



# American Exceptionalism and Direct-to-Consumer Advertising: Structural and Philosophical Impediments to Reform in Europe

## Citation

American Exceptionalism and Direct-to-Consumer Advertising: Structural and Philosophical Impediments to Reform in Europe (2002 Third Year Paper)

## Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965601>

## Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

## Share Your Story

The Harvard community has made this article openly available.  
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

# American Exceptionalism and Direct-to-Consumer Advertising: Structural and Philosophical Impediments to Reform in Europe

Andrea W. Trento  
March 2002  
Class of 2003

## **Abstract**

Despite a recent EC Proposal to relax its prohibition on direct-to-consumer (DTC) advertising of prescription drugs in certain, limited contexts, the prospects for broader reform in Europe on this issue are extremely grim. This essay argues that fundamental structural and philosophical differences in health care administration between the United States and Europe bode ill for the further relaxation of the prohibition in Europe. After exploring the causes and consequences of the emergence of DTC advertising in the United States, the essay examines the likelihood that a similar constellation of factors might align in Europe to produce similar results, concluding that the particular differences between the US and European systems render harmonization on this issue highly unlikely. Nevertheless, drawing on criticisms of the practice of DTC advertising in the United States, the essay notes that Europeans' emphasis on deference to the expertise of the physician would vitiate some of the problems associated with DTC advertising in the United States.

“Advertisements contain the only truths to be found in newspapers.”

-Thomas Jefferson, 1819.<sup>1</sup>

## I. INTRODUCTION

In July 2001, the European Commission proposed to relax its prohibition on direct-to-consumer advertising of prescription pharmaceuticals (DTC) in certain limited contexts,<sup>2</sup> reversing a long-standing<sup>3</sup> categorical ban on such advertising and sparking a flurry of protests from physician groups,<sup>4</sup> consumer affairs groups,<sup>5</sup> and editorialists<sup>6</sup> across the continent. Of course, the proposal had its proponents as well: pharmaceutical companies quietly supported the proposal, while one enthusiastic industry marketing representative heralded it as evidence that “Europe will go the U.S. way and relax laws aimed at preventing DTC prescription drug advertising.”<sup>7</sup> Of course, DTC prescription drug advertising is permitted in the United States,<sup>8</sup> but is this EC proposal really the chink in the regulatory armor that will ultimately spell defeat for DTC prohibitions even in Europe? Not likely.

---

<sup>1</sup>Quoted, in the prescription drug context, in Peter R. Seaver, *Prescription Drug Advertising: An Industry Perspective*, in PROMOTION OF PHARMACEUTICALS: ISSUES, TRENDS, OPTIONS (Dev S. Pathak, Alan Escovitz & Suzan Kucukarslan eds., 1992).

<sup>2</sup>Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM (2001) 404 (02), **available at** [http://europa.eu.int/eur-lex/en/com/dat/2001/en\\_501PC0404\\_02.html](http://europa.eu.int/eur-lex/en/com/dat/2001/en_501PC0404_02.html) [hereinafter EC proposal]. Specifically, the proposal permits the “dissemination of information relating to certain medical products . . . in order to respond to the expectations of . . . patients’ groups” for the purposes of AIDS, asthma, and diabetes. *Id.* See also *Additional Highlights from E.U. Drug Regulatory Proposals*, EUR. DRUG & DEVICE REP. (Jul. 30, 2001).

<sup>3</sup>Although the EU (then the EC) formally first assumed jurisdiction over, and banned, the practice in 1992, see Council Directive 92/28/EEC of 31 March 1992 on the Advertising of Medicinal Products for Human Use, art. 3, 1992 O.J. (L 113) 13 [Hereinafter 1992 Directive], the “longstanding-ness” refers to the universal prohibition among members states of DTC advertising of prescription drugs prior the EC’s acquisition of jurisdiction over this area.

<sup>4</sup>See, e.g., Simon Crompton, *Drugs Get a Hard Sell*, THE TIMES, July 10, 2001, at

<sup>5</sup>See, e.g., Rory Watson, *News Roundup: Consumer groups fight plans for “direct to patient” drug advertisements*, 323 BRIT. MED. J. 889 (2001). See also

<sup>6</sup>See, e.g., Sarah Boseley, *Just Say No to Drug Ads*, THE GUARDIAN, Dec. 10, 2001, at 17.

<sup>7</sup>Jason Dabek, *Prescription Products to Consumer Brands in Europe* (Aug. 2001), **available at** <http://www.inpharm.com/intelligence/frost020801.html>. Similarly, Wayne L. Pines, an American industry pharmaceutical industry representative, speculated that the emergence of the Internet as a source of information for health care consumers will lead to the dismantling of European prohibitions on DTC advertising. See Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L. J. 489, 517 (1999).

<sup>8</sup>See *infra* Part II.

In this essay, I argue that, despite the recent proposal, fundamental structural and philosophical differences between the United States and European countries effectively prevent further relaxation of the Union-wide prohibition on DTC advertising toward an American-style system. What is interesting about these differences, however, is not particularly the fact that they will likely prevent further regulatory convergence between the regions on this issue, but rather that they demonstrate Europe to be a perhaps more suitable environment than the United States for a regulatory regime that looks favorably upon such advertising. It is precisely because European attitudes towards health care (generally speaking) are less consumeristic, less individualistic, and more deferential to the expertise of the physician, that one might be more sanguine about the region's ability to harness the benefits of DTC advertising without some of the attendant costs than what one might be led to believe based on the American experience.<sup>9</sup>

Before examining the situation in Europe, however, this essay begins in Part II with an examination of DTC advertising in the United States. In particular, it begins with a historical account of the emergence and evolution of DTC advertising, with particular emphasis on its philosophical and structural underpinnings, before addressing the arguments put forth by its proponents and critics, respectively, in favor of or in opposition to the practice. After applying the American experience to the context of Europe in Part III, the essay concludes in Part IV with the observation that, in the end, Europe's cultural and philosophical attributes may have proven it to be a better testing ground for DTC advertising.

## II. THE AMERICAN EXPERIENCE WITH DTC ADVERTISING

### *A. History of DTC Advertising in the United States*

---

<sup>9</sup>The benefits and costs of DTC are explored in greater detail at *infra* Part II.C.

