Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs

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In August 1997, the Food and Drug Administration (FDA) announced a reinterpretation of its rules on direct-to-consumer (DTC) advertising, the effect of which was to permit branded broadcast advertisements and therefore to increase the volume of DTC advertising several-fold. A substantial body of research, consisting primarily of consumer surveys, provides the basis for a preliminary assessment of the effects of DTC advertisements. The FDA’s own assessment, that DTC advertisements can provide substantial benefits and do not appear to cause substantial harm, is consistent with survey and other data. Direct-to-consumer advertisements appear to provide valuable information (including risk information); induce information-seeking (mainly from physicians); prompt patients to discuss conditions not previously discussed; and generate significant, positive externalities including the possibility of improved patient compliance with drug therapy. The effects of DTC advertisements on drug consumption and on health care have yet to be assessed. The author suggests that a further relaxation of FDA rules would accelerate the dissemination of valuable information, with favorable consequences for drug development and consumer health.

The 1962 amendments to the Food, Drug, and Cosmetic Act, which charged the Food and Drug Administration (FDA) with regulating pharmaceutical effectiveness in addition to regulating safety, also transferred responsibility for prescription drug advertising from the Federal Trade Commission (FTC) (which still regulates advertising for over-the-counter [OTC] drugs) to the FDA. In the early 1980s, a few pharmaceutical manufacturers experimented with prescription drug advertisements directed at consumers. In September 1982, having previously announced that direct-to-consumer (DTC) advertising was not inherently in violation of FDA law and regulations, the FDA declared a “moratorium” on DTC advertising, with which the industry complied.

In 1985, the FDA lifted its moratorium but emphasized that DTC advertisements must meet the same standards as those aimed at professionals. Print advertisements were required to include a detailed “brief summary” of risk and other information. Broadcast advertisements required a much shorter but nonetheless lengthy “major statement” of risks, while also making “adequate provision” for viewers to obtain full FDA-approved prescribing information. Because meeting the broadcast requirements was impractical, advertisers were forced to take one of two approaches. “Reminder” advertisements could discuss that a treatment existed for a condition, but they could neither mention a drug by name nor make suggestions and representations about drug treatments. “Reminder” advertisements could emphasize drug brands but could not mention what conditions the drugs could treat. Under these constraints, DTC advertising gradually increased from $12 million in 1989 to $55 million in 1991, $164 million in 1993, $340 million in 1995, and $579 million in 1996 (Pines 1999).

In August 1997, the FDA (1997) issued a preliminary “Guidance for Industry” that reinterpreted FDA regulations without actually changing any regulations. Reiterating traditional requirements, the Guidance stated that in addition to being nondeceptive, prescription drug advertising must

1. Present a fair balance between information about effectiveness and information about risk,
2. Include a “major statement” conveying all of the product’s most important risk information in consumer-friendly language, and
3. Communicate all information relevant to the product’s indication (including limitations to use) in consumer-friendly language.

The new interpretation made clear, however, that the “major statement” in radio and television advertisements could be far simpler than what had previously been required. Adequate provision of required information could be achieved by including a concise summary of risks and related information (often through voice-over), while identi-
fying sources for more complete information: a toll-free number; an Internet Web site address; either concurrent print advertisements or information about specific, publicly accessible locations such as pharmacies; and a statement that information is available from all physicians and pharmacists. The FDA stated that it would review its policy after two years and invited interested parties to provide information and research on the effects of DTC advertisements.

In 1999, the FDA commissioned a consumer survey on DTC advertisements. In August 1999, with preliminary survey results in hand, the FDA (1999a, b) issued a final Guidance on DTC advertising. The requirements remained essentially unchanged from August 1997. The FDA also stated that it had not seen compelling evidence that DTC advertising had tended to cause any of the harms of which it had been accused. Reiterating its 1997 plan, the FDA (1999b) planned to evaluate the effects of DTC advertising during the next two years. In March 2001, the FDA announced plans for another consumer survey and a survey of physicians. It invited comments on survey design and on the effects of DTC advertising (FDA 2001a). Partial results from the consumer survey (the results of which have not been completely released) are discussed subsequently. The physician survey has progressed more slowly because of low response rates.

In the wake of the August 1997 policy change, DTC advertising continued to accelerate, reaching $1.3 billion in 1998, $1.9 billion in 1999, $2.5 billion in 2000, and $2.7 billion in 2001 (for years 1998–2000, see Peterson 2002; for year 2001, see IMS Health 2002). A pharmaceutical firm (Pfizer) was Advertising Age Magazine’s choice as 2001 marketer of the year, and was the ninth-largest advertiser during the first three quarters of 2001 (Goetzel 2001).

These events have been accompanied by vigorous debate on the effects of DTC advertisements. However, before considering that debate, it will be useful to review the context in which DTC advertising occurs.

The Market Context of DTC Advertising

Direct-to-consumer advertising of prescription drugs differs from almost all other advertising in two respects. The first is the requirement for consumers to obtain a physician’s prescription before purchase, a requirement that (significantly for an understanding of FDA regulation) was not originally dictated by legislation. This requirement has several effects. It alters consumer costs, in partially offsetting ways. The necessity of visiting or communicating with a physician increases costs in terms of time, inconvenience, and out-of-pocket expenditures for a visit. Marginal costs are minimal, however, when a prescription is obtained in an appointment that would have occurred anyway (as is almost always the case according to surveys). Out-of-pocket drug expenditures, in contrast, are reduced because health insurance typically covers most of the cost of prescription drugs (but not OTC drugs): The proportion of out-patient prescription drug costs paid by third parties has increased from 31% to 68% between 1980 and 2000 (Berndt 2001; U.S. Department of Health & Human Services [USDHHS] 2002a). The prescription requirement also insures (with few exceptions) that the buyer receives the benefit of a physician’s expert knowledge of the product, often with the addition of explicit information on product risks and benefits. Finally, the prescription requirement delays the effects of advertising. In some cases, the delay can be substantial. An example is advertising for the statin class of cholesterol-reducing drugs, a drug category in which a prescription (if any) is typically written only after laboratory testing followed by an attempt at lifestyle changes.

A second unique aspect of DTC advertising is its regulatory environment. The FDA regulation of prescription drug advertising is exceptionally stringent. The FDA staff members do not always review advertisements before publication (but they often accede to manufacturers’ requests to do so), but the most important advertising claims are essentially subject to preclearance, because FDA regulations prohibit therapeutic claims that have not been approved for listing in drug labeling. That labeling is usually extremely detailed, specifying such matters as the precise illness or condition to be treated (e.g., certain outdoor allergies but not indoor allergies), dosage, and even relationships with other or prior therapy. Therefore, the bulk of FDA advertising regulation has traditionally consisted of comparing ad claims to label contents (Fisherow 1987; Kessler and Pines 1990). The FDA also routinely challenges implied claims, and it systematically reviews advertising materials when voluntarily submitted either before or after they become public (Adams 2002; Ostrove 2001).

Perhaps the most important aspect of FDA advertising regulation is that it is essentially never challenged in court by pharmaceutical firms, which (often after negotiation with FDA staff) invariably accede to FDA demands to modify or drop challenged claims and advertisements. As Fisherow (1987, p. 230), a member of the FDA advertising regulation staff, notes, “This capacity to resolve difficulties to its satisfaction before they reach the courts has delivered what FDA wants most, the prompt cessation or transformation of a questioned advertising claim or campaign, with a relatively modest expenditure of resources.” This extraordinary level of cooperation arises because manufacturers know that in addition to regulating their advertising, the FDA approves all of their new products, manufacturing methods and facilities, and other essential operations including clinical trials. Therefore, firms believe it is to their great interest to maintain amicable relations with the FDA staff (Calfee 1996; 2On the obscure origins of the prescription requirement, see Temin (1979) and Marks (1995).

3A contrast with medical device marketing is worth noting. Direct-to-consumer advertising for devices is regulated by the FTC, not the FDA, and typically includes far less risk information. Most devices also require a physician’s prescription, but that requirement is often subordinate to the simple fact that a physician’s oversight is necessary to administer treatment using the device.

