of an equivalent

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142 Influencing Doctors’ Orders, supra note 142, at 10.

143 Ad Bonanza, supra note 140.

144 Id.

145 Health Plan Members are Twice as Likely to Leave Their Plans When Not Given Medications They Request, http://www.caredata.com/news/09 29 98.html.

146 PREVENTION MAGAZINE SURVEY, supra note 114, at 7.

147 Health Plan Members are Twice as Likely, supra note 145.

148 Id.
brand name or generic drug did not reduce the predilection to switch to another HMO.\textsuperscript{149}

If the perceptions are accurate, the causal chain is clear. The pharmaceutical companies and ad agencies believe that DTC can sell drugs. Patients believe that the brand names which they request from their physicians are sufficiently better than the alternatives to warrant looking for another provider. And the managed care organizations who are endeavoring to provide low cost treatment see DTC as a threat to their economic survival.

II. Content

The first advertisements to consumers were models of marketing restraint. Ads in the early 1980s, for example, were presented in the guise of “public service announcements” and merely declared that new treatments were available for particular illnesses. The ads did not name the pharmaceutical advertised.\textsuperscript{150} As a Merell Dow spokesperson explained, its advertisements for Seldane, an anti-allergy medication, were designed “merely to tell people that something new exists and [that] they ought to ask their doctors about it.”\textsuperscript{151}

In 1987, the Sandoz company became the first pharmaceutical company to name its product when it advertised Tavist-1, also an anti-allergy medication. Although bold enough to identify its product, Sandoz titled its ad as a “Special Update for Doctors,” and began the text with “Dear Doctor.”\textsuperscript{152}

\textsuperscript{149} Id.


\textsuperscript{151} Id.

\textsuperscript{152} Id.
When questioned about its intentions, the company explicitly denied any attempt to reach the consumers who read the general interest newspapers in which the advertisement appeared. Instead, the company vice president for external affairs asserted that Sandoz was merely “looking for a nontraditional way to get to physicians.”

Industry analysts reacted with scepticism. As the editor of medical industry advertising journal observed, “Sandoz can call it whatever they choose, but the ad is directed to consumers. Because it says ‘Dear Doctor’ you think consumers aren’t going to read it?”

Despite the criticism, others quickly followed Sandoz’s lead. Indeed, pharmaceutical advertisers quickly shed any semblance of restraint and adopted the tactics used to hawk other products. In 1989, for example, a manufacturer of oral contraceptives touted its brand-name pill as a cheaper alternative to the leading, and more expensive pill. Around the same time, a Pfizer company advertisement not only celebrated the qualities of the company’s angina medication, but lauded the life-saving benefits of its own advertising campaign. In a full-page ad in the Wall Street Journal, Pfizer reproduced the letter of a very satisfied customer: “Your [advertisement’s] description of mixed angina symptoms was exactly what I had been experiencing. . . . The next day I went to my family doctor . . . an angiogram showed 80 to 90 percent blockage in the left anterior artery. I know advertising can sell cars, furniture, washers

\[153\] Id.
\[154\] Id. (Quoting Styli Engl, editor of Medical Advertising News).
\[155\] Annetta Miller, Todd Barrett, Elizabeth Bradburn, Pitching to Patients, Newsweek, May 8, 1989, 40.
and dryers. But I never knew till now that it was capable of saving a life.”

By the turn of the turn of the decade, even companies which had initially avoided explicit pitches of their products began to get specific. Prior to 1990, Upjohn’s advertisements for its hair-loss product Rogain merely advised readers and viewers, “If you're concerned about hair loss ... see your doctor.” By 1990, the ads mentioned Rogain by name.

Recently, pharmaceutical companies have adopted the tactics of the manufacturers of other products in targeting specific markets with advertising. Some simply advertise in places they expect to find likely consumers. Astra Merck places ads for a smoking cessation product in theaters and taxis. Bristol-Myers Squibb advertises an HIV medication at a Washington, D.C. bus stop it believes is frequented by gays.

Pharmaceutical company websites, of course, have used technological innovation to optimize this scheme. The website shapes it pitch not just to appeal to the apparent needs of a market segment, but to appeal to the desires of the individual consumer. The manufacturer can email to the visitor ads tailored to the visitor’s requests.

The marketing strategies evident in psycho pharmaceuticals ads may be the most varied.

156 Id.


158 Id.

159 Madison Ave. loves drug ads, supra note 57.

160 Id.

161 See supra text & notes .
Some carefully avoid any explicit sales pitch. In 1997, for example, Galaxo sponsored an entire special health care issue of *Time Magazine*. The pages of the magazine were filled with full-page and two-page color Galaxo advertisements for asthma, smoking cessation, allergy, migraine, HIV, Cancer, and herpes medications. Galaxo did not, however, present specific advertisements for its depression medication. The sole reference consisted of the word “depression” in a list of all the other categories of medications Galaxo offers. The list appeared at the bottom of a full color page. Above the list, the text provided, “At Galaxo, Wellcome, we discover breakthrough medicines so people can enjoy the miracles of every day life.” Above that, and dominating the ad, were four color photographs of a woman enjoying a day at the beach with a child.¹⁶²

Other psycho pharmaceutical ads have seemingly eschewed subtlety. Wyeth-Ayerst Laboratories ads for Effexor, for example, tout the antidepressant’s results. In one ad a woman declares, “I got my marriage back.” In another, a man avows, “I got my brother back.”¹⁶³

Eli Lilly, manufacturer of Prozac, the world’s most prescribed antidepressant,¹⁶⁴ has taken both tacks. Prozac’s recent print ads have been quite assertive. The left hand page depicts a wilting tree against a rainy backgrounds and warns that “Depression hurts.” The right hand page depicts a healthy tree against a sunny background and announces that “Prozac Can help.” The ad copy touts the product and reminds the consumer that “only your doctor” can prescribe it.

    Depression isn’t just feeling down. It’s a real illness with real causes.


¹⁶⁴ *Lusting after Prozac*, supra note 9, at C8, graphic. The company sold 1.45 million prescriptions in 1988, the year it began to sell Prozac, and 9.88 million in 1997. *Id.* at C8.
Depression can be triggered by stressful life events, like a divorce or a death in the family. Or it can appear suddenly, for no apparent reason.