## 1. The Emergence: 1962 - 1985

Contrary to popular opinion, DTC advertising has never been explicitly illegal in the United States.<sup>10</sup> In fact, prescription drug advertising has always been regulated by the Food and Drug Administration (FDA) as simply prescription drug advertising, without reference to or restriction on the targeted audience,<sup>11</sup> subject to a mere paragraph in the Food, Drug, and Cosmetic Act as amended in 1962.<sup>12</sup> The rules promulgated under § 701 (e) of the Act<sup>13</sup> in the years immediately following the 1962 amendments fleshed out the essence (and many of the particulars) of the Act's requirements, establishing the particular "information in brief summary relating to side effects, contraindications, and effectiveness" that had to accompany every advertisement,<sup>14</sup> and identifying particular grounds for a determination that an advertisement is "misbranded" under the statute.<sup>15</sup> But the regulations remained grounded in the now-antiquated notion that prescription drugs would only be marketed to the prescribing physicians – not because DTC advertising was frowned upon, *per se*, but because promoting prescription drugs to consumers was simply seen as "inconceivable."<sup>16</sup>

---

<sup>10</sup>One British publication has suggested that DTC advertising has been effectively permitted in the United States only since 1997. See Charles Medawar, *Health, Pharma, and the EU: A Briefing for Members of the European Parliament on Direct-to-Consumer Drug Promotion* (2001), available at <http://www.socialaudit.org.uk/5111-005.htm>. Needless to say, this is incorrect. The 1997 reference, however, refers to a draft guidance, later adopted into the administrative code, clarifying disclosure requirements for broadcast advertisements of prescription drugs. The guidance significantly reduced the amount of information required to be disclosed in broadcast ads, permitting companies finally to advertise their products on television without fear of administrative action. See *infra* Part II.B.

<sup>11</sup>The EU, on the other hand, permits only targeted prescription drug advertising to health care professionals (i.e., in medical journals, by direct mail, etc.). See 1992 Directive, *supra* note 3, art. 6.

<sup>12</sup>21 U.S.C. § 352 (n). Prescription drugs as a separate class have only existed since 1938, see Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J. L. & ECON. 91, in *FOOD AND DRUG LAW: CASES AND MATERIALS* 405 – 407 (Peter Barton Hutt & Richard A. Merrill eds., 2d ed. 1991). Prior to 1962, however, the Federal Trade Commission (FTC) had jurisdiction over the regulation of prescription drug advertising. As the history with which this paper concerns itself takes place after 1962, the 1962 Amendments that shifted regulatory control over prescription drug advertising to the FDA, therefore, present a convenient starting point for its analysis.

<sup>13</sup>21 U.S.C. § 371 (e) (providing an administrative mechanism for establishing rules to promulgate the statutory requirements).

<sup>14</sup>21 U.S.C. § 352 (n) (3). This is referred to as the "brief summary," although anyone who has attempted to read the entirety of a prescription drug print advertisement will attest that the summary is anything but. The particular requirements for what needs to be included in the "brief summary" are set forth in 21 C.F.R. § 202.1 (e) (1)-(4).

<sup>15</sup>21 U.S.C. § 371. The regulations require that the "brief summary" not be false, lack fair balance, or fail to reveal any material information, 21 C.F.R. § 202.1 (5), and denote numerous (but non-exhaustive) specific instances where an advertisement would violate this requirement, 21 C.F.R. § 202.1 (6)-(7).

<sup>16</sup>See Michael S. Wilkes, Robert A. Bell, & Richard L. Kravitz, *Drug Research and Development: Direct to Consumer Prescription Drug Advertising: Trends, Impact, and Implications*, HEALTH AFF. (Mar. 2000 – Apr. 2000).

Fast-forward to 1981. Boots Pharmaceuticals and Merck Sharpe & Dohme run ads for, respectively, an ibuprofen product and a pneumonia vaccine, directed not to physicians, however, but to consumers.<sup>17</sup> These ads were the first of their kind since the advent of prescription drugs, and stirred some unease among FDA regulators. In the wake of these advertisements, the agency's Division of Drug Labeling and Advertising was inundated with proposed DTC ads from across the industry,<sup>18</sup> prompting FDA Commissioner Arthur Hayes to request of the industry a voluntary moratorium on DTC advertising "in order to permit time for a reasoned assessment of this complex issue."<sup>19</sup> Industry obliged, and a two-year period of careful study began. By this point, though, the results of this "assessment" were foreordained. In response to two of its own studies demonstrating a strong consumer desire for more information about prescription drugs and health care,<sup>20</sup> the FDA lifted the moratorium and declared existing advertising regulations sufficient for the protection of the general public.<sup>21</sup>

What happened between the early 1960s and early 1980s that provoked, then permitted the emergence of DTC advertising? In short, everything. The 1960s saw the principle of patient autonomy and the doctrine of informed consent trump the pre-existing dogma that patients must rely on trust in the benevolence of physicians for understanding, treatment, and personal coping with their diseases.<sup>22</sup> Patient autonomy – manifested in the right of patients to refuse medical treatment – arose within the general climate of the civil rights movement's skepticism of authority and paternalism.<sup>23</sup> Meanwhile, the doctrine of informed consent – which assigns to a physician the duty to inform her patient of the risks and benefits of a proposed

---

<sup>17</sup>See Pines, *supra* note 7, at 491.

<sup>18</sup>Id. at 492. In addition, FDA Commissioner Arthur Hayes, in a speech to the Pharmaceutical Advertising Council in 1982, predicted "exponential growth" in DTC advertising, inadvertently touching off a wave of speculation that the FDA was prepared to accept such advertising. Id.

<sup>19</sup>FDA Commissioner Arthur Hayes, Statement of Policy of Sept. 2, 1983.

<sup>20</sup>See Pines, *supra* note 7, at 492; see also Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 FOOD DRUG COSM. L.J. 497 (1984); Louis A. Morris, David Brinberg, Ron Klimberg, Carole Rivers & Lloyd G. Millstein, *The Attitudes of Consumers Toward Direct Advertising of Prescription Drugs*, 101 PUB. HEALTH REP. 82 (1986).

<sup>21</sup>Direct to Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36677 (Sept. 9, 1985)

<sup>22</sup>See James C. Robinson, *The End of Asymmetric Information*, 26 J. HEALTH POL. POL'Y & L. 1045, 1052.

<sup>23</sup>See Edmund D. Pellegrino, *Patient And Physician Autonomy: Conflicting Rights And Obligations In The Physician-Patient Relationship*, 10 J. CONTEMP. HEALTH L. & POL'Y 49.

treatment before obtaining consent to perform the treatment – was adjusted to base the physician’s disclosure requirement not on prevailing professional standards, but on whether the information would reasonably be perceived by the physician to be material to the patient for decision-making purposes.<sup>24</sup> The professionalism ethos was shattered in the anti-authoritarian 1960s, giving way to notions of patient autonomy and greater control over treatment.<sup>25</sup>

But philosophical change was not the only significant development of the era. Medicine itself was developing in ways that inevitably invoked greater participation in health care decisions by patients themselves, with the emergence of non-essential medical treatments that nevertheless still required prescriptions. Birth control pills were the first manifestation of this phenomenon in the 1970s, and were followed by treatments for baldness in men in the 1980s. One scholar has suggested that the “patient package insert” – first mandated by the FDA in the 1960s for use with asthma inhalers for directions for use purposes, but later expanded to products like birth control pills and controversial estrogen replacement therapies – was the precursor to DTC advertising, because it represented an acknowledgement on the part of the FDA of “the importance of the patient understanding a prescription drug and deriving the maximum benefit from it.”<sup>26</sup> The inescapable fact was that, for the first time, *healthy* people were using prescription medications on a purely voluntary basis; no element of medical necessity was involved, and the decision to take the medications turned more heavily on the preference – and understanding of the costs and benefits – of the patient than ever before.