4The FTC and FDA actually share responsibility for prescription drug DTC advertising, but the more expansive FTC approach to advertising regulation ensures that FDA regulations are usually the constraining ones. The FDA does not have responsibility for regulating medical device advertising, even for such sophisticated devices as magnetic resonance imaging, in which a physician’s intervention is required. The FTC regulates device advertising, albeit with obvious deference to the views of the FDA.
Hutt 1993). These forces are clearly described by Fisherow (1987, pp. 231–32):

One may speculate about why the Agency has been so successful. It may be that it is always correct in its analysis and persuasive enough in its communication to deter an advertiser from continuing to disseminate a questioned message. The more likely case is that the Agency is not always right, but that it succeeds anyway because of the nature of its relationship with pharmaceutical advertisers.

The author continues (pp. 231–32), comparing this situation with that surrounding FTC regulation,

[The FDA licenses the prescription drug products subject to its regulation and approves labeling which effectively sets the limits on what may be communicated about product performance. This pervasive involvement in the industry’s current and future business means that a corporate decisionmaker needs to consider more than just the merits of the company’s position in the particular advertising dispute at hand. The executive must also weigh how much disagreement with the FDA staff in a current matter might affect future treatment. No such continuing relationship exists between the FTC and any industry.]

The willingness of FDA staff to link enforcement actions in one area, such as manufacturing facilities, with regulation in another area, such as new drug approvals, is well known and has been widely reported in the news media. Firms have recently paid fines of as much as $500 million because of FDA dissatisfaction with manufacturing facilities, even when neither the FDA nor the medical community has deemed any of the products from the factories in question unsafe or worthy of recall (Anand 2002).

Notwithstanding industry forbearance from challenging the FDA in court, the First Amendment’s protections for commercial speech also play a role. The Washington Legal Foundation, an independent public interest group, has launched several First Amendment challenges to FDA regulation of advertising and promotion directed at physicians (Washington Legal Foundation 1995; Washington Legal Foundation v. Kessler 1994). Other litigation has challenged FDA regulations for the advertising of supplements (Pearson v. Shalala 1999). These cases have proceeded slowly but with considerable success, forcing the FDA to loosen its policies about manufacturers’ dissemination of “off-label” information (i.e., information not listed in the FDA-approved materials about a prescription drug; see Oliphant 2000).

Even critics who vigorously advocate even stronger FDA regulation have stated that nondeceptive DTC advertisements (the only kind that FDA regulations permit) are protected by the First Amendment (Wolfe 2002). A return to the years before any DTC advertisements took place or to the regulatory regime that existed before 1997 would be constitutionally suspect. Reflecting these circumstances, the FDA recently published a Federal Register notice asking for public comments on how it can ensure that its regulatory activities conform to recent Supreme Court rulings on First Amendment protections for commercial speech (FDA 2002a, which also briefly summarizes the related litigation).

The Debate over DTC Advertising

The United States and New Zealand are the only developed nations that permit DTC advertising of prescription drugs. Canada and the European Union (EU) nations have continually debated whether to follow the United States’ example. The EU recently began a limited experiment in which manufacturers would be permitted to provide consumers with information on treatments for three therapeutic categories (diabetes, AIDS, and asthma) through pamphlets and other materials (but only in response to consumer requests) and in Web sites (European Commission 2001; Meek 2001). There is little reason, however, for Canada or the EU to substantially alter their policies in the near future (Meek 2001).

In the meantime, DTC advertising has prompted considerable discussion and analysis in the United States. Most of the criticism has come from the physician community (Hollon 1999) and health insurance organizations. A late 1997 poll of physicians found a strong majority desiring tighter regulation or a ban on DTC advertising (IMS Health 1997; McGinley 1999). Managed care organizations and large employers have complained that DTC advertising causes excess prescribing or shapes consumer preferences toward more expensive branded drugs (Blue Cross Blue Shield Association 2002; Burton 2002; National Institute for Health Care Management [NIHCM] 2001).

The medical community’s opposition to DTC advertising has greatly moderated in the past few years. In 1998, Lancet, a leading British medical journal, published an unsigned editorial arguing that DTC advertising would benefit European consumers. Hoek and Gendall (2002b) note that both the New Zealand Medical Association and the Royal College of New Zealand General Practitioners have issued statements that endorse the continuation of DTC advertising in New Zealand under the current self-regulatory regime. In 2000, the American Medical Association (AMA; 2000) issued a statement that concluded, “If used appropriately, direct-to-consumer (DTC) advertising has the potential to increase patient awareness about treatment options and enhance patient-physician communication. Advertising directly to the public educates patients, enabling them to better understand and participate in medical care.” The statement emphasized that this observation applied only to

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5In their article on current FDA effects to raise manufacturing standards through enforcement actions, Petersen and Abelson (2002) note, “The agency has also begun holding up approval of new drugs until the companies can convince it that they have fixed manufacturing problems—an action that gets investor attention quickly and can send the price of a company’s stock down.”

6The New Zealand experience is of interest not just because DTC advertisements are permitted but also because they are regulated by the Advertising Standards Authority, a self-regulatory body. See Hoek and Gendall (2002a, b). The pharmaceutical industry view of DTC in New Zealand is provided in Researched Medicines Industry Association of New Zealand (n.d.).


8Leading reviews are Wilkes, Bell, and Kravitz (2000); Lyles (2002); Rosenthal and colleagues (2002); plus a May 2001 conference, complete with papers, convened by the office of the Assistant Secretary for Planning and Evaluation in Health and Human Services (see Bero and Lipton 2001; Frank et al. 2001; Schommer and Hansen 2001). Other useful reviews include Meek (2001) and National Health Council (2002b).
advertisements that “do not distort information and mislead patients.”

Especially significant is a January 2002 report on DTC advertising, with an accompanying statement from the National Health Council, an organization of approximately 50 voluntary health associations (e.g., American Heart Association), 35 professional and membership organizations (including the AMA, medical specialty associations, and the main pharmaceutical trade association), other nonprofit associations (including AARP and the Rosalynn Carter Institute), and large businesses (mainly pharmaceutical firms). The National Health Council report was reviewed by all member organizations and approved unanimously. The accompanying statement concluded, “After completing a thorough review of Direct-to-Consumer (DTC) prescription drug advertising, the National Health Council believes that DTC advertising is an effective tool for educating consumers and patients about health conditions and possible treatments” (National Health Council 2002a, b). At about the same time, the National Medical Association (an organization of African American physicians) published the results of a member survey, in which attitudes toward DTC advertising were largely (but by no means universally) favorable. It also published a policy statement that noted the existence of an “educational benefit” in DTC advertising, sought an increase in DTC advertisements in African American media, and urged physicians to be open to such advertisements as a communication device so long as the advertisements are balanced. This policy is consistent with research that shows that African Americans are disproportionately likely to have undetected and untreated elevated cholesterol and with an earlier appeal by the Association of Black Cardiologists to the FDA to support petitions (which failed) from Merck and Bristol-Myers Squibb to move the two oldest statin drugs (Mevachor and Pravachol) to OTC status. The research reached the same conclusions about Hispanics, and the leading organization of Hispanic physicians also supported switching those two drugs to OTC status (Elliott 2000; Lueck 2000).

In July 2001, the FDA official in charge of DTC advertising regulation and research stated in congressional hearings that “At present, FDA is not aware of any evidence that the risks of DTC promotion outweigh its benefits” (Ostrove 2001), a view that reinforced what the agency had said in 1999. Speaking at an April 2002 conference, former FDA Commissioner David Kessler, who had vigorously opposed opening up DTC advertising during his tenure from 1990 to 1997, said that he had changed his mind and now supports the expanded role of DTC advertising (Mishra 2002). The FTC, which shares jurisdiction with the FDA, argued in a 1996 comment to the FDA that DTC advertising can be valuable for consumers, and it reiterated its support for DTC advertising in a 2001 comment to the Office of Management and Budget (FTC 2001).