Some people think that you can just will yourself out of depression. That’s not true. Many doctors believe that one thing that may cause depression is an imbalance of serotonin -- a chemical in your body. If this happens, you may have trouble sleeping. Feel unusual sad or irritable. Find it hard to concentrate. Lose your appetite. Lack energy. Or have trouble feeling pleasure. These are some of the symptoms that can point to depression – especially if they last for more than a couple of weeks and if normal, everyday life feels like too much to handle.

To help fight depression, the medicine doctors now prescribe most often is Prozac. Prozac isn’t a “happy pill.” It’s not a tranquilizer. It won’t turn you into a different person.

Some people do experience mild side effects, like upset stomach, headaches, difficulty sleeping, drowsiness, anxiety, and nervousness. These tend to go away within a few weeks of starting treatment, and usually aren’t serious enough to make most people stop taking it.

As you start feeling better, your doctor can suggest therapy or other means to help you work through your depression. Prozac has been carefully studied for nearly 10 years. But remember, Prozac is a prescription medicine, and it isn't right for everyone. Only your doctor can decide if Prozac is right for you -- or for someone you love. Prozac has been prescribed for more than 17 million Americans. Chances are someone you know is blossoming again because of it.

Ely Lilly Co. Prozac advertisement

The ad has been criticized for being misleading. One writer, for example, decried the Prozac ad for suggesting that “normal emotions can – and perhaps even should – be remedied.” This “trivializ[es] a serious illness,” which is precisely what Eli Lily has asserted it does not wish to do with its ad campaign.

Perhaps influenced by this criticism, Eli Lilly took a more subtle approach in its

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165 Prozac ad, Newsweek, June 29, 1998.

166 The Problem with Mixing Drugs, supra note 103.

167 Id.

168 Id., citing an Eli Lilly ad in professional journals which stated that prescribing Prozac for mere unhappiness would constitute “trivializing a serious illness.” Id.
television ads which first aired in September 1998. One black and white ad depicts people glumly sitting, curled up in bed, or unable to finish a meal. The ad asks, “Have you stopped doing things you used to enjoy? Are you sleeping too much? Have you noticed a change in your appetite?” The narrator of another ad, also in black and white, observes, “If you break an arm, people say get a cast. But why is it if you’re depressed people tell you to just snap out of it?” Without mentioning the product name, the ads end with a toll-free number for product information and a symptoms check list, the Eli Lilly logo, and, “Welcome back.”

The reaction to the television ad illustrates the dilemma facing the marketer of psycho pharmaceuticals. On the one hand, a Los Angeles Times advertising critic condemned the ad for being too subtle: “Lilly’s pitch is so subtle that these moody, 60-second ads seem like public service announcements. . . . The ads don’t say enough. Lilly should disclose that it markets a leading anti-depressant – its motivation for the ads.” On the other hand, the critic questioned the propriety of any advertising for psycho-pharmaceuticals: “and it’s worth asking whether drug companies should be targeting people whose judgment might be impaired by depression.

The result is a rating of two dollar signs out of a possible four.

III. Impact on the Therapeutic Relationship


170 Id.

171 Id.

172 Id.
At the outset of *The Silent World of Doctor and Patient*, an eloquent manifesto of patient autonomy, Jay Katz notes that the Hippocratic Oath makes no mention of a physician’s obligation to speak with her patients. Indeed, the only reference to the issue in the Hippocratic Corpus advises against conversation:

> Perform [these] duties calmly and adroitly, concealing most things from the patient while you are attending to him. Give necessary orders with cheerfulness and serenity, turning his attention away from what is being done to him; sometimes reprove sharply and emphatically, and sometimes comfort with solicitude and attention, revealing nothing of the patient’s future or present condition. For many patients through this cause have taken a turn for the worse, I mean by the declaration I have mentioned of what is present, or by a forecast of what is to come.

Conversation between physician and patient would impede the physician in carrying out her mission of gaining the patient’s confidence to ensure compliance with treatment orders.

Although occasionally criticized, this Hippocratic ideal has persisted, at times playing an even more important role in medical practice than it did in ancient Greece. In Medieval times, for example, the notion of a non-communicative physician and patient relationship gained religious significance. Viewed as “the minister of nature,” the physician had taken up a sacred calling:

> The . . . intimate relationship between physicians, patients, and their God made

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any critical questioning of doctors’ practices difficult. During the Age of Faith such an encounter came close to blasphemy. Thus, not only would patients find it difficult to question their Aesculpain physicians but the latter, being appointed by God, also would disdain explaining themselves and their practices.\textsuperscript{177}

The post-Medieval history of the content of conversations between physicians and their patients might be characterized as a triumph of hope over truth. The English physician Thomas Percival was the chief modern proponent of communicating hope over all else. In his 1803 work, \textit{Medical Ethics: A Code of Institutes and Precepts Adapted to the Professional Conduct of Physicians and Surgeons}, Percival cautioned physicians against providing patients with any negative information:

A physician should not make gloomy prognostications ... . ... For the physician should be the minister of hope and comfort to the sick; that by such cordials to the drooping spirit, he may smooth the bed of death, revive expiring life, and counteract the depressing influence of those maladies which rob the philosopher of fortitude, and the Christian consolation.\textsuperscript{178}

Nearly half a century later in 1847, the AMA’s first code of ethics incorporated Percival’s mandate of communicating hope, admonishing the physician to adhere to his “sacred duty” “to avoid all things which have a tendency to discourage the patient and to depress his spirits.”\textsuperscript{179} Moreover, the AMA explicitly advised against allowing the patient any voice in diagnosis and treatment: “[Physicians should unite in tenderness with firmness, and condescension with

\textsuperscript{177} \textit{Id.} at 9.


\textsuperscript{179} KATZ, \textit{supra} note 173 at 20, \textit{quoting CODE OF ETHICS OF THE AMERICAN MEDICAL ASSOCIATION} Chpt. 1, Art. 1, §1 (1847).
authority, [so] as to inspire the minds of their patients with gratitude, respect, and confidence.”