In this context, the emergence of DTC advertising seemed hardly surprising, notwithstanding the trepidation

---

<sup>24</sup>See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir. 1972). (“Any definition of scope in terms purely of a professional standard is at odds with the patient’s prerogative to decide on projected therapy himself.”). See also Frederick R. Abrams, *Patient Advocate or Secret Agent?*, 256 J. AM. MED. ASS’N 1784 (describing the case’s additional holding that “deception even in the patient’s interest was unacceptable”).

<sup>25</sup>Other significant works of the era reflecting this change include Elliot Freidson, *PROFESSIONAL DOMINANCE: THE SOCIAL STRUCTURE OF MEDICAL CARE* (1970); Boston Women’s Health Book Collective, *OUR BODIES, OURSELVES* (1969); and Ivan Illich, *MEDICAL NEMESIS* (1976).

<sup>26</sup>Pines, *supra* note 7, at 490.

with which the pharmaceutical industry appeared to approach the issue at first.<sup>27</sup> By the late 1970s, the *Physician's Desk Reference*, previously marketed only to physicians, had hit consumer book shelves, the population was becoming increasingly more educated, and the mass media – with more news reports on, and television programs about, health topics to reflect increasing demand – were becoming more accessible to the general public. All of these reflected existing demand on the part of consumers to become more involved in their health care decisions. In light of these developments, the FDA-commissioned studies during its voluntary moratorium that reflected consumer desire for *more* information on pharmaceuticals, and general receptivity to DTC advertisements, made perfect sense.<sup>28</sup>

One final aspect of the emergence of DTC advertising during this period bears mentioning. Although the constitutional concerns about prohibiting DTC advertising do not appear to have weighed heavily on the FDA during its deliberations before lifting the moratorium, it is possible that under existing First Amendment doctrine an outright prohibition would have been found unconstitutional. In 1980, the Supreme Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York* articulated a four-part test in determining whether a government regulation of commercial speech violates the First Amendment, looking first at whether the expression concerned lawful activity and was not misleading, second at whether the asserted governmental interest was substantial, third at whether the regulation directly advanced the asserted governmental interest, and fourth at whether the regulation was more extensive than was necessary to serve that interest.<sup>29</sup> The answer to these four questions, at least in the context of an outright prohibition on DTC advertising, would likely be in the affirmative, with the last one being dispositive. The governmental interest in protecting the public is undeniably substantial, but the Court would likely have concluded that

---

<sup>27</sup>See *id.* at 491 (noting that “any drug company marketer that suggested a program of communicating directly with consumers likely would be categorized as suicidal because there was a fear that doctors never would accept a program that bypassed them”).

<sup>28</sup>See Morris & Millstein, *supra* note 20; Morris et al., *supra* note 20

<sup>29</sup>447 U.S. 557, 566. See also William E. Holtz, *Consumer-Directed Prescription Drug Advertising: Effects on Public Health*, 13 J. L. & HEALTH 199 (1999) (arguing that stricter FDA regulation of DTC advertising would likely be upheld, but to attempt a ban on DTC advertising would be unwise).

there were less draconian means than an outright ban of ensuring that protection.<sup>30</sup> Given the reluctance of the Court to uphold categorical bans on advertising in other contexts around this time, it is unlikely that it would it would have reacted favorably to an FDA ban.<sup>31</sup>

## 2. *The Expansion: 1985 – 2002*

Despite its lifting of the moratorium, the FDA was hardly in the camp of DTC advertising proponents. Rather, the lifting merely represented the “reluctant recognition . . . of a new trend, and was intended to ensure that FDA had jurisdiction and that the industry had a framework within which to consider DTC advertising.”<sup>32</sup> While the pharmaceutical industry was given the go-ahead to market its products directly to consumers, it remained constrained by the cumbersome disclosure requirements of the rules promulgated under 21 U.S.C. § 352 (n).<sup>33</sup> As a result, print-advertisements, predictably, exploded; but product-specific commercial television advertisements remained unfeasible, as adequate disclosure of the “brief summary” made them prohibitively expensive.<sup>34</sup>

Companies immediately began to exploit other “categories” of advertisements that were exempted under the FDA regulations, including “help-seeking” ads – popularized by Upjohn, the manufacturer of Rogaine, in the mid-1980s with ads admonishing viewers with mail pattern baldness to see their doctor for treatment options

---

<sup>30</sup>See *In re R.M.J.*, 455 U.S. 191 (1982) (holding unconstitutional a range of restrictions on potentially misleading lawyer advertisements because the restrictions were not sufficiently narrowly drawn).

<sup>31</sup>Even in the health-related products context, the Court was speaking relatively often on this issue. See, e.g., *Va. Pharmacy Bd. v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976) (holding unconstitutional a ban on pharmaceutical price advertisements); *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60 (1983) (holding unconstitutional a federal statute prohibiting the mailing of unsolicited advertisements for contraceptives). See generally Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63 (1995) (describing issues surrounding labeling and advertising and First Amendment protections).

<sup>32</sup>Pines, *supra* note 7, at 493.

<sup>33</sup>21 C.F.R. § 202.1.

<sup>34</sup>Wilkes, Bell & Kravitz, *supra* note 16. With respect to the “brief summary” requirement, at the time that it lifted the moratorium the FDA made an exception for electronic advertisements, stipulating instead that it could be replaced with a “major statement” of the risks followed by “adequate provision” for dissemination of the labelling. See Pines, *supra* note 7. As interpreted by the FDA, however, the “adequate provision” requirement remained too onerous for pharmaceutical companies to engage in product-specific television advertisements. *Id.*

– and the truly bewildering “reminder” ads – which featured the name of the product superimposed (or voiced) over tangentially related imagery, but without explicit reference to the product’s medicinal function.<sup>35</sup> Typically, manufacturers would use these categories of unregulated television ads in conjunction with more specific print advertisement campaigns. The FDA was unsatisfied with the results of this regulatory regime, however. Not only were many of these television ads difficult to comprehend, but they became an increasing part of manufacturers’ marketing arsenals.<sup>36</sup> Once again, change was imminent.

In October 1995, the FDA’s Division of Drug Marketing, Advertising, and Communications held a public meeting on the state of DTC advertising within the regulatory structure promulgated under § 352 (n).<sup>37</sup>

In the wake of this meeting, and after considerable debate, the FDA produced a Draft Guidance that significantly relaxed the rules governing DTC advertisements in the context of television and radio media.<sup>38</sup>

Under 21 C.F.R. part 202.1(e)(1), manufacturers were permitted in lieu of the brief summary to make “adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation.”<sup>39</sup> The Guidance interpreted “adequate provision” to encompass the inclusion in the advertisement of (1) a toll-free phone number where further information could be obtained, or where a request that further information be mailed to the consumer can be made; (2) a reference to a concurrently running print advertisement with the statutorily required information; (3) a website where such information could be obtained; or (4) an indication that more information was available from a doctor or pharmacist.<sup>40</sup>

---

<sup>35</sup>Pines, *supra* note 7. 21 C.F.R. § 202.1(e)(2)(i) exempts reminder ads, “which call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product,” from the “brief summary” requirement. “Help-seeking” ads evade regulation altogether by referring only to particular symptoms, conditions, or diseases without mentioning any specific product or treatment. See Kelly N. Reeves, *Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population?*, 53 FOOD & DRUG L.J. 661, 667 (describing the various categories of advertisement available to pharmaceutical marketers).