Nonetheless, debate continues, with both congressional and state legislators considering legislation to restrict DTC advertising (Pallarito 2001; Pear 2002; Senate Commerce Committee Subcommittee 2001). An overarching issue is the impact of DTC advertisements on total health care costs, on the financial costs of impaired health, and on consumer welfare including nonfinancial benefits. An assessment of this impact would require extensive use of the medical and health economics literature to determine the net impact of increased drug usage, assuming that DTC advertising increases pharmaceutical demand. These topics are not dealt with in this article beyond noting the following points: The literature yields clear evidence that for some therapeutic categories (but by no means all), increased pharmaceutical use is associated with reduced health care costs (e.g., AIDS treatments and anti-ulcer drugs; see Neumann et al. 2000). Reductions in workplace and personal costs have also been documented (Kleinke 2001; Lichtenberg 2001). Some analysts have concluded that pharmaceutical advances, similar to technological progress in general, tend to reduce overall health care costs (see Kleinke 2001; Lichtenberg 2001). Beyond the matter of health care costs lie the benefits realized primarily by consumers, as when heart disease drugs prolong life even though they increase the probability of a person eventually suffering other illnesses, such as cancer, and when antidepressants reduce the very large perceived degradations in quality of life caused by depression (see, e.g., Bennett et al. 2002 on the disutility of depression).

The concern, however, is with DTC as an advertising phenomenon. Obvious issues include DTC’s impact on pharmaceutical prices and expenditures, its impact on consumer information, and the extent to which DTC advertising is deceptive. Also important are the questions whether DTC advertising affects physician’s prescribing behavior and the patient–physician relationship. Finally, there is the question whether DTC advertising confers positive externalities on the marketplace, such as by increasing drug therapy compliance and conveying useful information about nonbranded drug therapy or lifestyle changes. One interesting topic not addressed here is the impact of DTC advertising on product liability litigation, in which the New Jersey Supreme Court ruled that DTC advertising can abrogate the “learned intermediary” defense that normally requires patients to sue physicians, rather than manufacturers, in cases regarding prescription drug safety and appropriateness (see Berger 2000; Gemperli 2000).

The Potential Role of DTC Advertising

A preponderance of research shows that advertising improves markets by providing consumers with essential information that they would otherwise ignore, fail to receive, or receive too late. The FTC, which regulates most advertising (but not prescription drug advertising), has emphasized that advertising plays an essential role in improving consumer information and otherwise improving markets (Calfee 1997; Calfee and Pappalardo 1989; Pitofsky 1996).

There are compelling reasons to expect similar effects from DTC advertising for the prescription drug market. Recent decades have seen a rapidly expanding role for drug therapy in medical practice (Altman and Parks-Thomas 2002). These years have also seen a powerful trend toward greater consumer involvement in health care. The FDA pol-

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9See Allison-Ottey, Ruffin, and Allison (2002) and National Medical Association (2002). The USDHHS (2002b) recently launched a campaign to encourage African-Americans to see physicians to learn of possible preventive care.
policy reflects these trends. In the past two decades, the FDA has moved more than 600 drugs from prescription to OTC status, including such potent drugs as nicotine patches, the anti-inflammatory drug Naproxen, and treatments for genital yeast infections (FDA 1999d; Lueck 2000). The FDA has also stated that “It [DTC advertising] is consistent with the whole trend toward consumer empowerment. We believe there is a certain public health benefit associated with letting people know what’s available” (Stolberg 2000).

The medical literature provides strong evidence that some of the most important pharmaceutical information—especially relatively new information—often fails to reach physicians or patients in a timely manner. This situation is reflected in the proliferation of practice guidelines for physicians as well as in published findings that medical practice often falls short of what can be achieved by following even the least controversial aspects of consensus guidelines (e.g., Ayanian et al. 1994; Felch and Scanlon 1997; Kane and Garrard 1994).

Consumers and patients tend to be less well informed than their doctors. Many of the most valuable new drugs involve conditions or illnesses that require consumers to take the initiative in seeking medical advice for dealing with depression, for example, or to learn whether they are at risk for heart disease, and if so, what can be done to reduce that risk. Many studies and consensus statements from the medical community have documented the existence of large numbers of underdiagnosed and undertreated consumers who suffer from serious, yet treatable, medical conditions, such as depression, AIDS, diabetes, and osteoporosis.  

A 2001 report from the National Cholesterol Education Program at the National Institutes of Health illustrates these trends. The report concluded that elevated cholesterol should be treated much more aggressively than in the past, even as earlier studies have found that most people who should have been treated under the previous guidelines were not treated and, often, not even identified (Expert Panel 2001; see also Cleeman and Lenfant 1998). Recent research has also found that African Americans and Mexican Americans are less likely than others to undergo cholesterol screening or to be treated after being identified as requiring medication (Nelson, Norris, and Mangione 2002).

These circumstances dictate that patients and consumers must play an active role in their own health care. In particular, consumers need to acquire information about medical therapies, talk to their physicians about medical symptoms and conditions, and decide with their doctors how to deal with illnesses and conditions. The FTC and FDA statements cited previously are consistent with this view.

Direct-to-consumer advertising can confer substantial benefits because it provides firms with incentives to attach missing information to their brands and to disseminate that information to increase brand demand. The consumer benefits would come partly from consumption of the advertised brand (yielding consumer surplus in the economic sense) and partly through positive externalities or spillover, such as providing information that can lead to improved health without using the advertised brand.

It is worth noting here that the increasing role of pharmaceutical marketing extends well beyond the escalation of DTC advertising and even beyond the continuing importance of promotion to physicians (through detailers, sponsored seminars, and other techniques). Drug research and development has become more marketing driven in recent years, sometimes with clinical trials being designed with an eye toward specific marketing claims. A striking example from the early 1990s was the launching of large clinical trials on statin cholesterol-reducing drugs for preventing heart attacks in people with only moderately elevated cholesterol and no history of heart disease. This research, which was undertaken in search of superior marketing claims, provided the first persuasive scientific evidence that reducing cholesterol would prevent heart attacks. The blend of marketing with pharmaceutical research and development continues to evolve.

Empirical Research on the Effects of DTC Advertising

Empirical research on the effects of DTC advertising is scarce (at least in the public domain), befitting a phenomenon that became of interest to the public policy community only in 1997. Thus, a May 2001 conference convened by the USDHHS to examine DTC advertising focused almost exclusively on how to perform research on DTC advertising, rather than on the results of prior research (Bero and Lipton 2001; Frank et al. 2001; Schommer and Hansen 2001; USDHHS 2001).

Most research to date has consisted of consumer surveys. In this section, I address the few topics in which research not based on surveys has been of value and then briefly describe the most important consumer survey work. Succeeding sections address major topics for which surveys have been essentially the sole research tool.

DTC Advertising and Drug Prices

Expenditures for outpatient prescription drugs have been increasing approximately 15% annually (Berndt 2001; NIHCM 2002). Several studies have found that approximately three-fourths of these increases have been caused by expanded usage and switching to newer and more effective drugs, whereas price increases have accounted for only

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11See the discussion in Calfee (2000a, pp. 30–31), which relies partly on Langholtz (1998). For more recent developments, see Kranhold (1999; on the acquisition of a clinical trials research firm by an advertising group), Harris (2001; on the growing role of marketing executives in drug development at Merck), and O’Connell (2002; “What you’re seeing is an emerging convergence between the clinical development and the commercialization of drugs,” said Thomas Harrison, chief executive officer of the Diversified Agency Services division of Omnicom Group Inc.”). On the importance of conceptual connections between pharmaceutical research and development and marketing considerations, see Calfee (2000b, 2001c, 2002) and Galambos (2001).
about one-fourth.12 Even this modest role for price increases is overstated, because standard measures of pharmaceutical prices fail to take into account improvements in the quality and value of new drugs or drugs that have found expanded uses (Tripplett 1999).

These facts suggest that even if DTC advertising increases prices, such an effect has been quite limited simply because overall price increases have been small and the amount of DTC advertising is only about 2% of total pharmaceutical expenditures.13 Research has found that advertising tends to reduce prices, rather than increase them, primarily because advertising makes markets more competitive (Calfee 1997, pp. 10–11).

However, there are scenarios in which pharmaceutical advertising would be an exception. For pharmaceuticals, whose value lies exclusively in information about a relatively simple product and in broad dissemination of that information, it is possible for advertising to be positively associated with prices. Firms sometimes conduct expensive research on a drug after it has been approved for marketing. For example, clinical trials and more fundamental research on the statin class of cholesterol-reducing drugs have been exploring several topics, including the benefits of treating lower cholesterol levels and the prevention or cure of osteoporosis, stroke, and Alzheimers, at a cost of hundreds of millions of dollars so far.14 This is typical of research on the closely targeted drugs developed using modern pharmaceutical research methods, because the targeted proteins and other entities often turn out to be important for other illnesses. Another example is research on cox-2 inhibitors (Celebrex, Vioxx, and emerging competitors), which appear promising in treating colon cancer (Chau and Cunningham 2001). A logical consequence of this kind of research could be both higher prices and additional marketing to inform the market of the new information. However, there is little evidence of this actually taking place.