The rise of the informed consent doctrine signaled the decline, but perhaps not the demise of this Hippocratic ideal. First embraced in 1957 by the California court of appeals, the doctrine subsequently found favor in the courts of all states and the AMA’s code of ethics. In its most common formulation, the doctrine requires disclosure to the patient of the material risks of treatment.

As more fully discussed in the next section, Jay Katz has criticized the informed consent doctrine as failing to embrace patient self-determination fully because it allows physicians to “make a judgment of materiality.” And a legislative and judicial retreat in the 1980s from any broader disclosure standard has enabled physicians to continue “to shape the disclosure process so that patients will comply with their recommendations.”

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180 Katz, supra note 173 at 20, quoting Code of Ethics of the American Medical Association Chpt. 1, Art. 1, §1 (1847).


182 For a history of informed consent, see generally Katz, supra note 173 at 48-84.

183 The AMA’s Opinions of the AMA’s Judicial Council (1957) discussed a physician’s obligation to disclose to the patient “all facts relevant to the need and the performance” of medical procedures. The Current Opinions of the Judicial Council (1980) embraced informed consent as “a basic social policy.” See generally Katz, supra note 173 at 22-3.


185 Katz, supra note 173 at 79.

186 Id. at 26. For a summary of judicial retreat from a subjective materiality standard, see generally id. at 48-49. For a summary of the legislative retreat, see generally Health Care
Katz concludes *The Silent World of Doctor and Patient* with a plea for physicians to go beyond the requirements of informed consent doctrine and to allow patients a more vital role in the decision-making process. “‘Second medical opinions’ may be one answer, but ‘first patient opinions’ may be a better answer.”\(^{187}\)

Perhaps DTC could function as a catalyst in this development. As an FDA spokesperson has put it, DTC “opens up a dialog between the doctor and the patient and in some ways empowers the patient more. They will know a little more about what the various treatment options are and can at least ask about them.”\(^{188}\) As two members of the FTC have added, “[c]onsumers who do not recognize in their physical condition symptoms of a treatable problem will, obviously, not consult a physician. Therefore, physicians are not an efficient substitute for advertising.”\(^{189}\)

There are at least two potential barriers to obtaining this benefit from DTC. First, the form and content of the DTC information may not serve Katz’s vision. We might not reasonably expect advertising aimed at generating sales to provide a basis for a “first patient opinion.” Rather, the ads might better be described as supplying a “first marketing opinion.”

\(^{187}\) *KATZ, supra* note 173 at 228. For a critique of Katz’s approach as impractical, see generally Thomas P. Duffy, *Agamemnon’s Fate and the Medical Profession*, 9 W. NEW ENG. L. REV. 21 (1987).


Second, the dynamics of the psychiatrist/patient relationship may blunt any tendency DTC may have in catalyzing patient self-determination. In particular, the psychiatrist’s wish to allow the patient to relate an uninterrupted narrative, free from any attempts early in the relationship to separate fact from fiction, may be undermined by a patient bent on obtaining a prescription for an advertised drug.

The remainder of this article will explore these two issues. Adopting Eli Lilly’s Prozac print ad as a prototype, this part will first explore whether the information the ad conveys might assist patients in developing “first patient opinions” of the nature that will foster self-determination. This part will conclude by examining the impact of the ad on the dynamics of the patient/psychiatrist relationship.

A. DTC, “first patient opinions,” and patient self-determination

Jay Katz defines patient self-determination as “the right of individuals to make their own decisions without interference from others.”\textsuperscript{190} The paternalism which is a traditional component of the physician/patient relationship is “one of self-determination’s contrary siblings.”\textsuperscript{191} Only by attending to “patients’ \textit{individual} informational needs and patients’ concerns, doubts, and misconceptions about treatment” can the physician avoid this sinister relative.\textsuperscript{192}

Katz’s demand for disclosure formulated according to the individual needs of patients puts him at odds with informed consent doctrine as adopted in all jurisdiction. States split over whether the materiality of information is to be measured from the physician’s or patient’s

\textsuperscript{190} \textit{Katz}, \textit{supra} note 173 at 105.

\textsuperscript{191} \textit{See} id. at 110.

\textsuperscript{192} \textit{Id.} at 78 (emphasis in original).
position. In either case, courts determine materiality from the objective perspective of a reasonable person in the patient’s or physician’s perspective.\textsuperscript{193} Katz’s vision of self-determination requires determining the necessity of disclosure from the patient’s perspective.\textsuperscript{194} In addition, Katz would reject the objective measure and focus on the needs of the particular patient. The physician would ascertain those needs through conversation.\textsuperscript{195}

Patients, of course, may not know enough about their ailments and the choices of treatment to bring to the physician’s office an existing “first patient opinion.” And physicians have often been reluctant to engage in the sort of conversation with patients necessary to determine the level of information the particular patient needs to make an informed choice. Indeed, Katz asserts that “physicians have generally maintained that patients do not have the \textit{capacity} to participate in decision making.”\textsuperscript{196}

Perhaps DTC can assist patients in attaining this capacity. Or if, as Katz suggests, physicians are unwilling to take the initiative, information from ads might at least enable patients to ask the right questions.

An initial examination of the Prozac ads provides cause for optimism. The first line of copy, for example, simply repeats what a number of psychiatric texts\textsuperscript{197} and depression support

\begin{footnotesize}
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\item See, e.g., Peter Schuck, \textit{Rethinking Informed Consent}, 103 \textit{Yale L.J.} 899, 916 (1994).
\item \textit{Katz}, \textit{supra} note 173 at 78.
\item See \textit{id.} at 79.
\item \textit{Id.} at 104 (emphasis in original).
\item See, e.g., \textit{Psychiatry}, \textit{supra} note 2, at 990.
\end{enumerate}
\end{footnotesize}
groups\textsuperscript{198} advise. "Depression isn't just feeling down. It's a real illness with real causes."