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

<sup>37</sup>Transcripts of this meeting are available at <http://www.fda.gov/cder/ddmac/meetings.htm>.

<sup>38</sup>The Draft Guidance was finalized with little significant change in 1999. See Guidance for Industry, Consumer-Directed Broadcast Advertisements, Department of Health and Human Services, Food and Drug Administration, available at <http://www.fda.gov/cder/guidance/1804fn1.htm> [hereinafter DTC TV Guidance].

<sup>39</sup>21 C.F.R. § 201(e)(1). For a brief description of the origin of this exception for broadcast advertisements, see *supra* note 34.

<sup>40</sup>DTC TV Guidance, *supra* note 38.

Since the “major statement” requirement was left untouched by the Guidance, manufacturers would still be required to disclose major risks associated with the product in the broadcast portion of the advertisement, but the effective elimination of the “brief summary” requirement made product-specific advertisement a much more viable marketing alternative for pharmaceutical manufacturers.

Predictably, broadcast advertising immediately shot up, even at the expense of traditional print advertising outlets.<sup>41</sup> By 2000, DTC television advertising expenditures rocketed to \$1.574 billion from \$.220 billion in 1996.<sup>42</sup> On the other hand, DTC print and other forms of advertising experienced significantly slower, yet still substantial, increases, hitting \$.893 billion in 2000 from \$.571 billion in 1996.<sup>43</sup> Throughout this period, however, overall pharmaceutical promotional and marketing expenditures as a percentage of sales remained relatively constant, suggesting that rather than increasing marketing budgets the expansion of DTC advertising has had the effect of redirecting expenditures within those budgets.<sup>44</sup>

### *C. The Debate Over DTC Advertising in the United States*

#### *1. All opposed?*

The soaring advertising expenditures by pharmaceutical companies in recent years have not been for naught: obviously, DTC promotion works. According to some, however, it works too well. The increased advertis-

---

<sup>41</sup>From 1997 to 1998, industry expenditures on print and other forms of non-television advertisements declined by 14% (\$759 million to \$652 million), while expenditures on television advertisements more than doubled (\$310 million to \$664 million). Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donahue, Richard G. Frank, & Arnold M. Epstein, *Promotion of Prescription Drugs to Consumers*, 346 *NEW ENG. J. MED.* 498, 500 (2002). The data included in this *New England Journal of Medicine* study appear to be the most recent, so when at all possible I will refer to this study when necessary.

<sup>42</sup>*Id.*

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

<sup>44</sup>*Id.* Marketing and promotion expenditures were 14.1% of sales in 1996 and 14.0% of sales in 2000. Other forms of marketing include physician detailing and free samples, the latter of which comprises the bulk of an average companies marketing budget.

ing expenditures have not occurred within a vacuum; to an extent depending on whom one asks, they are recouped through higher retail prices.<sup>45</sup>

Criticism of the practice largely springs from the proposition that the primary goal of a for-profit pharmaceutical company is to maximize profits; even if this goal in many cases dovetails with that of promoting the public health, “when the two goals conflict profit must win.”<sup>46</sup> On the other hand, a doctor’s primary responsibility is as a fiduciary to her patient; secondary goals such as increased income or professional stature must defer to the fiduciary relationship in the event that they should conflict. Since all prescriptions must flow through a physician gatekeeper, criticism of DTC advertising from a public policy perspective must begin with the premise that the gatekeeper is somehow thwarted in an environment that permits DTC advertising; that DTC advertising somehow undermines the doctor-patient relationship. How does it accomplish this?

First, so it goes, the doctor-patient relationship is undermined by the undue pressure felt by physicians to prescribe the particular products requested by their patients, perhaps at the expense of what optimal treatment for a given condition would dictate.<sup>47</sup> This undue pressure may result from either a concern that the patient will resent her request being turned down, thereby undermining what would otherwise be an amicable and trusting relationship, or a concern that the patient will up and “shop” her request until she finds a doctor that *will* provide her with her desired prescription. Either alternative is unappealing: in

---

<sup>45</sup>This is unsurprising. The most recent and comprehensive studies to date on pharmaceutical pricing and DTC advertisements, as well as consumer responses to such advertisements, was conducted by the Henry J. Kaiser Family Foundation. See Henry J. Kaiser Family Foundation, *PRESCRIPTION DRUG TRENDS – A CHARTBOOK UPDATE* (2001) [hereinafter KFF, *CHARTBOOK UPDATE*]; Henry J. Kaiser Family Foundation, *UNDERSTANDING THE EFFECTS OF DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING* (2001) [hereinafter, KFF, *UNDERSTANDING THE EFFECTS*]. In the interests of consistency, I will quote data on these topics exclusively from these studies. However, the purpose of this essay is not to engage in an empirical evaluation of the merits of the arguments surrounding DTC advertising. Instead, I will be looking more at the normative claims for the purposes of analyzing the extent to which they similarly, hypothetically, apply in the European context.

<sup>46</sup>Jerome R. Hoffman & Michael Wilkes, *Direct to Consumer Advertising of Prescription Drugs: An Idea Whose Time Should Not Come*, 318 *BRIT. MED. J.* 1301, 1302 (1999).

<sup>47</sup>According to the Kaiser Family Foundation study, 30 percent of all participants asked their doctor about a prescription product that they had seen advertised. Of these 30 percent, 44 percent were prescribed the product they inquired about. KFF, *UNDERSTANDING THE EFFECTS*, *supra* note 45, at 3.

the one outcome, the relationship suffers even as the patient is treated optimally; in the other, the patient receives sub-optimal and overly expensive treatment elsewhere. The easy solution for the physician is simply to appease the “consumer” and send her on her way, script in tow.

In a similar vein, the doctor-patient relationship might be undermined by the unreliability of the advertisements themselves.<sup>48</sup> Physicians know from experience that pharmaceutical advertisements, despite being subject to strict FDA regulation, can nevertheless be misleading.<sup>49</sup> Where in a regime that forbids DTC advertisement, physicians can simply steer clear of anything they might be uncertain or skeptical about, “the duped gatekeepers may not adequately resist patients’ exhortations to write a prescription” in a regime that permits the pharmaceutical bombardment of their patients with advertisements.<sup>50</sup>

Alternatively, the doctor-patient relationship is undermined by the “hassle” factor – the physician being forced to devote valuable time of every visit to discussing treatments that may be wildly inappropriate for the patient, reducing the time available to discuss more constructive or relevant issues concerning the patient’s health.<sup>51</sup> The physician must spend time “reeducating” the patient, or disabusing her of the misleading idea, perhaps perpetuated by DTC advertising, that there is a “pill for every ill.”<sup>52</sup>

A second line of criticism admits the possibility that DTC advertising, if well-regulated, can provide the benefits its proponents frequently invoke, but that FDA’s enforcement procedures lack the teeth to deter would-be violators.<sup>53</sup> Notably, FDA does not require pre-clearance of pharmaceutical advertisements;<sup>54</sup>

---

<sup>48</sup>See Wilkes, Bell, & Kravitz, *supra* note 16

<sup>49</sup>Sidney M. Wolfe, *Direct-to-Consumer Advertising: Education or Emotion Promotion?*, 346 NEW ENG. J. MED. 524 (2002)

<sup>50</sup>*Id.* at 526 (2002).