There appears to be no econometric research on DTC advertising and prices. Considerable data suggest, however, that there is little relationship between DTC advertising and prescription drug prices. Manning and Keith (2001, Fig. 7) reexamine the NIHCM (2001) data and note that a rank ordering of brands according to DTC spending bears essentially no relationship with percentage increases in cost per prescription. Detailed data are available for the statin class of cholesterol-reducing drugs such as Pravachol, Zocor, and Lipitor. Total expenditures for statin drugs have increased rapidly, making this one of the three largest therapeutic cat-

gories in total sales.15 Statin drugs have also been among the leaders in DTC advertising (NIHCN 2001). Yet average statin drug prices increased only 7% in real terms between 1995 and 2000.16 That the original statin drug, Mevachor, has gone off-patent and competes with generics will exert new downward pressure on statin drug prices.

DTC Advertising and Pharmaceutical Consumption

Little research seems to have been performed on the effects of DTC advertising on pharmaceutical consumption. This is hardly surprising for such a new phenomenon, given that such research is rare even in long-established markets (the exceptions are markets for controversial products such as tobacco and alcohol).

Findlay (2002, drawing on NIHCM 2001) and others have described an association between rapidly growing therapeutic categories and DTC advertising. Neither Findlay nor the NIHCM report attempts to assess causality, nor do they take into account confounding variables in a systematic way. The authors of the NIHCM report conclude (p. 15) that their calculations “add to the growing circumstantial evidence that such ads are one element—and perhaps an increasingly important one—in the recent trend to the expanded use of newer prescription drugs and the resultant increased overall spending on pharmaceuticals.” Nonetheless, some observers have assumed that the tables presented in NIHCM (2001) amount to a demonstration of causation (Families USA 2002, p. 15; U.S. General Accounting Office 2002, p. 6).

Again, Manning and Keith (2001, Fig. 6) reexamined the NIHCM (2001) data. They show that a rank ordering of brands according to DTC spending bears no discernible relationship with percentage increases in sales. One unpublished paper has examined DTC advertising for a single therapeutic category, the statin class of cholesterol-reducing drugs (Lipitor, Zocor, Pravachol, and competitors). Using data from 1995–2000 and exploring many dependent variables and lagged structures, Calfee, Winston, and Stempski (2002) find no relationship between DTC advertising and either prescriptions or sales. Indeed, statin prescriptions increased at a steady rate both before and after the August 1997 change in FDA policy toward DTC advertising.

This limited body of research is inconclusive. A problem in this line of research is the length and complexity of the relationship between DTC advertising and the consumption of pharmaceuticals for chronic conditions. In the case of statin drugs, one reason for the apparent lack of a short-term connection between advertising and prescriptions is that several steps of varying length must take place between the time a consumer reacts to an advertisement and receives a prescription (initial physician visit, cholesterol test, advice

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12 The most rigorous study is Dubois and colleagues (2000). A useful wide-ranging survey of the factors causing expenditure increases in the past two decades is Berndt (2001). The NIHCM (2002) finds that price increases accounted for 37% of expenditure increases in 2001. That study, however, uses Scott-Levin price data that do not reflect individual drug discounts or rebates to pharmaceutical benefit managers or managed care and that ignore dosage size and prescription length (30-day versus 90-day).

13 Total outpatient pharmaceutical expenditures were $122 billion in 2000 and were predicted to be $142 billion in 2001 (USDHHS 2002a). As noted, DTC advertising in 2001 was $2.7 billion.


15 Table 1 of NIHCM (2002) shows “cholesterol reducer” as the third-ranking therapeutic category in 2001. The bulk of those sales are for statin drugs, which are the dominant cholesterol-reducing therapies and were still on patent in 2001, in contrast to older cholesterol-reducing drugs. Two of the three best-selling brands were statin drugs.

16 Proprietary price data were provided by IMS Health and are summarized in Calfee, Winston, and Stempski (2002). The IMS price series takes into account discounts but not rebates.
for lifestyle changes, and so forth), if a prescription is written at all.

Given the inexperience of pharmaceutical firms in the art of broadcast advertising (the dominant DTC media), it is possible, if not likely, that major DTC advertisers have sometimes met with disappointment. Economic intuition suggests, however, that DTC advertising, on average, helps the brand being advertised. That does not imply that DTC advertising in aggregate increases overall pharmaceutical demand (see the discussion of the “fallacy of composition” by Calfee [2000c]). Nonetheless, it is likely that DTC advertising, which is a new tool for promoting products that are themselves quite new and are also strongly dependent on the dissemination of information, tends or will tend to increase consumption of Therapeutic categories being promoted.

The extent of consumption increases induced by DTC advertising must be very small, thus far. Pharmaceutical consumption has been increasing rapidly in all developed economies, in some cases achieving much greater per capita usage than in the United States (Calfee 2000a, pp. 6–7). Price controls in EU nations and Canada are probably the main reason pharmaceutical expenditures in these nations have increased less rapidly than in the United States. Direct-to-consumer advertising in the United States equals only about 2% of outpatient pharmaceutical expenditures (noted previously), and advertising expenditures in 2001 increased only slightly over those in the year before. This is contrary to what would be expected if firms had discovered that very large consumption increases followed increased in advertising for major therapeutic categories. Moreover, experience has shown that formerly advertised brands rapidly lose market share in the face of new generic competition. For example, Prozac, an extremely well-known brand that went off-patent in 2001 lost most of its market share to generics within a few months because of the aggressive actions of pharmaceutical benefit managers determined to reduce costs (Mantz 2001).

DTC Advertising and Inappropriate Prescribing

Beyond the matter of whether DTC advertising increases usage lies the question whether it induces inappropriate prescribing. The proposition that newer drugs tend to be medically inferior or just expensive variants of older drugs is difficult to defend. Scholarly reviews of drug therapy (e.g., Yanovski and Yanovski [2002] and other articles in the drug therapy series in the New England Journal of Medicine) typically focus on newer drugs and their superiority to older treatments. This also holds true in major consensus reports on treating important chronic conditions such as depression, osteoporosis, diabetes, and elevated cholesterol. Rare side effects from new drugs tend to appear more rapidly than in earlier decades because of the growth of managed care and other changes in health care that accelerate the dissemination of newer treatments. This trend does not support a finding that newer drugs are more dangerous (Friedman et al. 1999). Thus, little direct evidence seems to have emerged that recent increases in drug expenditures have disproportionately involved medically unwise prescriptions or that DTC advertising in particular has caused medically inappropriate prescribing. More targeted research supports the same conclusion. A study of the rapidly growing and heavily advertised statin drugs finds no tendency toward less appropriate prescribing (Dubois et al. 2001). Calfee, Winston, and Stempinski (2002) similarly find no significant decline in the initial cholesterol levels of patients receiving new statin prescriptions in recent years, even though the medical literature and federal government recommendations have urged more aggressive treatment of elevated cholesterol.

Increases in drug utilization seem to be driven primarily by health care organizations, physicians, and patients finding many of the newer drugs to be extremely valuable. A large body of evidence indicates that many of the most effective drugs are underused, rather than overused. Therefore, the intense public debate over prescription costs for Medicare patients has focused almost exclusively on how to pay for broader and more aggressive drug therapy, rather than on how to curtail the inappropriate use of pharmaceuticals.

Nonetheless, anecdotal evidence suggests that DTC advertising may drive consumption away from generics and toward expensive branded antihistamines, anti-ulcer treatments, and arthritis analgesics, for example. For the first two categories, this has not raised safety or efficacy problems, as the leading brands have received the endorsement of FDA expert panels to move to OTC status as patents for those brands expire and low-cost generics emerge. Whether these and other popular branded prescription drugs are inappropriate from an economic standpoint is largely a matter of whether third-party payments for prescription drugs undermine reasonable consumer diligence in balancing costs and benefits.