The ad’s references to loss of sleep, loss of appetite, and lack of energy merely mimic the diagnostic criteria of DSM-IV, the dominant psychiatric diagnostic manual, for a “Major Depressive Episode.”\textsuperscript{199} Similarly, the statement that depression exists if these symptoms last for more than a couple of weeks is consistent with the DSM-IV diagnostic requirement of a display of symptoms “most of the day, nearly every day, for at least 2 consecutive weeks.”\textsuperscript{200}

Other aspects of the ad copy depart from traditional diagnostic criteria. For example, while death and divorce may trigger depression, psychiatrists might denounce any implicit suggestion that one can expect to be clinically depressed after these events. And psychiatrists might find problematic the claim that Prozac can make you feel “sunny again” if it leads all those who do not feel that they are shining to believe that they are suffering clinical depression.

The most problematic aspect of the ad, however, stems from its role as a marketing tool: it does not mention alternatives. The ad does not mention other pharmaceutical treatments and it

\textsuperscript{198} See, e.g., www/alt.support.depression.com; www/depression.recovery.com.

\textsuperscript{199} The essential feature of a Major Depressive Episode is a period of at least 2 weeks during which there is either depressed mood or the loss of interest in nearly all activities. ... The individual must also experience at least four additional symptoms drawn from a list that includes changes in appetite or weight, sleep, and psychomotor activity; decreased energy; feelings of worthlessness or guilt; difficulty thinking, concentrating, or making decisions; or recurrent thoughts of death or suicidal ideation, plans, or attempts.

\textsuperscript{200} Id. at 320.
only refers to therapy as a tool to be used after Prozac has spurred a recovery from depression.

If, as the FTC has asserted, “physicians are not an efficient substitute for advertising,”[201] neither is advertising an effective substitute for the physician’s role in patient self-determination. Courts have uniformly interpreted the informed consent doctrine to require disclosure of reasonable alternatives.[202] And, if as Katz suggests, physicians have not embraced joint decision-making with their patients,[203] advertising will not assist in filling the void regarding information about alternative treatment regimes.

To be sure, the ad’s failure to discharge the physician’s obligation does not prohibit the physician from doing so herself. Indeed, we might conclude that having the ad’s information is better than having none at all, especially if the physician can fill in the gaps when questioned about the advertised drug. But an ad which, by virtue of its nature as a marketing tool, pitches one treatment to the exclusion of others, might inhibit the patient in reaching a “first patient opinion” which meaningfully chooses a course of treatment over all of the options. Moreover, the bias instilled in the patient who has seen the ad might inhibit the patient in working with the physician toward an informed choice. This may be especially true in the practice of psychiatry.

B. DTC, patient, and psychiatrist

[M]ental processes are in themselves unconscious and of all mental life it is only certain individual acts and portions that are conscious. ... [Psychoanalysis] cannot accept the identity of the conscious and the mental. It defines what is mental as processes, such as feeling, thinking, and willing, and it is obliged to maintain that

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202 *Rethinking Informed Consent, supra* note 193.

203 *KATZ, supra* note 173 at 84.

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there is unconscious thinking and unapprehended willing. ... [T]he hypothesis of
there being unconscious mental processes paves the way to a decisive new
orientation in the world and in science.

Sigmund Freud, *Introductory Lectures on Psychoanalysis* 204

Psychoanalytic theory, this paper’s focus, certainly has suffered criticism in recent years. Jeffrey Masson has asserted the Freud concealed evidence of the abuse which his patients suffered in their childhoods in order to attain some respectability for his theories. 205 Frederick Crews has been more explicit in his attack, claiming that “Freudian theory and practice unmistakably lies behind [the] tragic deception of both patients and jurors” in child sexual abuse cases. 206

Freud’s defenders have conceded that some of his conclusions may be questionable and that he may have exaggerated the recoveries of some of his patients. 207 But they have also answered Masson’s and Crew’s specific allegations by pointing out that Freud himself recognized both that child sexual abuse is more prevalent than thought and that children’s memories cannot always be trusted. 208

Freud’s defenders have also made a broader point. In maintaining that Freud’s work remains valuable despite some valid criticism, modern Freudians have focused on his chief innovation: constructing the first psychological theory which focused on the internal. As Jay


208 See, e.g., *Open Minded*, supra note 207, at 19-21.
Katz has put it, “The pervasive influence of the unconscious on the lives of human beings has been one of psychoanalysis’ most significant discoveries.” 209

Jonathan Lear, perhaps the best known of current defenders of Freudian psychiatry, 210 has addressed the critics by attempting to broaden the discourse from only Freud’s work to include his considerable legacy: “Freud began a process of dealing with unconscious meaning, and it is important not to get stuck on him . . . . The many attacks on him, even on psychoanalysis, refuse to recognize that Freud gave birth to a psychoanalytic movement which in myriad ways has moved beyond him.” 211 That movement has produced considerable benefit.

Freud’s achievement . . . is to locate . . . meanings fully inside the human world. Humans make meaning, for themselves and others, of which they have no direct or immediate awareness. People make more meaning than they know what to do with. This is what Freud meant by the unconscious. And whatever valid criticisms can be aimed at him or at the psychoanalytic profession, it is nevertheless true that psychoanalysis is the most sustained and successful attempt to make these obscure meanings intelligible. 212

The history of psychiatry in the last several decades can be described as an evolution of psychoanalysis. 213 In large measure, this evolution is the result of economic strictures which

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209 SILENT WORLD, supra note 173, at 114.

210 See, e.g., Mark Edmunds, Why Democracy Needs Freud, N.Y. TIMES, Aug. 16, 1998, §7, p. 10 (describing Lear as “[t]he writer who finally came up to thrust a finger in the dike” of Freud criticism); Christopher Lehman-Haupt, BOOKS OF THE TIMES; Disturbing Signs Behind Reports of Freud's Demise, N.Y. TIMES, Aug. 3, 1998, §E, p. 6 (quoting Janet Malcolm’s dust cover endorsement to Lear’s Open minded: "since [Lear began writing on this issue], talk about 'the death of psychoanalysis' has noticeably subsided").