<sup>51</sup>Wilkes, Bell, & Kravitz, *supra* note 16; see generally American Society of Internal Medicine, *The Hassle Factor: America’s Health Care System: Strangling in Red Tape*, INTERNIST, Sept. 1990, 4 – 31.

<sup>52</sup>*Id.*; see also Bette-Jane Crigger, *Ask Your Doctor or Pharmacist*, HASTINGS CENTER REP., Mar.-Apr. 1998, at 47 (stating that prescription drug advertisements are simplistic and misleading, nurturing unrealistic expectations of benefit that physicians will not be able to counter effectively, and that this tension adds to the already fraying doctor-patient relationship when patients demand the medications they have seen advertised).

<sup>53</sup>See Milind Kale, Lee W. Schwendig, Vaughn Culbertson, Paul S. Cady, William Sharp, & Barbara Adamcik, *Monitoring the Regulatory Processes of Prescription Drug Advertising*, 5 J. PHARMACY & L. 229 (1996).

<sup>54</sup>21 U.S.C. § 352 (n) (“except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement”).

instead, it enforces its regulations through “notice of violation” letters – letters that, when issued, are largely complied with.<sup>55</sup> However, resource constraints may prevent FDA from evaluating promotional materials and sending “notice of violation” letters when necessary the “vast majority” of the instances such letters are called for.<sup>56</sup>

Finally, a third line of criticism centers on the increased costs of DTC advertising, resulting in higher prescription drug prices.<sup>57</sup> On the one hand, the issue of cost is difficult to disentangle from that of the hamstrung doctor-patient relationship; higher costs, per se, are not socially sub-optimal, so long as doctors aren’t inappropriately prescribing the medications about which their patients are inquiring. Rather, “[t]he proper use of prescription drugs is often the most effective and least expensive form of health care,”<sup>58</sup> which proper use is encouraged by DTC advertisements that prompt patients to seek treatment for problems to which they wouldn’t otherwise be alerted. Not surprisingly, insurance companies and health maintenance organizations lead the charge on this line of criticism,<sup>59</sup> as any increase in pharmaceutical company profits derived from DTC advertisement is likely to come at the expense of insurance companies’ bottom lines.<sup>60</sup> Nevertheless, to the extent that physicians are inappropriately over-prescribing medications due to inordinate pressures wrought by DTC advertisements, cost is an issue.<sup>61</sup>

On the other hand, the issue of cost is most easily identifiable with reference to the particular prices of

---

<sup>55</sup>Information gleaned from the esteemed Professor Peter B. Hutt in a January 2002 class on Food and Drug Law at Harvard Law School.

<sup>56</sup>See Kale et al., *supra* note 53, at 240 (quoting Arthur Yellin of the FDA’s Division of Drug Advertising, in FDA’s Drug Promotion Problems, 1389 SCRIP 14 (1989)).

<sup>57</sup>According to the Kaiser Family Foundation survey, prescription drug expenditures have increased relative to other health care-related expenditures in recent years. Since 1995, annual prescription drug expenditures have increased from the previous year at rates ranging from 10.5% to 17.4%, with the three single-biggest yearly increases (13.4%, 16.9%, 17.4%) occurring in the three most recent years of the study, which happen also to be the first three years of the relaxed regulation of DTC television advertisements. KFF, A CHARTBOOK UPDATE, *supra* note 45, at 19. Correspondingly, prescription drug expenditures have risen to 10% of total health care spending in 2000, from 6% in 1995 (vis-à-vis expenditures on physician services and hospital care). *Id.*

<sup>58</sup>Alan F. Holmer, *Direct-to-Consumer Advertising: Strengthening our Health Care System*, 346 N. ENG. J. MED. 526, 527 (2002).

<sup>59</sup>See, e.g., National Institute of Health Care Management Research and Educational Foundation, *Prescription Drugs and Mass Media Advertising, 2000*, (2000) available at <http://www.nihcm.org>;

<sup>60</sup>See Pines, *supra* note 7, at 511.

<sup>61</sup>In this case, not only is cost an issue with respect to over-spending on health care, but the cost of adverse events (i.e. pharmaceutical side effects) resulting from this delivery of excessive care must be factored in.

heavily advertised drugs.<sup>62</sup> Heavy advertisement promotes loyalty to expensive brand-name drugs, at the expense of cheaper, equally effective generic products. This, in turn, stimulates greater demand for the brand name drugs and drives their prices up even further.

## 2. *All in favor?*

Those leading the charge in favor of DTC advertising, from the outset, have been the pharmaceutical companies.<sup>63</sup> What are the specific benefits trumpeted by proponents of DTC advertising?

First, DTC advertisements provide consumers with a valuable source of information about treatments they might not know existed, or health problems they might not know they had. That millions of Americans go about their daily lives unaware of a medical problem for which treatment might involve the use of a prescription drug is uncontroverted.<sup>64</sup> The majority of DTC promotion is concentrated within three distinct therapeutic classes that are particularly susceptible to this phenomenon: conditions with easily recognizable symptoms that might not otherwise, by themselves, prompt the consumer to seek treatment (such as arthritis, seasonal allergies, and obesity); chronic conditions that are often under-diagnosed (such as high cholesterol, osteoporosis, and depression); and conditions that simply affect the quality of life (such as skin problems, hair loss, or erectile dysfunction).<sup>65</sup> To the extent that DTC advertisements motivate affected consumers who might not have otherwise done so to seek treatment, they achieve the dual purpose of promoting public health and enhancing product sales. The data suggest that something along these lines is, in fact, taking

---

<sup>62</sup>Average retail price of brand name drugs has increased at a greater rate than that of generic drugs since 1990. KFF, CHARTBOOK UPDATE, *supra* note 45, at 27.

<sup>63</sup>*See, e.g.*, Pharmaceuticals Research and Manufacturers Association of America, *Backgrounders and Facts: Direct to Consumer Spending* (2000), available at <http://www.phrma.org/publications/documents/backgrounders//2000-11-05.189.phtml>; Seaver, *supra* note 1; Robert A. Ingram, *Some Comments on Prescription Drug Advertising*, in PROMOTION OF PHARMACEUTICALS: ISSUES, TRENDS, OPTIONS, *supra* note 1.