In general, the FDA seems satisfied that DTC advertisements are not the cause of substantial medically inappropriate

18 An interesting exchange is Lasser and colleagues (2002) and Temple and Himmel (2002) in the same issue of the Journal of the American Medical Association. Lasser and colleagues argue that recently approved drugs have proved unusually dangerous and that physicians should be reluctant to prescribe them. The opposing view, an editorial, is from two members of the FDA division responsible for approving new drugs.

19 Mintzes and colleagues (2002) reported the results of a survey of 78 physicians (38 in Sacramento, Calif., the rest in Vancouver, Canada). Physicians felt “ambivalent” about granting a patient’s request for a prescription for an advertised drug more often (50%) than they did when acceding to a request for a nonadvertised drug (39%), but the difference was not statistically significant. No other information on the appropriateness of these prescriptions was provided.

20 A recent advertising campaign by AARP has focused on encouraging the use of generics rather than brand names, but AARP has apparently not argued that a significant proportion of pharmaceutical prescribing is medically inappropriate as opposed to being unnecessarily expensive (Greene 2002). The organization strongly advocates comprehensive drug coverage for Medicare patients.

21 Thus, the battle between older generics and the newer generation of branded allergy and anti-ulcer drugs is becoming moot. Claritin, the leading nonsedating antihistamine, is losing patent protection in late 2002 or 2003 and is likely to be converted to OTC status. The same is true of Prilosec, the pioneering proton pump inhibitor for gastric distress, which in 2001 was the second best-selling brand in the United States at $4.0 billion. Generic Prilosec will probably also greatly reduce sales of Prevacid, another proton pump inhibitor, which ranked third in 2001 with $3.2 billion in sales (NIHCM 2002, Table 3).
gate prescribing. This is evident from the July 24, 2001, Senate testimony of FDA official, Nancy Ostrove, who mentioned the possibility that DTC advertising could cause inappropriate prescribing and concluded (regarding that and other issues), “At present, FDA is not aware of any evidence that the risks of DTC promotion outweigh its benefits.”

Consumer Surveys
The bulk of research on DTC advertising consists of several nationally representative consumer surveys. The most notable examples include two surveys commissioned by the FDA itself (FDA 1999b, c, 2002b, c), a series of surveys commissioned by Prevention Magazine (Rodale Publications 1999, 2000), and an unusual online Web-TV survey by the Kaiser Family Foundation (KFF; 2001). The 2002 FDA project includes both consumer and physician surveys, fielded in early 2002. The consumer survey was completed by early April, when FDA staff began presenting partial results in public meetings (Aikin 2002; FDA 2002b, c). The FDA and Prevention surveys were large nationally representative telephone surveys using random digit dialing. The KFF survey involved drawing a random sample from a nationally representative panel (subject to the usual constraints on the representativeness of panels) and having each respondent view three different advertisements by Web-TV. Respondents were randomized into two groups, one of which saw no DTC advertisements and the other group saw one of three different DTC advertisements.

Other more limited, but nonetheless useful, research includes national consumer surveys by AARP, the National Consumers League (1998), and NewsHour with Jim Lehrer (2000a, b, with the KFF and the Harvard School of Public Health). A more limited survey of only California consumers (Bell, Kravitz, and Wilkes 1999) and two content analyses of individual DTC advertisements (Bell, Wilkes, and Kravitz 2000a, b; Woloshin et al. 2001) are not considered here.23 These surveys shed light on many of the central topics in public policy toward DTC advertising. This article focuses on the FDA and Prevention Magazine surveys, with citations to KFF and others where they are of interest.

Advertising and Information
Awareness of DTC Advertising
All the surveys found high levels of awareness of DTC advertisements. Of FDA respondents in 2002, 81% (up from 72% in 1999) recalled seeing a prescription drug advertisement in the past three months (mostly on television), and most recalled seeing several advertisements. This is comparable to the 85% recall level in the 2000 Prevention survey, which represents a modest increase from previous years: 63%, 70%, 81%, and 80% in 1997 through 2000, respectively. In the Prevention survey, follow-up questions about individual brands revealed virtually universal aided recall levels. Other surveys, all asking for unaided recall of DTC advertisements, also found very high awareness levels: 91% in the PBS NewsHour–Kaiser–Harvard, 80% in the National Consumers League, and 65% in the AARP survey (which was restricted to print advertisements).

Information-Seeking Triggered by DTC Advertising
Half of the FDA respondents in 1999 who recalled seeing DTC advertisements indicated that the advertisements had sometimes caused them to seek additional information. They sought information from a variety of sources, including books, friends, the Internet, and the news media, but the most common sources were physicians (81% talked to their own doctor and 22% talked to another doctor), followed by pharmacists (52%) (totaling more than 100%, because respondents could indicate more than one source).

In the 2002 FDA survey, 18% of those recalling advertisements said that DTC advertisements had at some time caused them to talk to their doctor about a specific medical condition or illness for the first time. This is a remarkable result, suggesting that approximately 17% of the adult population that has seen doctors in the past three months has been motivated by advertising to discuss a new topic. (The number in the 1999 survey was higher, 27%, whereas the 1999 Prevention survey, which unlike the FDA survey did not oversample people who had recently seen a doctor, found 14%.) The 1999 FDA survey also asked whether respondents were likely to ask their doctor about a drug that was advertised to treat a condition that was “bothering you.” A large proportion (80%) said they were somewhat or very likely to ask.

Risk Information
The FDA survey addressed readership of the detailed risk information in print advertisements. Forty percent said they read half or more of that information, and another 26% said they read a little of it. This may reflect a modest degree of socially responsible yea-saying by respondents. More significant, however, is that 85% said they would read all or almost all of the information if they were especially interested in the drug (see Table 1).

The 2000 Prevention Magazine surveys also found high readership of risk information. Of those recalling print advertisements, 54% recalled that the advertisements contained technical information, and 37% recalled skimming the brief summary, looking for key information, or reading most of the summary. Several questions explored this topic further, revealing that readership of the fine print was higher for those taking a prescription drug and highest for those taking the advertised drug. Only 35% thought the technical information was “very clear,” however, documenting a long-standing situation of which the FDA is well aware (Pines 1999). Finally, 86% of those who at least skimmed the fine print said it provided sufficient information for them to ask their doctors about risks associated with the drug. Of

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24The California survey, in addition to being smaller and restricted to California residents, was not nearly as comprehensive as the FDA or Prevention Magazine surveys. The content analyses were used to support the argument that DTC advertisements fail to provide some useful information, such as mechanism of action, success rate, supportive behaviors, and alternatives to the brand being advertised.
special interest is that those who gave higher ratings to the adequacy of risk information in advertisements were more likely to have discussed an advertised drug with their doctor, and the same relationship held for those who had brought up a new medical condition with the physician (based on cross-tabulations).

These results are of great interest because a considerable body of research shows that patients receive surprisingly little risk information from either physicians or pharmacists, and often they tend to ignore the information they do receive (Lyles 2002, pp. 82–83). The 2000 Prevention survey asked how often physicians provided various kinds of risk information about the drugs they prescribed (a topic not addressed in the FDA survey). Patients who had spoken with their doctor about an advertised drug were more likely to receive information about side effects than were patients who had not (64% versus 54% for serious side effects; 56% versus 47% for annoying, nonserious side effects).

The AARP also asked a series of questions about receiving risk-benefit information from physicians. A total of 54% said their doctor “usually” talks to them about the risks and potential side effects of drugs being prescribed, 18% said doctors “sometimes” did this, 18% said “rarely,” and 9% said “never.” Physicians talked less frequently about alternative prescription drugs (43% usually and 27% rarely or never) and nonprescription drugs (35% usually, 35% rarely or never).

### A Note on Advertising Deception

Section 502(n) of the Food, Drug, and Cosmetic Act requires drug advertisements to include the drug’s name, ingredients, and “such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations” to be issued by the FDA. Those regulations, set forth in the Code of Federal Regulations (21 CFR Part 202.1), contain requirements that advertisements must meet in order not to be judged “misleading.” The FDA’s focus on the concept of “misleading” is parallel to the FTC’s mandate to policy “deceptive” acts or practices. Therefore, the benefits of DTC advertisements depend partly on whether the FDA has established reasonable standards for deception.