211 OPEN MINDED, supra note 207, at 32.

212 Id. at 18-9.

213 See PSYCHIATRY, supra note 2, at 1373.
make long-term psychoanalysis impractical: insurance companies and managed care organizations will only pay for a finite number of treatment sessions. As a result, “brief psychoanalytically informed psychotherapies” have emerged to dominate psychiatric therapeutics.\textsuperscript{214}

Consequently, despite the criticism of Freud, and though in many ways transformed by financial concerns, psychotherapy in many new formulae\textsuperscript{215} remains a vital concept in modern psychiatry.\textsuperscript{216} On the other hand, traditional therapy of any form does not play as prominent a role in treatment as it did in Freud’s day. “[T]he computer, symptom-specific drugs, neuroimaging techniques, and rigorous statistical methodology, [psychiatrists’] interests have shifted away from the individual. Psychiatrists often rely more on fluoxetine (Prozac) than on the spoken word.”\textsuperscript{217} But this may provide even greater reason to study the impact of DTC in general, and of Prozac’s ads in particular, on the therapeutic relationship.

1. Rationality and irrationality

Jay Katz would not limit psychoanalytic invention to a recognition of the unconscious. The other tenet central to understanding patient autonomy in the psychoanalytic context is the

\textsuperscript{214} Id.

\textsuperscript{215} “These include, but are not limited to the methods of Malan, Mannm Sifneos, Davanloo, Horowitz, Luborsky, and Strupp and Binder.” Id. (footnotes omitted).

\textsuperscript{216} See, e.g., Erica Goode, Return to the Couch: A Revival for Analysis, N.Y. TIMES, Jan. 12, 1999, F1 (“Even in a Prozac-smitten society, where quick fixes are the rule, Freud’s emphasis on deeper meaning and the unconscious mind still exerts and appeal. Psychoanalytic patients may be scarce, by psychoanalytic ideas inform a variety of academic disciplines and provide the basis for a wide range of ‘psychodynamic’ therapies.”).

\textsuperscript{217} PSYCHIATRY, supra note 2, at 1874.
The distinction between rationality and irrationality. While rationality “refers to the impact on thought and action of consciousness,” irrationality “refers to the impact on thought and action of unconscious impulses and ideation.”

Rationality and irrationality operate simultaneously. Moreover, irrationality does not evidence pathology. Indeed, the denial of irrationality strips an individual of the ability to adapt to aspects of the external world. Obsessive-compulsive behavior, for example, may result from the denial of the irrational. The disorder is characterized by the intrusion of irrational thoughts – the obsessions – and repetitive behaviors – the compulsions -- which are intended to reduce the anxiety which the obsessions cause. Treatment typically involves assisting the patient in accepting the irrational thoughts and resisting the compulsive behaviors.

Irrationality, then, “is an essential ingredient of life” which both patient and psychiatrist will experience. Consequently, Katz contends that a psychiatrist/patient relationship involves a scrutiny by both of their own and the other’s rationality and irrationality. Moreover, “[p]remature struggles to convince the other of his or her ‘irrationality’ are counterproductive;
they only preclude the possibility of mutual understanding.”

Others have cautioned against premature attempts to separate the rational from the irrational and the real from the imagined. The leading treatise, for example, characterizes the psychiatric technique as “listening.” Treatment is really a “history-taking journey” which must be “free of judgments, opinions, criticisms.” Only after the psychiatrist has heard the patient’s “inner experience” can she begin to address that experience. And she facilitates the storytelling not by confronting possible inaccuracies, but by conveying to patients that they “are safe to tell” their stories. Throughout, “it is better to be deceived than to reject the patient prematurely.”

DTC certainly could interfere with this process. Consider again the Prozac ad. A student who has found it “hard to concentrate” or who has experienced a “lack of energy” and who is hoping for a cure before either symptom impacts a grade point average might visit a school psychiatrist seeking a prescription for Prozac. The student’s story may be shaped by the ad copy. And this can occur consciously or unconsciously. Moreover, identifying with the ad may be

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225 Id. at 118.

226 Psychiatry, supra note 2, at 5:

“All psychiatrists, regardless of theoretical stance, must learn this skill and struggle with how it is to be defined and taught. The psychodynamic psychiatrist listens for the unconscious conflicts; the cognitive psychiatrist listens for the patient’s hidden distortions and assumptions about the world; the behaviorist listens for hidden associations and patterns; and the interpersonal psychiatrist listens for stereotypical role definitions, interpersonal conflicts, and repertoire deficits.

227 Id. at 9.

228 Id. at 17.

229 Id. at 9, citing R. R. Greenson, Explorations in Psychoanalysis (1978).
either rational or irrational.

The psychiatrist must eventually determine whether the student is suffering from clinical depression and whether a Prozac prescription is appropriate. And if we are critical of implications of the data indicating that between 80 percent and 92 percent of those who request a Prozac prescription receive it, we might demand that the psychiatrist take great care in parsing fact from fiction. Yet a premature confrontation with the ad copy may cause significant harm. It will, as Katz puts it, “prevent mutual understanding.” And without that, “individual self-determination may be compromised by condemning physicians and patients to the isolation of solitary decision making, which can only contribute to abandoning patients prematurely to an ill-considered fate.”

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2. Transference and counter-transference

Two central concepts in the psychotherapeutic relationship assist the patient and physician in developing a mutual understanding. Transference occurs when the patient transfers to the analyst feelings she has for important figures in her life. Counter-transference occurs when the analyst transfers her feelings to the patient. Both processes may be compromised when the subtext to the physician/patient relationship is ad copy.

a. Transference

Freud considered transference to be vital to psychotherapy:

230 SILENT WORLD, supra note 173, at 128.


232 Id. at 110.
The most remarkable thing [about the analyst/patient relationship] is this. The patient is not satisfied with regarding the analyst in the light of reality as a helper and advisor who, moreover, is remunerated for the trouble he takes and who would himself be content with some such role as that of a guide on a difficult mountain climb. On the contrary, the patient sees in him the return, the reincarnation, of some important figure out of his childhood or past, and consequently transfers on to him the feelings and reactions which undoubtedly applied to this prototype. ²³³

Transference, then, takes on an “undreamt-of importance.” ²³⁴ By placing the analyst in the role of a parent, for example, the patient can achieve an “after-education” through which she can correct her parents’ mistakes. ²³⁵ In addition, transference assists the patient in filling in the details of her life story. ²³⁶ By acting out the past instead of reporting it, the patient can provide a more complete narrative.