<sup>64</sup>Indeed, the American Diabetes Association estimates that of the 16 million estimated Americans with diabetes, 5.4 million do not know it. *Recent Developments which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. 57 (prepared statement of Gregory J. Glover, for the Pharmaceuticals Research and Manufacturers of America) [Hereinafter Glover statement]. Additionally, “one-third of the people with major depression do not seek treatment and millions of Americans are unaware that they have high blood pressure.” *Id.*

<sup>65</sup>Holmer, *supra* note 58, at 527.

place: A recent study by the Henry J. Kaiser Foundation found that some 30% of Americans have consulted their physician about a prescription medication that they had seen advertised, of whom 44% were prescribed the specific product they requested.<sup>66</sup> Even with respect to quality of life requests, the ancillary benefits of DTC advertising appear to be significant: for every million men that have consulted their physician about erectile dysfunction, an estimated 30,000 had untreated diabetes, 150,000 had untreated high blood pressure, and 50,000 had untreated heart disease.<sup>67</sup>

Second, the emergence and expansion of DTC advertising is “consistent with the whole trend toward consumer empowerment” and greater patient involvement in health care decisions.<sup>68</sup> Indeed, in this respect it is not intended to undermine, but rather to enhance, the doctor-patient relationship by “prompt[ing] a discussion that may lead to better understanding and treatment of the patient’s condition.”<sup>69</sup> Meanwhile, the critical focus on DTC advertisement by physicians has obscured the fact that the primary promotional targets of pharmaceutical companies remain prescribing physicians - only 15% of pharmaceutical marketing budgets are devoted to DTC promotions.<sup>70</sup> Instead, “[t]he continued importance of promotion to health care professionals reinforces the conventional wisdom that physicians are unlikely to prescribe a drug unless they are familiar with it and are comfortable prescribing it.”<sup>71</sup>

Third, DTC advertising presents an informational counterweight to the “numerous financial factors that already influence the delivery of medical care.”<sup>72</sup> To wit, there are payment incentives imposed from above

---

<sup>66</sup>KFF, UNDERSTANDING THE EFFECTS, *supra* note 45. Other doctor recommendations in response to the request were: recommend behavioral or lifestyle change (35%); recommend a different prescription drug (25%); recommend no drug (19%); recommend an over-the-counter drug (15%); something else (14%). *Id.*

<sup>67</sup>Glover statement, *supra* note 64, at 57.

<sup>68</sup>*See* Holmer, *supra* note 58, at 527 (quoting Dr. Nancy Ostrove, Deputy Director of the FDA Center for Drug Evaluation and Research’s Division of Marketing, Advertising, and Communications).

<sup>69</sup>Glover statement, *supra* note 64, at 58.

<sup>70</sup>Rosenthal et al., *supra* note 41, at 498.

<sup>71</sup>*Id.* In other words, “[i]t may thus be accurate to characterize direct-to-consumer advertising as a marketing strategy that complements rather than displaces promotional efforts targeted at professionals. . . .” *Id.*

<sup>72</sup>*See* Holmer, *supra* note 58, at 527-28.

that influence the prescription-practices of physicians, formularies that are based in part on financial considerations, and cost-sharing arrangements with patients for certain types of medications.<sup>73</sup> Additionally, HMOs and insurers have begun lobbying the FDA to shift certain drugs from prescription to over-the-counter status,<sup>74</sup> and pleading with patients and doctors already administering a particular therapy to switch to a generic substitute, if available.<sup>75</sup> No less than DTC advertising, all of these are strategies designed to influence prescription decisions; DTC advertising “is a healthy development that helps balance the system.”<sup>76</sup>

### III. THE CASE OF EUROPE: WHITHER DTC ADVERTISING?

Having sketched both the history and debate of DTC advertising in the United States, this essay turns now to the question that launched its quest: will Europe soon follow the United States’ lead in permitting DTC advertising? For virtually impenetrable philosophical and structural reasons, I will argue that it simply cannot.<sup>77</sup> Barring a sea change in how Europeans’ approach the idea and administration of health care, DTC advertising will remain a feature of American exceptionalism.

#### *A. Structural Impediments to DTC Advertising in Europe*

---

<sup>73</sup>Id.

<sup>74</sup>See Laura B. Benko, *Ugly Wait at the Counter: Insurer Pushes to Make Allergy Drugs non-Prescription*, MOD. HEALTH-CARE, Aug. 6, 2001 (documenting Wellpoint Health Networks’ attempt to make Claritin, Allegra, and Zyrtec available over-the-counter).

<sup>75</sup>See Ron Winslow & Barbara Martinez, *Message Filters Through: Switch to Generic Prozac: Pharmacy-Benefit Managers Strive to Cut Costs*, ASIAN WALL ST. J., Aug. 21, 2001, at 8.

<sup>76</sup>Holmer, *supra* note 58, at 528.

<sup>77</sup>As I will show below, these structural and philosophical reasons are very much related.

The most important structural impediment to the emergence of full-blown DTC advertising in Europe is the degree to which member state governments control (rather than simply regulate) nearly every step of the health care delivery process. “Typically the final consumer does not pay for the product,... the producer is not free to fix his product price, and... government is simultaneously the principal paying agent and price controller.”<sup>78</sup> The effect that this has on the disposition of an institution, the EMEA, comprised of member states whose national health services are already strapped for cash and crippling under the weight of pharmaceutical expenditures, and whose populations continue to age at staggering rates, towards DTC advertising is, to say the least, considerable.

As a function of their greater administration of health care delivery, European governments (to varying degrees) control the prices of pharmaceuticals sold within their borders.<sup>79</sup> Nevertheless, per capita pharmaceutical expenditures in some countries exceed those in the nominally free U.S. market, suggesting that artificially depressed prices stimulate considerable excess demand.<sup>80</sup> Even assuming that the introduction of DTC advertising will have only the salutary effects of prompting the under-treated elements of society to seek treatment (ignoring for the moment attendant concerns of over-treatment), the volume shock will likely be too great for some of the more precariously situated national health administrations to bear without engaging in politically difficult price restructurings. To be sure, such price restructuring occurs in the United States, but the primary difference is that the third party payers doing the restructuring are insurance companies and HMOs rather than national governments. Insurance companies and HMOs do not possess the regulatory

---

<sup>78</sup>Louis H. Orzack, Kenneth I. Kaitin, & Louis Lasagna, *Pharmaceutical Regulation in the European Community: Barriers to Single Market Integration*, 17 J. HEALTH POL., POL'Y & L. 847, 849 (quoting Paolo Cecchini, *THE EUROPEAN CHALLENGE*, 1992: THE BENEFITS OF A SINGLE MARKET 66 (1988)).

<sup>79</sup>France and Italy regulate prices directly; Germany, the Netherlands, and Denmark reimburse patients according to a “reference price system,” whereby prices for specific pharmaceuticals are set according to the prevailing rates in other countries; and the U.K. regulates prices to the extent that they yield no more than a target overall profit. Stewart O. Schweitzer, *PHARMACEUTICAL ECONOMICS AND POLICY* 148 (1997).