Clearly, it is possible to set standards too high. Advertising regulation involves a trade-off because regulators cannot be certain which claims will turn out to be deceptive and which will prove truthful and nonmisleading (Caffee and Pappalardo 1989, 1991). If the rules are too tight, the loss to consumers from the suppression of useful information will exceed the gains from eliminating deceptive information. The attempt to strike a reasonable balance provides the conceptual foundations for FTC regulation of deceptive advertising (Craswell 1991; Ford and Caffee 1986; FTC 1983).

Two factors strongly suggest that FDA advertising regulation is almost certainly too strict. The first pertains to regulatory incentives. The problem is most easily shown by examining new drug approvals, not advertising regulation. Regulators of the FDA face pressure to avoid making Type I errors, permitting harmful new drugs into the market, in favor of making Type II errors, prohibiting or delaying useful new drugs. This is because Type I errors are severely penalized, as they arouse adverse publicity and provoke criticism of the FDA approval authorities. A recent example is the awarding of a Pulitzer Prize for a series of newspaper stories on the FDA approval process for several drugs that encountered safety problems. In contrast, relatively few people are aware of the potential value of drugs that have been kept from the market. The tendency for these distorted incentives to unduly delay new drug approvals is well documented.

Similar forces apply to the regulation of advertising, that is, to decisions about what advertising claims to permit. Although the FDA deserves credit for expanding DTC advertising to broadcasting in 1997, it still faces powerful incentives to tightly circumscribe the content of advertising claims. Since the FDA’s 1997 initiative, DTC advertising has been much criticized (and little praised) in the medical and popular press. Much of that criticism has been directed at the FDA either directly or by implication (because most advertising passes unchallenged by the FDA). In contrast, criticism of the FDA’s near-ban on broadcast DTC advertising before 1997 emanated from a narrow group of academics and industry spokesmen, and it attracted little public attention. The FDA’s bias against making Type I errors (i.e., possibly allowing claims that turn out to be deceptive) at the expense of making Type II errors may be appropriate for drug approvals, but not advertising regulation.

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24The recipient was David Willman of the *Los Angeles Times* [http://www.pulitzer.org/year/2001/investigative-reporting]. Also see Lasser and colleagues (2002), for an article in the *Journal of the American Medical Association* critical of the FDA’s safety standards in new drug approval.

25This reasoning gave rise to a rich, empirically robust literature, beginning with Peltzman’s (1973) analysis of the drug approval slowdown in the wake of the 1962 amendments to the Food, Drug, and Cosmetic Act. Subsequent analyses include Wardell and Lasagna (1975), DiMasi (1996), and Tabarrock (2000; who reviews much of the drug lag literature).
expense of Type II errors (suppressing truthful claims) may be even stronger than its bias against taking risks in approving new drugs. This is because manufacturers usually have a bigger stake in new drug approvals than in advertising claims; therefore, they will fight harder behind the scenes to overcome regulatory resistance to new drug approvals than they will for innovative advertising claims. In addition, patient groups sometimes exert pressure for new drugs, but they seldom press for new advertising claims.

Worth noting in this context is the change in regulatory incentives that occur after a new product has been approved. When a group of grateful users has been created, the FDA may face pressure to keep a useful drug on the market even if it encounters problems. An example is the recent reintroduction of Latronex, which the FDA had pulled from the market in the wake of intense popular criticism of the approval process only to be met with criticism from patients who wanted to regain access to the drug.26 Again, parallel forces apply to DTC advertising, whose popularity with consumers may help preserve its existence even as the FDA faces pressure to curtail it.

The second factor suggesting excessively strict FDA advertising regulation is the reinforcement of the incentives to avoid public attacks and blame. Here, the contrast between how the FTC and the FDA deal with advertising deception is illuminating. Both agencies enforce a vague mandate against false or misleading advertising. However, the FTC has for decades been forced to articulate predictable, empirically based standards that can withstand scrutiny in the courts, including First Amendment challenges (see Ford and Calfee 1986; FTC 1983, 1984). The FDA, in contrast, has never had to defend its policies in court.

This leaves the FDA free to establish broad per se standards for advertising content. These standards are not based on empirical findings on how physicians or consumers perceive or act on specific advertising claims.27 A salient example is the FDA’s prohibition on off-label therapeutic claims. The FDA policy assumes that even a sophisticated audience (physicians) requires protection from all therapeutic claims. This is almost certainly unnecessary. For decades, a steady flow of off-label therapeutic information has been widely accepted and fruitfully used by the medical community, which often finds off-label information to be essential to good practice (Calfee 1996; Tabarrock 2000; Thakkar 1997 [summarizing Calfee and McGinniss 1997]; USGAO 1991; Yanovski and Yanovski 2002). Off-label information (such as practice guidelines) has been disseminated by authoritative sources including agencies other than the FDA within the USDHHS, such as the National Cancer Institute and the National Cholesterol Education Program. Yet the FDA prohibits manufacturers from disseminating that same information, even if its off-label status is explicitly noted.

The FDA has brought no litigation against DTC advertisements. Instead, it has issued a series of warning letters and other reprimands (summarized in Ostrove 2001; Wolfe 2002). These have rapidly declined in frequency by more than half since 1998, when the industry was still discovering the contours of the FDA’s new DTC policy. Given that pharmaceutical firms invariably accede to FDA requests to alter or halt advertising claims, the likelihood of sustained deception, even based on the FDA’s own views of what is misleading, is very small. The remarkably even balance between risk and benefit information in DTC advertisements (reviewed in the next section) also indicates a lack of deception (although a disproportionate emphasis on benefits would not necessarily be deceptive). In addition, the FDA has itself concluded that it is unaware of any evidence that DTC advertisements are harming public health through deception or other means.28

These circumstances, considered in combination, strongly suggest that deception in DTC advertising is rare. An important additional factor is the prescription requirement for obtaining advertised drugs. It provides a potent check on adverse consequences of consumer deception, if it should occur.

The Balance of Risk and Benefit Information

Risk and Benefit Information

Of central importance from the FDA’s perspective is evidence on the balance of risk and benefit information conveyed by DTC advertisements. Doubts about the ability of DTC advertisements to convey reasonably balanced risk and benefit information were arguably the chief reason for the FDA’s DTC moratorium in the 1980s and its suppression of broadcast advertisements before 1997 (Morris and Millstein 1984; Morris, Ruffer, and Klimberg 1985; Pines 1999). The FDA surveys devoted considerable attention to risk and benefit information, as did the series of surveys by Prevention Magazine and, to a lesser extent, the 2001 KFF survey.

The FDA was interested in learning whether DTC advertisements tend to emphasize the benefits of prescription drugs while downplaying the risks. A series of detailed questions revealed a remarkably balanced assessment. When asked what kinds of information respondents saw in television advertisements, 90% (87% in 1999) said, “the benefits of the drug;” 90% (82% in 1999) said, “risks or side effects;” and 89% (81% in 1999) said, “who should not take the drug.” (These high levels were not caused by yeasaying, as only 10% said they had seen information on over-

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26 See Aoki (2002) for an insightful view of the entire process from approval to withdrawal to reappraisal. Latronex was one of the drugs analyzed in the Los Angeles Times’ Pulitzer Prize–winning stories. See Willman (2001).

27 I am unaware of empirical research underpinning the FDA’s assertions of what advertising claims are likely to mislead either consumers or physicians. Wazana (2000) reviews the research literature on the extent to which physician prescribing is influenced by pharmaceutical promotion (mainly detailing rather than advertising). As Lexchin and Mintzes (2002) point out, much of this research is critical of the influence of physician detailing. That research appears not to address deception directly, however. In contrast, a recent survey of physicians (KFF 2002) found that 74% thought the information they received from industry detailers was very or somewhat useful, and 81% thought the information was very or somewhat accurate.

28 See FDA (1999a) for an assessment of DTC advertising since it began. Ostrove (2001) reviews the limited FDA legal actions against DTC advertising in recent years.
dosage, which is not covered in DTC advertisements.) Respondents in the 1999 surveys were also asked what kinds of information the advertisements did not provide enough of: 59% said advertisements do not give enough information about risks and related matters, and 49% said advertisements do not give enough information on the benefits of drugs.

The FDA surveys asked several broad questions about the relationship between DTC advertising and the nature of prescription drugs. One question asked whether advertisements make drugs seem better than they really are, and 58% (in 1999) agreed that they did. This is a rather low level of agreement. For decades, consumer surveys on advertising have found that roughly 70% of consumers expect advertisements to be strongly biased in favor of the product being advertised. Consumers are routinely skeptical of advertising (Calfee and Ringold 1994). The FDA survey revealed that the nearly universal assumption that advertising exaggerates benefits applies to DTC advertisements, though with somewhat less force.