Consider the impact of the Prozac ad copy on transference. Rather than helping to fill out the narrative, the ad’s reference to some of life’s events – a divorce or death in the family – may actually short circuit the story telling. Convinced that one of those events may have caused depression, the patient may feel reluctant to explore any other aspects of her past.

Similarly, the patient’s focus on the ad’s description of her illness and its promise of a treatment may give her incentive to assign her psychiatrist a specific role: a prescriber of pharmaceuticals. The psychiatrist is no longer a blank screen onto which a patient can project whatever she wishes, but is a conduit for pharmaceutical treatment. Moreover, the failure to

²³³ Sigmund Freud, AN OUTLINE OF PSYCHO-ANALYSIS 52 (Standard ed. 1949).

²³⁴ Id.

²³⁵ Id. at 53.

²³⁶ Id. at 54.
receive that treatment may generate anger or disappointment which further hinders the relationship and/or hastens its demise.\textsuperscript{237}

Of course, it may turn out that the ad and the patient are right: the patient is suffering from a serotonin imbalance which can be corrected by an appropriate dose of Prozac. Yet if other psychological issues remain, and if we grant analysts some value in transference, treatment may have been compromised. Or, at the very least, in Jay Katz’s language, to reach a mutual understanding about the rational and irrational and the conscious and unconscious, patient and physician should both be aware of DTC’s impact on transference.

b. Counter-transference

Freud’s works contain only two fleeting references to counter-transference.\textsuperscript{238} In *The Future Prospects of Psycho-analytic Therapy* Freud first identified the phenomenon:

> We have become aware of the ‘counter-transference,’ which arises in [the physician] as a result of the patient’s influence on his unconscious feelings, and we are almost inclined to insist that he shall become aware of this counter-transference in himself and shall overcome it.\textsuperscript{239}

Freud again broached the subject five years later in *Observations on Transference-Love*.\textsuperscript{240} As in his first reference to the concept, Freud again characterized counter-transference as something which the physician should overcome in an attempt to remain a neutral observer:

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\begin{itemize}
\item \textsuperscript{237} See supra text and notes for a discussion of patients switching health care providers when they do not receive prescriptions for advertised drugs which they request.
\item \textsuperscript{238} Michael Gorkin, *The Uses of Countertransference* 2 (1987).
\item \textsuperscript{239} Sigmund Freud, *The Future Prospects of Psycho-analytic Therapy* 144-45 (Standard ed. 1910), as quoted in *Countertransference*, supra note 238, at 2.
\item \textsuperscript{240} Sigmund Freud, *Observations on Transference-Love* 164 (Standard ed. 1915).
\end{itemize}
Our control over ourselves is not so complete that we may not suddenly one day go further than we intended. In my opinion, we ought not to give up the neutrality towards the patient which we have acquired through keeping the counter-transference in check.\textsuperscript{241}

Freud, then sought to resist the temptations of counter-transference. Indeed, many have since criticized Freud’s treatment of some of his fabled patients on the ground that he overlooked the impact of his own counter-transference. Freud’s treatment of Dora, one of his most documented early patients, many have contended, was flawed because he failed to perceive his own sexual feelings toward her.\textsuperscript{242}

Although Freud sought to avoid the pull of counter-transference, his psychoanalytic descendants have embraced the concept as “a tool of some value in the therapeutic process.”\textsuperscript{243} Michael Gorkin, for example, describes the psychiatrist as at times employing counter-transference to “participate emotionally in the drama directed by the patient.” At other times, the psychiatrist defies counter-transference so that she can make an objective assessment of the patient’s progress. The result is a continuing process which facilitates the psychiatrist in “merging with and separating from the patient.”\textsuperscript{244}

Two aspects of DTC may impact counter-transference. First, the essence of the therapeutic use of counter-transference is the physician’s recognition of her feelings about the patient. She needs to realize that the anger or desire she is experiencing, for example, are the

\textsuperscript{241} \textit{Id.} at 164, \textit{as quoted in COUNTERTRANSFERENCE, supra} note 238, at 2.

\textsuperscript{242} \textit{Freud’s “Dora” Case, supra} note 231, at 111-13.

\textsuperscript{243} COUNTERTRANSFERENCE, \textit{supra} note 238, at 53.

\textsuperscript{244} \textit{Id.} at 77.
result of projecting onto the patient her feelings about others in her past. The extent to which the psychiatrists should disclose these feelings to her patient are a matter of some dispute.\textsuperscript{245} Contemporary analysts, however, “now regard the analyst’s experience as quite relevant to what she and the patient are struggling to understand.”\textsuperscript{246} In essence, by attending to her own feelings, the analyst gets a better idea of the patient’s feelings and how to assist the patient in therapy.

If the analyst notices twinges of irritation in himself, he might speculate about the patient’s awareness of that irritation resulting in a wariness the patient seems to display around him. If the analyst discovers a sexual excitement in the patient’s presence, she might learn something about an unnoticed erotic dimension of the patient’s demeanor.\textsuperscript{247}

With the advent of DTC, however, the analyst’s wariness may have a very different source. Instead of comparing her feelings with those of the patient’s, she may feel compelled to compare the patient’s narrative with relevant ad copy. Instead of using her own emotional responses to detect the various dimensions of the patient’s state, the analyst may endeavor to separate fact from marketing fiction. In either event, the analyst may not be able to serve effectively as a conduit for the patient’s associations voiced during analysis.

The second aspect of DTC’s impact on counter-transference derives from its economic impact on the psychiatrist/patient relationship. Not only will she be tempted to ignore her own feelings while comparing the patient’s story with advertising copy, but she may also be concerned with the impact on her practice if she decides that the copy does not match her

\textsuperscript{245} See, e.g. Stephen A. Mitchell & Margaret J. Black, \textit{Freud and Beyond} 247-50 (1995).

\textsuperscript{246} \textit{Id.} at 248.

\textsuperscript{247} \textit{Id.} at 247.
patient’s needs. Patient’s who do not receive the prescriptions they request are twice as likely as others to switch managed care organizations. That, of course, may also result in switching psychiatrists. The economic incentive to give the prescription may impede the psychiatrist in identifying her feelings about the patient. Instead of focusing on what figure the patient represents from her own past, the psychiatrist may be tempted to act in the interest of her economic future. In any event, DTC will complicate the process of “finding meaning through an exploration of concealed wishes.”