<sup>80</sup>France, for instance, has some of the cheapest drug prices in the developed worlds, but its pharmaceutical expenditures as a percentage of total health care expenditures (16%) were double those of the United States (before 1997). *Id.*

authority to prohibit DTC advertising themselves, even though they would like to. European governments, on the other hand, do. Faced with the prospect of unleashing DTC advertising and its salutary effects of drawing more patients under the state-administered health care umbrella, the member state governments and their cash-strapped national health services will be under considerable pressure to uncover reasons for why DTC advertising might be detrimental to the public good. Given the liveliness of the debate on the issue within the United States, such reasons would not be hard to find. Therefore, national governments will have strong administrative incentives to prevent DTC advertising from ever reaching levels currently seen in the United States.<sup>81</sup>

A second structural reason for why DTC advertising will likely not emerge in the EU is the extent to which the prohibition will not be subject to legal challenge under most European systems. As intimated earlier, it is likely that an outright ban on DTC advertising would run afoul of First Amendment protections in the United States.<sup>82</sup> Indeed, although the issue of constitutional protection was not explicitly mentioned by FDA in its lifting of the moratorium, the lengths to which it went to specify that it would not require that proposed advertisements be submitted for pre-clearance smacked of a constitutional tail-covering.<sup>83</sup> On the other hand, commercial speech does not appear to be accorded the same sorts of privileges in Europe. In Germany, for instance, Article 5 of the Constitution contains no express protection of commercial speech, and has in fact been interpreted not to protect such speech.<sup>84</sup>

---

<sup>81</sup>One sees the logic, through this analysis, of pharmaceutical company opposition to the expansion of Medicare to cover prescription drugs. Were the United States government to become more directly involve as a third payer, it might be prompted to rethink certain regulatory policies that have allowed costs – for better or for worse – to spiral in recent years.

<sup>82</sup>See Wolfe, *supra* note 49, at 526 (acknowledging the likelihood of a constitutional violation in the event of a ban on DTC advertising).

<sup>83</sup>See 21 C.F.R. § 202.1.

<sup>84</sup>See Edward J. Eberle, *Public Discourse in Germany*, 47 CASE W. RES. L. REV. 797, 806, n. 32 (1997).

*B. Philosophical Impediments to DTC Advertising in Europe*

Even, however, were structural concerns not as big of an impediment as they are, there remain strong philosophical differences between Europe and the United States in how health care is viewed that might prevent the emergence of DTC advertising. In particular, the doctor-patient relationship remains grounded in a paternalistic conception of delivery of care; doctor still knows best in Europe – an aspect of culture that has much to do with philosophy as it does with structure.

First, the idea of patient autonomy, and the related doctrine of informed consent, have not developed in Europe to the extent that they have in the United States. Where courts in this country began to shift from applying professional to more individualized standards of disclosure in due care cases in the 1960s and 1970s,<sup>85</sup> courts in Britain have “found against the ‘American rule’... [and have] declared the physician to have given proper information and to have obtained informed consent according to professional standards.”<sup>86</sup> In the context of foregoing life-sustaining therapy, one recent study has shown that recommendations for making and implementing treatment decisions, developed in the United States, that emphasize patients’ wishes over a uniform standard of care, are routinely not observed in France.<sup>87</sup> Instead, “decisions to forgo life-sustaining therapy... were driven primarily by an evaluation of objective medical data... The wishes of the patients or families... were rarely evaluated.”<sup>88</sup> In short, clinicians know best in France, as they do

---

<sup>85</sup>See *Canterbury*, 464 F.2d at 781.

<sup>86</sup>Abrams, *supra* note 24, at 1784.

<sup>87</sup>See Frederic Pochard et al., *French Intensivists Do Not Apply American Recommendations Regarding Decisions to Forgo Life-Sustaining Therapy*, 29 CRITICAL CARE MED. 1887 (2001).

<sup>88</sup>*Id.* at 1890.

in Great Britain. The culture of active patient involvement in her health care decisions has simply not developed to the extent that it has in the United States. To the extent that patient demand for greater participation in health care decisions made the emergence and expansion of DTC advertising in the United States possible,<sup>89</sup> it is unlikely that European regulators will make the structurally difficult decision to relax the community-wide prohibition on DTC advertising in the absence of such strong consumer demand.

It is important, too, to note the structural underpinnings of the philosophical preference exhibited by European societies for a managerial, professionalist model of health care administration. Doctrines like informed consent and others emphasizing patient autonomy in medical decisions are effectively prevented from fully emerging by European health care systems' economic limitations.<sup>90</sup> Routinely, potential dialysis patients in the United Kingdom are being turned away without understanding that they could have been treated but for the economic constraints on the health system.<sup>91</sup> Contrast this with the environment in the United States in which DTC advertising emerged: "In the U.S. . . . efficiency was not at first a concern. Physicians just became dispensers of relatively unlimited medical services, subsidized uncritically by health insurers."<sup>92</sup> While the emergence of managed care and greater insurance company involvement in treatment decisions has altered this scenario significantly,<sup>93</sup> one important difference between the European and American cost-controlling mechanisms is that, in Europe, the holder of the purse strings also holds the keys to regulatory vault. If, in this country, insurers controlled health regulation, one could be sure that DTC advertising would play less of a role in society than it does today.

In sum, the "doctor knows best" approach to patient involvement in health care decisions has remained a

---

<sup>89</sup> See *supra* Part II.A.1. Surveys continue to show that patients are generally pleased with DTC advertising (and appropriately skeptical of its objectivity). See, e.g., Ingram, *supra* note 63, at 70 (citing a study that found that over 70% of consumers "believed that direct-to-consumer ads are an important and valuable educational tool").

<sup>90</sup> See, e.g., R. Schwartz & A. Grubb, *Why Britain Can't Afford Informed Consent*, 15 HASTINGS CENTER REP. 19 – 25 (1985).

<sup>91</sup> Abrams, *supra* note 24, at 1784.

<sup>92</sup> Robert G. Lee and Frances H. Miller, *The Doctor's Changing Role in Allocating U.S. and British Medical Services*, 18 L. MED. & HEALTHCARE 69 (1990).

<sup>93</sup> *Id.*

mainstay of European health care administration for both philosophical and structural reasons. Not only do Europeans, generally, “decry what appears to them to be self-centered individualism pursued to the detriment of the whole society [in the United States],”<sup>94</sup> but doctors in particular have been conditioned by their employers – their governments – to make specific care decisions with the greater public good, rather than the patient’s individual preferences, at heart. Where third-party payers in the United States engage in the same sorts of tactics, they don’t, as in Europe, simultaneously control the regulatory structures that govern the administration of medical care. To be sure, I am not suggesting that nationalized health care systems are inherently unethical; rather, it is my contention that when an issue as murky as DTC advertising is introduced for debate, the fact that the decision-makers will also bear the brunt of the decision’s consequences inescapably factors into the decision-making process. In such instances, where strong arguments can be invoked to preserve the status quo, it is likely that that status quo will, in fact, be preserved. The absence of the specter of a strong legal challenge to the ensuing course of action – for instance, along constitutional free speech grounds in the United States – only serves to cement the likely policy outcome.