Relevant here is that these advertisements are for products that can be obtained only after getting a physician’s prescription. In one 1999 FDA question, 70% of respondents agreed that advertisements provided sufficient information for them to talk to their doctor about the drug (parallel responses to similar questions in the 1999 Prevention survey). When asked in the same survey whether DTC advertisements “make it seem like a doctor is not needed to decide whether a drug is right for me,” 70% disagreed. Finally, in responding to a question that is particularly relevant to debates over DTC advertising, just 29% agreed that advertisements are allowed only for the “safest” prescription drugs.

The Prevention surveys also addressed consumer perceptions of risk information in advertising. The most comprehensive question was asked in 1999:

Does the information in these advertisements about the possible risks of taking the prescription medicine make you MORE confident or LESS confident about the overall safety of the medicine—or doesn’t it make a difference in the way you feel about the overall safety of the medicine?

Thirty-six percent said the advertisements made them “less confident,” as opposed to 24% who said “more confident” and 34% who found “no difference.” This striking result suggests that in the course of providing a mix of positive and negative aspects of drugs, DTC advertisements raise awareness of risk even as they raise awareness of medical conditions and treatments. It is consistent with findings from consumer research conducted in the mid-1980s by the FDA that paved the way to the lifting of the FDA’s moratorium on DTC advertising (Morris et al. 1984, 1985, 1986).

Additional questions addressed more specific aspects of risk and benefit communication. Respondents in the 2001 survey thought that advertisements were moderately better at providing information about benefits (60% said excellent or good) than they were at providing information about annoying side effects (50%) or serious warnings (51%). Significantly, these numbers were almost constant regardless of whether respondents were asked about television or print advertisements (an example of how brief risk information can be as salient as detailed information, something that was also found in the FDA’s research) (Morris et al. 1984, 1985, 1986). In the 2001 survey, a large majority of respondents thought that the information in advertisements was sufficient to prepare patients to ask a physician about risks and benefits (62% and 68%, respectively). In the 1999 survey, virtually all respondents (90%) remembered that television advertisements included advice to see a physician, and 70% recalled that advertisements contained a toll-free number for additional information.

The 2002 KFF survey also provided information about consumer perceptions of risk information. The nature of the exercise generated primarily brand-level data. The most interesting information pertained to Lipitor (a statin-class cholesterol-reducing drug). When asked about side effects, 70% of those who saw an advertisement for Lipitor said the side effects were potentially very or somewhat serious. Between 74% and 83% of Lipitor ad viewers correctly said the drug should not be taken by people in three specific categories, but viewers tended to exaggerate risks by agreeing to the mistaken statements that Lipitor should not be taken by those with high blood pressure (29%) or heart problems (34%).

Patient–Physician Discussions

In the 2000 Prevention survey, 32% of those recalling advertisements said that they had talked with a physician about an advertised drug as a result of seeing an advertisement. This figure has been amazingly stable: 31%, 33%, 31%, and 32% in 1997 through 2000, respectively. The great majority (84% in 2000) said they talked to their physicians during a regularly scheduled appointment. Among 1999 FDA survey respondents (total respondents, not just those recalling advertisements), only 21% said they had seen or heard anything that made them want to ask a specific question in their last visit to a doctor. Among the sources that inspired questions, advertisements (46%) ranked equally with news media (45%) and somewhat higher than friends (28%) and other doctors (23%). In the 2002 survey, only 4% said their more recent physician visit was motivated by a prescription drug advertisement. Thus, surveys provide little reason, so far, to believe that DTC advertisements play a major role in generating new appointments.

Several 1999 FDA questions (total respondents, not just those recalling advertisements) focused on what transpired in the doctor’s office. Two-thirds of respondents were already on prescription medications. Of those, 54% expected no change in prescriptions, whereas most of the rest expected either to switch to another drug or to get a new drug for a different condition. When asked in various ways why they thought they might receive a new prescription, respondents generally ranked advertisements well below past prescription history, information from friends or relatives, and previous discussion with physicians. A substantial proportion were prepared to ask about a specific prescription drug. Of those who did not expect simply to continue their medication, about one-third said they asked their doctor whether there was a prescription drug for their condition.

29The combined totals for advertising and news media are not limited to 100% because respondents could choose more than one subcategory in both the advertising and news media categories.
Of these, 13% asked about a specific brand (amounting to approximately 9% of the entire group who had seen physicians in the past three months), 8% mentioned a specific advertisement, and 4% brought some kind of information with them (not necessarily an advertisement).

A crucial segment of the FDA surveys asked patients about physicians’ reactions to their questions. Large majorities said their doctor welcomed their questions (93%; 81% in 1999), reacted as if those questions were an ordinary part of a visit (83%; 71% in 1999), and proceeded to discuss the drugs with the patient (86%; 79% in 1999). Only 3% (4% in 1999) said their physician “seemed angry or upset.” When asked whether their relationship with their physician had gotten better or worse in the visit in which they had asked about an advertised drug, 20% said it got better and only 2% said it got worse. In the 1999 survey, 85% of respondents were satisfied or very satisfied with their discussions with physicians about advertised drugs, and only 7% were unsatisfied or very unsatisfied. Sixty-two percent agreed or strongly agreed that DTC advertisements helped them have better discussions with their physicians.

The 1998 National Consumers League survey provided results similar to those in the FDA surveys. When asked to choose among eight statements to describe the results of ad-motivated conversations with their physician, 30% of respondents said it “helped us talk about the drug/disease,” and only 5% said the conversation “caused tension” with the physician, the doctor was unwilling to talk about the advertised drug, or the doctor “did not like the information I gave.”

The FDA surveys did not ask whether a patient had requested a specific prescription. For those who had brought up a specific advertisement or had asked about a specific brand, the FDA asked what the physician did. In both the 1999 and 2002 surveys, about half prescribed the brand the patient asked about, and about one-third prescribed a different brand. Roughly 15% recommended an OTC drug, and about the same recommended no drug therapy at all. Most important, approximately 40% recommended changes in lifestyle or behavior (it was 29% in 1999, when the survey asked only those who did not receive the prescription they asked about).

The Prevention survey asked whether those who had talked to physicians (or someone in the physician’s office) had also asked their doctor to prescribe the advertised medicine. Seventy-two percent did not request a prescription. For the 26% who did, physicians prescribed the requested medicine 69% of the time and did not prescribe any drug 19% of the time. The FDA survey, in which respondents said what happened when they asked about a drug, rather than for one, found physicians providing a prescription for the brand in question only 50% of the time.

The imprecision of both the FDA and Prevention questions should be considered. Those questions could comprehend a variety of circumstances. Patients may start out asking about one brand, receive a prescription for a different brand after a friendly discussion, feel satisfied with the outcome, and then, when responding to a survey, recall the event as something other than a refusal by their doctors to prescribe what they had requested. Another possibility is that physicians had already made clear their own views of whether a particular drug was appropriate, and patients chose to make an explicit request mainly in situations in which the physician had either encouraged the request or made clear that it was purely a matter of choice for the patient. These comments are consistent with the fact that 71% did not request a specific prescription, despite having discussed a drug because of an advertisement, and that both the Prevention and FDA surveys found little evidence of any conflict or tension between patients and physicians in discussions about advertised drugs. Only 5% of respondents in the 1999 Prevention survey said that physicians were “not too willing” or “not willing at all” to talk to them about the drugs they had requested.

### Externalities from DTC Advertising

Economic theory, supported by empirical evidence, indicates that advertising can improve consumer markets by providing useful information beyond what is strictly associated with the advertised brand. The best documented example is health claims for foods, which buttressed consumer information about diet and health, improved consumer diets, and motivated competitive improvements in products (Calfee 1997; Calfee and Pappalardo 1989, 1991).

Direct-to-consumer advertising could impose harm as well as benefits. Frequent false or misleading claims could reduce the credibility of true claims or cause consumers to exaggerate the safety or appropriateness of drug therapy. As noted previously, however, there is little reason to expect substantial deception from DTC advertisements and little, if any, evidence of deception. If new drugs cause more harm than good, DTC advertising could increase or accelerate those adverse effects, but again, there is scant evidence that newer drugs in aggregate fail to provide large net benefits to patients.30

However, the consumer surveys described here strongly suggest that DTC advertisements have conferred substantial positive externalities or spillovers that have little to do with the specific brands being advertised. These externalities fall roughly into four categories.