V. A Recommendation

The growth of DTC since the FDA’s August 1997 decision leads to two inescapable conclusions. First, having crumbled, the Berlin wall of advertising will not be rebuilt. Once experiencing the marketing benefits of DTC, pharmaceutical companies are unlikely to relinquish their new-found freedom to advertise. Indeed, given an apparent public acceptance of DTC, pharmaceutical companies now may be willing to assert a long-dormant constitutional claim to a right to advertise. Moreover, the FDA has given no sign of reconsidering its decision. David

248 See supra text and note.

249 Freud’s “Dora” Case, supra note 231, at 114.

250 Pharmaceutical companies have been reluctant to assert a commercial free speech rights to advertise for at least two reasons. First, even those companies which might have benefitted from marketing were unsure that consumers would react positively to advertising of drugs. See supra text and notes. Moreover, not all manufacturers have supported advertising. Manufacturers of generic drugs, represented by the National Association of Pharmaceutical Manufacturers, for example, in 1991 petitioned the FDA to ban DTC, urging the FDA to recognize that advertising is not protected free speech. Ban Consumer Rx ads, petition asks, 26 Medical Marketing & Media (Oct. 1, 1991). Second, the brand-name manufacturers “have been reluctant to antagonize the FDA over free-speech rights when drug approvals hang in the balance.” Richard T. Kaplar, It's time to remove the brief summary from DTC print ads, 33 Medical Marketing & Media 44 (May, 1998). Encouraged by the apparent success of DTC,
Kessler, former FDA chair, last summer identified himself as the person who “more than any other individual stood in the way” of DTC. Yet, he all but conceded the inevitability of continuing DTC when he spoke of “a move to a culture that increasingly pushes prescription drugs.”

Given the FDA’s recent setback in its efforts to regulate the advertising of tobacco, it would be surprising if the current FDA chair did not join in Kessler’s surrender to pharmaceutical DTC.

Second, the existing model of psychotherapy cannot accommodate DTC. The leading treatise, although advising the psychiatrist to consider a number of aspects of the patient’s emotional and cultural makeup, does not advise the psychiatrist to take into account the extent of the patient’s knowledge of symptomology or of pharmaceuticals. Yet, that knowledge, especially if gained through DTC, may shape the patient’s expectations and impact transference and counter-transference.

Psychiatry has addressed analogous issues. For example, when addressing therapy for the

pharmaceutical companies are beginning to assert claims to free speech. See, e.g., Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.C. Dist., 1998) (Enjoining enforcement of FDA policy prohibiting pharmaceutical manufacturers from disseminating text book and journal articles on off-label pharmaceutical use, Judge Lambert wrote, “The speech that the manufacturers wish to ‘communicate’ is the speech of others the work product of scientists, physicians and other academics. Scientific and academic speech reside at the core of the First Amendment.”).

Seminar, supra note 117.

Brown and Williamson Tobacco Corp. v. FDA, 153 F.2d 155, (4th Cir. 1998), rehearing denied, nov. 10, 1998, LEXIS 28409 (striking down as beyond the FDA’s authority granted under the Food, Drug, and Cosmetic Act the FDA’s prohibition of tobacco advertising directed toward children).

Psychiatry, supra note 2, at 26-28.
delusional patient, the same treatise which overlooks the impact of DTC observes that “[t]he interviewer risks any chance of alliance, with almost no chance of benefit, by trying to persuade a patient that he or she is wrong.”254 Similarly, when treating a patient of cultural background disparate from that of the therapist, the treatise warns that “it is the interviewer’s responsibility to give reassurance of a commitment to understanding the patient as best as possible and to take steps to minimize the chance of distortion.”255

DTC’s effect, at its most extreme, might approximate these illustrations. If wrongly convinced of a diagnosis and treatment, the patient’s belief that she must obtain a prescription for an advertised drug might well be described as delusional. A patient who derived her medical knowledge from a marketing campaign might, in terms of medical sophistication, be said to be of a culture different from her psychiatrist. In either event, a dismissal of the patient’s wishes would reduce the possibility of therapeutic alliance. And the treatise’s advice to avoid a premature challenge to the patient’s views and to commit to understanding the patient’s needs before diagnosing or embarking on a course of treatment would be well taken.

Understanding the origins of the patient’s views and, if appropriate, distinguishing those views from her needs, would entail familiarity with the contents of advertising which has shaped her views. Yet, it would be very time consuming, if not practically impossible, for a physician to be informed of all ads relevant to a practice. Eli Lilly, for example, circulates its Prozac print ads in five magazines: *Time*, *Newsweek*, *U.S. News and World Report*, *Good Housekeeping*, and *Sports Illustrated*. It follows no clear pattern, but each issue places the ads in one or more of

254 Id. at 34.

255 Id. at 36.
those magazines. Moreover, even if a physician could track down all relevant advertising, she would not see the copy before her patients see it. As a result, she might not be able to evaluate its claims meaningfully before conducting a psychotherapy session for a patient whose expectations had been informed by the ad.

A modest change in the regulatory scheme could assist physicians. Pharmaceutical companies could distribute ad campaigns to physicians before presenting them to the public. This would enable physicians to become aware of any misleading or incomplete information in the ad copy. In addition, advanced notice would aid psychiatrists in any quest to discern whether patient narratives too closely resemble ad pitches.

With proper design, this scheme could also provide physicians with a platform for voicing concerns about ad campaigns. Moreover, it could also provide pharmaceutical companies with an efficient vehicle for ascertaining the medical community’s response to ads. Given a thirty day notice period, physicians could submit comments to manufacturers, who could revise ad campaigns in light of the comments.

This process could perhaps most easily be accomplished through the Internet. Pharmaceutical companies could post proposed ad campaigns on secure web sites. Existing technology could easily accommodate print, audio, and video formats. Physicians could access the sites by submitting an identification code, perhaps professional society membership identification numbers, state licensure codes, or the Drug Enforcement Agency codes which entitle them prescribe controlled substances. The participants could then easily exchange comments. Security would ensure physician notice before consumer notice.