### *C. The EC Proposal of July 2001*

What to make, then, of the recently introduced EC Proposal?<sup>95</sup> If not a sign of things to come, then what? The proposal should be interpreted as nothing more than a pragmatic response to the emergence of the internet as a tool of health care education. According to Per Haugaard, Spokesman for the European

---

<sup>94</sup>Abrams, *supra* note 24, at 1784.

<sup>95</sup>EC Proposal, *supra* note 2.

Commisison, “The thinking is that we have a total ban on such advertising in Europe, but we also have the Internet, where people can download information from non European websites, some of which may be inappropriate. . . . It is also unsatisfactory that the information should be available to some people and not to others. So we are facing up to this situation and want to improve the flow of information to patients.”<sup>96</sup>

The Proposal itself is limited in a number of important respects. First and foremost, it does not permit blanket DTC advertising, but rather permits only “dissemination of information relating to certain medical products. . . in order to respond to the expectations of patients’ groups.”<sup>97</sup> The British Government’s understanding of this proposed provision is that it would permit pharmaceutical companies to provide information upon patient request, and is consistent with the fashioning of the proposal as a response to the fact that much information is available on-line in any event.<sup>98</sup> The restriction of information dissemination to active requests by interested patients is hardly the sort of watershed erosion in European DTC regulation that would signal the eventual dismantling of the prohibition.

Second, the EC Proposal is limited with respect to the conditions to which it applies. Rather than allow pharmaceutical companies to distribute promotional materials regarding requests centering on any product, the Proposal limits its scope to products for the treatment of AIDS, asthma, and diabetes. The three were chosen because the populations involved were “known and easily identifiable,”<sup>99</sup> giving further indication that the Proposal’s authors were concerned about making pharmaceutical promotional material widely available.

By restricting access to patients that are known and easily identifiable, compliance with, and enforcement

---

<sup>96</sup>Crompton, *supra* note 4; see also *Is Online Drug Marketing Ready for Takeoff in Europe?*, DATAMONITOR, Jan. 1, 2002, available at <http://www.inpharm.com/intelligence/datamonitor010102.html> (“It’s looking like the EC would rather relax its rules over patient-company interaction than risk greater numbers of patients using sites beyond its control.”).

<sup>97</sup>Proposed Art. 88, EC Proposal, *supra* note 2, at 109.

<sup>98</sup>This is seen by many European groups as far more palatable than blanket DTC advertisement: “The Internet is a very special type of DTC that requires an active search for information on a particular medicine or disease – whereas DTC in the guise of print or television advertisements is barely more than passive brand awareness to generate demand.” Richard Sullivan, *Direct-to-Consumer Advertising: The Future in Europe*, 93 J. ROYAL SOC’Y MED. 400, 401 (2000).

<sup>99</sup>*Additional Highlights from the European Drug Proposals*, *supra* note 2.

of, the regulations becomes is much more manageable. The proposal envisions the creation of a database of patients with one of the three specified conditions for whom such information would be available.<sup>100</sup>

In light of the structural and philosophical impediments to the emergence of full-scale DTC advertisement in Europe, it is clear that the recent EC Proposal on relaxing the community-wide prohibition on DTC advertising, is not the harbinger of things to come. The European prohibition on DTC advertisements is likely to remain largely intact.

#### IV. DTC ADVERTISING IN EUROPE: UNLIKELY AND UNFORTUNATELY SO

I have argued that the prohibition on DTC advertising in Europe is under no threat of being dismantled, even with the recent proposal to relax the prohibition on the dissemination of promotional materials to patients with three particular conditions. Interestingly, however, aspects of Europe's philosophical distinctness from the United States, while certainly impeding the emergence of DTC advertising there, would make it in some respects a more ideal environment for its emergence than that of the United States, from a public health perspective. In particular, the individualism and inclination to question authority exhibited by the American patient can have detrimental effects on the net result of DTC advertising, to the extent that concerns about the undermining of the doctor-patient relationship wrought by DTC advertising are valid.

To demonstrate how this is so, I revisit the arguments against DTC advertising introduced in Part II.C.1 above. An overly individualistic consumer might be inclined to question more readily her physician's refusal to prescribe the consumer's desired medication, until either the physician relents and writes the prescription or the consumer finds a doctor who will prescribe her the medication. Writ large, such over-medication can

---

<sup>100</sup>Id.

lead to artificially higher pharmaceutical costs, as well as the costs associated with unnecessary side effects and other adverse events. I would hypothesize, however, that Europeans, generally more deferential in the health care context, conditioned to believe that “doctor knows best,” would be far less likely to engage in such behavior, and, as a result, in a far better position to reap the unmistakable benefits of DTC without some of its attendant costs. Data culled in a comparison of American and Dutch attitudes towards health care at least tangentially suggests that such a hypothesis is not so far-fetched.<sup>101</sup> In the study, participants were given a series of statements involving “dimensions” of care,<sup>102</sup> and were asked to assess them with number values based on their perceived importance to the quality of care. The most significant variance between the two groups was in the relative importance placed on the “continuity” and “empathy” dimensions. While in both groups “effectiveness” ranked first, the Americans placed a greater premium on “empathy” than the others (with “continuity” ranking sixth out of nine), while the Dutch ranked “continuity” ahead of the others (with “empathy” ranking sixth out of nine).<sup>103</sup> This illustrates the hypothesis that Dutch patients (hypothetically) prompted by DTC advertising to inquire with their doctors about a treatment might be less willing than their American counterparts to forfeit the “continuity” they value so highly and seek an alternative opinion in the event that they are rebuffed; whereas American patients who are rebuffed by their physicians after requesting a DTC-promoted product, stung by what they perceive to be a lack of empathy shared by their physician, will be *more* likely than their Dutch counterparts to “physician shop.”

In this (albeit elementary) scenario, Dutch society is potentially better off than American society with the presence of DTC advertising by virtue of its retention of the culture of deference and professionalism –

---

<sup>101</sup> See Jacob Jay Lindenthal, Christiaan J. Lako, Marieke A. E. van der Waal, Tjerd Tymstra, Margriet Andela, & Mareleyn Schneider, *Quality and Cost of Healthcare: A Cross-National Comparison of American and Dutch Attitudes*, 5 AM. J. MANAGED CARE 173 (1999).

<sup>102</sup> Dimensions included knowledge, empathy, information, physician-patient relationship, effectiveness, efficiency, continuity, waiting time for treatment, and autonomy. Id. at 176.

<sup>103</sup> Id.

cultural traits that, to a much greater extent, have been abandoned in the United States. Furthermore, while the individualism that made DTC advertising in the United States possible are likely not present to similar degrees in Europe, the fact of the United States' "first move" in this area may be enough to sufficiently lower its philosophical "barriers to entry." DTC advertising, once established, becomes easier to export, so the thinking goes. Nevertheless, I have argued that, in Europe, the prevailing structure and philosophy of health care administration will prevent any full-fledged removal of the prohibition on DTC advertising. The recent EC proposal, rather than signal the dawning of a new era of EU policy on DTC advertising, merely reflects a pragmatic approach to an unalterable reality.