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256 Conversation with Eli Lilly Marketing Division, November 1998.
To avoid creating any semblance of a prior restraint and to minimize the incursion on both pharmaceutical companies and physicians, the program would mandate only the posting of the ads and a thirty day waiting period before publication. Physician commentary and pharmaceutical company response would be voluntary.

Using the Internet offers distinct advantages over other forms of information exchange. First, a web site minimizes distribution costs by eliminating postal or similar fees. Second, it speeds information exchange, making a relatively short notice and comment period workable.

A speedy and efficient mechanism for transmitting information might also foster the formation of an alliance between physicians and pharmaceutical companies. Physicians would have reason to hope for less biased ad campaigns. By responding to physician critiques, pharmaceutical companies might be able to mollify their critics in the medical community. Any progress toward an alliance would help to minimize the disruption on the therapeutic relationship because psychiatrists would have less reason to suspect the ad copy which might function as a subtext to patient narratives.

Some physicians have already instituted a similar process. For example, the director of the family practice residency at a Pennsylvania hospital initially opposed in-hospital pharmaceutical sales pitches. But, influenced by residents’ appreciation of the information company representatives offered and yielding to the inevitability of marketing, the director organized “information management” sessions. The sessions allow the sales representatives to push their wares and the physicians to critique the presentations. Presumably, both physicians and pharmaceutical companies can benefit from the program.257

257 *Fever Pitch, supra* note 64.
All available data suggest that most physicians would welcome this approach. A November 1998 survey revealed that two thirds of all physicians would like advanced information of DTC campaigns.²⁵⁸ Given the current prototype for psychotherapy, one might expect that an even greater percentage of psychiatrists would welcome the information.

More than signaling a change in the psychotherapeutic model, the institution of information exchange would simply confirm and support a shift that has already taken place. A substantial portion of patients obtain medical information through DTC and psychiatrists have already begun wrestling with how to adapt to the aftermath. Given the trends in spending and the shift from print ads to television, the 70 percent share of the population who are already aware of DTC can only be expected to grow. Providing advanced copy to and involving physicians in advertising campaigns can only make the new model more effective.

DTC has taken its place on the couch. The exchange of information between physicians and pharmaceutical companies would at least minimize the damage DTC might work on the therapeutic relationship. At best, the proposed scheme might serve to catalyze the formation of a therapeutic alliance among physicians, pharmaceutical companies, and Madison Avenue advertising agencies.

VI. Conclusion

Even its critics concede that psychoanalysis has revolutionized our notions of the human condition:

The theory of the unconscious, so at odds with daily life and ordinary speech, remains the most radical of Freud’s contributions (even though the idea of it had long preceded him). For it is here, in the once known and then repressed, or, as some analysts are thinking these days, in the never known and dissociated, that exists what cannot be thought. In the tension between conscious and unconscious lies the potential for psychic integration, for, paradoxically, personal change and meaning.259

In the words of Muriel Dimen, “[i]t’s not much fun, . . . but it’s got possibilities.”260

DTC may limit those possibilities. At the very least, it injects a new level of scepticism into the therapeutic relationship. Psychiatrists must ascertain whether a patient is emulating symptoms presented in advertisements in order to obtain prescriptions. Put simply, the psychiatrist cannot “go along with” the patient’s story.

At worst, DTC may disassemble the very components of the psychiatrist/patient relationship. Informed and motivated by the ad copy, all the patient can transfer to the psychotherapist is a desire for a prescription. And wary of a patient narrative driven by Madison Avenue marketing executives, psychiatrists’ concerns about the influence of ad copy may obscure their own feelings about the patient.

A number of concerns militate against any attempt to ban DTC. First, the FDA’s recent actions really just reflect a concession to the inevitable. Existing limitations made little sense in the age of television and the voices of pharmaceutical manufacturers and advertisers were growing louder. DTC simply is not going to go away.

Second, DTC’s impact is neither all bad nor all that bad. Prevention Magazine’s study

259 Muriel Dimen, Strange Hearts, On the Paradoxical Liaison Between Psychoanalysis and Feminism, in CONFLICT AND CULTURE supra note 231, at 207, 218.

260 Id. at 220.
revealed that advertising does provide consumers with information which they might otherwise not obtain. And it has led some to seek treatment.\textsuperscript{261}

Moreover, although DTC may disrupt the psychotherapeutic relationship, it need not destroy it. If psychiatrist and patient both make their concerns about the advertisement clear, its relevance to the patient’s symptomology may be another topic for discussion. Jay Katz has laid out a framework for physicians and patients sharing of authority in treatment: “Only after physicians have professed their esoteric professional knowledge and patients their esoteric personal knowledge, and both have confessed . . . to what they can do and what they expect, can a mutually satisfactory recommendation emerge.”\textsuperscript{262} Part of the patient’s knowledge may be her belief that she fits the patient described in the ad copy. Part of the physician’s knowledge may be her knowledge of the multi-dimensional aspects of the patient’s condition and the alternatives to the advertised drug.

The Internet-borne notice and comment arrangement proposed here could accommodate psychiatrists’ concerns. Yet, because it would be both economical and speedy, it should not draw much pharmaceutical company ire. And patients should have no objection to an efficient system which both informs their psychiatrists of marketing campaigns and enables the psychiatrists to notify manufacturers of concerns about misleading ads.

In the age of advertising and increasing pharmaceutical treatment of mental illness, patients and psychiatrists cannot expect the traditional one-on-one relationship to endure. Many sources of information have invaded the once near-sacred relationship of therapist and patient.

\textsuperscript{261} See supra text and notes .

\textsuperscript{262} SILENT WORLD, supra note 173, at 103.
Self-help books and first-person accounts of therapy, including Prozac use, are available and widely read. The therapist must account for these forms of information in assessing a narrative and shaping a therapy.

Marketing information has also taken its place on the couch. But it differs from the other forms of information which have invaded the psychiatrist’s office. Although some first-person accounts may advocate for others the treatment which the authors found successful, only advertising is intended from inception to promote one form of treatment to the exclusion of all others.

At best, a program to augment DTC campaigns with physician insight of the subtleties of mental illness and treatment alternatives could play a role in catalyzing Jay Katz’s “first patient opinions.” At the very least, it’s got possibilities.