### Risk Awareness

DTC advertisements apparently increase the salience that virtually all prescription drugs are risky and have side effects. The survey findings showing high awareness of risk information clearly apply to pharmaceuticals, rather than just to specific brands. This is not surprising, given the prominence of the “brief summaries” in print advertisements and the staccato list of warnings in television advertisement voice-overs. In addition, as noted previously, the 2000 Prevention Magazine survey found that physicians tend to provide more risk information to those patients who ask about advertised drugs.

The dynamics of competitive advertising are also relevant. Firms will sometimes emphasize safety in ways that call attention or spring from consumers’ prior attention to the riskiness or downsides of competing brands. Examples include advertising for cigarettes, food, insurance, politi-

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30A separate debate addresses a larger and more philosophical question, which is whether DTC advertising tends to “medicalize” conditions that should not be addressed through medical interventions at all (Bonaccorso and Sturchio 2002; Mintzes 2002).
cians, and many other products, including cough drops containing heroin when it was legal around the turn of the twentieth century. The FDA rules inhibit this strategy for prescription drugs by imposing extremely high standards for comparative claims. In addition, DTC advertisements often emphasize reduced side effects, but do so without making direct comparisons with competing brands. This tends to call attention to the problem of side effects in general.

Nondrug Ways to Improved Health

Another spillover benefit from DTC advertisements involves calling consumers’ attention to nondrug approaches to improved health. This appears to be inevitable. When DTC advertisements prompt consumers to talk to their doctors about obesity, diabetes, depression, and cholesterol levels, the patients almost certainly learn that behavioral and lifestyle changes are the first line of treatment. Many DTC advertisements (e.g., for cholesterol-reducing drugs) begin by mentioning the value of dietary changes and exercise, thus focusing viewers’ attention on alternatives to getting a prescription. In response to a 2000 Prevention survey question asked of respondents who said that advertisements had caused them to talk to their physician, 53% said their doctor had mentioned a nondrug therapy for their condition. The proportions were much higher for certain conditions: diabetes (77%), high cholesterol (92%), and obesity (84%) (Rodale Publications 2000, p. 58).

Information on Conditions Not Previously Discussed with Physicians

In both the FDA and Prevention surveys, substantial numbers of respondents said advertisements had caused them to ask physicians about problems they had not discussed previously. New discussions about elevated cholesterol, diabetes, obesity, and other chronic conditions do not invariably lead to prescriptions for the advertised drugs. On the contrary, when advertisements induced patients to talk to their doctor, most patients did not actually ask for or about the brand whose advertising sparked the discussion, and when they did, the result was a prescription for the advertised drug, a prescription for a competing drug, recommendations for an OTC drug, and/or advice to change lifestyle or behavior. In general, advertisements can raise awareness of the possible need for a particular type of drug to treat a particular condition, but the benefits of raising that consciousness may go to competitors rather than to the advertiser, as well as to the patient.

Drug Therapy Compliance

Research has shown that inadequate compliance with physician instructions when taking prescription drugs is extremely common, often causing serious danger to patients and others (Ellickson, Stern, and Trajtenberg 1999; Reissman 1998). Because consumers tend to pay disproportionate attention to advertising for brands they use, DTC advertisements could prove to be an excellent vehicle for inducing better compliance. The FDA and Prevention surveys found that consumers pay special attention to advertisements for drugs they are taking or in which they have a special interest.

The Prevention surveys contained a highly relevant series of questions that produced consistent results. Of respondents, 50% were taking one or more drugs, up slightly from 46%, 47%, and 46% in the three preceding years. More than half (57%) of those taking drugs recalled seeing an advertisement for a drug they were using. When asked whether advertisements made them feel better or worse about the safety of their prescriptions, 34% said the advertisements made them feel better, and only 4% said the advertisements made them feel worse (in 1999 and 1998 it was 36% better, 3% worse and 46% better, 1% worse, respectively). A parallel question about benefits yielded similar responses: 40% felt better, and 1% felt worse (52% versus 1% in 1999). In response to the question, “Do ads make you more or less likely to take your medicine regularly?” “more likely” outsored “less likely” by 17% to 2% (22% to 3% and 31% to 2% in 2000 and 1999, respectively). In addition, 33% in the 1999 survey said that prescription drug advertisements reminded them to refill their prescription.

There seems little reason to expect the reminder effects of DTC advertising to be restricted to the advertised brand. Although no research appears to have been conducted on the topic, these survey results strongly suggest that by reminding patients to take their medicine and refill their prescriptions, DTC advertisements tend to encourage patients to persist in their drug therapy. The National Health Council (2002 p. 6, citing the Prevention survey results) statement explicitly endorsed the ability of DTC advertisements to increase patient compliance.

Global Attitudes Toward DTC Advertising

Survey questions about global attitudes are of some value. When asked in the 1999 FDA survey whether respondents liked seeing DTC advertisements, those who did outnumbered those who did not by nearly two to one. Eighty-six percent said the advertisements “help make me aware of new drugs.” Consumers did not react unthinkingly but responded in ways that reflected the unique nature of prescription drugs and the necessity of making decisions in collaboration with their physicians. Thus, whereas only 47% agreed that advertisements help them make better decisions about their health, 62% said DTC advertisements help them have better discussions with their physician about their health. These percentages were higher for those who had asked their physicians about a new condition as a result of seeing advertisements: 59% said advertisements led to better decisions, and 75% said advertisements helped them have better discussions with their doctors.

31Caffee (1997, pp. 46–57), drawing on Musto (1991), quotes from an advertisement for cough drops containing heroin. The advertisement claimed that the brand in question was less likely than other heroin products to be addictive.
The 1999 and 2000 Prevention surveys provided roughly similar results. In the 1999 survey, 76% thought that advertisements “allow people to be more involved with their health care.” Comparable majorities agreed that DTC advertisements “help people make their own decisions about prescription medicines” (64% in 2001, 63% in 1999) and “educate people about the risks and benefits of prescription medicines” (72% in 1999). Much smaller proportions agreed with negative assessments, such as advertisements “cause tension between patients and their doctors” (37% in 2001) and “make prescription medicines seem harmless” (49% in 2001). The entire series of questions may have induced yea-saying, however, partly because they asked for opinions about how advertising works for everyone rather than asking about respondents’ own experiences (unlike the FDA survey, which found little tension between patients and physicians).

The National Consumers League survey asked two questions on global attitudes toward DTC advertisements. Seventy-six percent agreed that prescription drug advertisements “increase consumer knowledge about medicines,” and 78% agreed that prescription drug advertisements “increase consumer knowledge about disease.”

The PBS NewsHour–Kaiser–Harvard survey took a different approach, asking respondents about their level of trust in six sources of information about prescription drugs: their doctor, their pharmacist, family and friends, the FDA and other government agencies, advertising, and product packaging. Advertising was the least trusted, with only 48% saying they trusted advertisements “somewhat” or “a lot.” Family and friends were the second lowest, at 61%. The others ranged between 80% (government agencies) and 95% (physicians). The low global ratings for advertising are hardly surprising, because consumer surveys generally show that roughly 70% of consumers distrust advertising claims in general (Calfee and Ringold 1994). Those results do not apply, however, to attitudes toward advertisements at the brand level, which explains why consumers find advertising in general (Calfee and Ringold 1994), and DTC advertising in particular, to be useful tools.

### A Preliminary Assessment of DTC Advertising

In 1999, when the FDA reaffirmed its August 1997 policy of permitting broadcast DTC advertising, it stated, “FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency’s actions in facilitating consumer-directed broadcast advertising” (FDA 1999b, p. 4). The available evidence supports that conclusion. Overall, DTC advertising appears to convey substantial benefits with little obvious cost. However, this is a preliminary assessment. Little is known yet about such basic matters as the effects of advertising on consumption. New evidence could either contradict or reinforce the conclusions offered here or even illuminate new benefits yet to be identified.

Six tentative conclusions can be inferred from leading consumer surveys and other evidence on DTC advertising. In essentially every case, the survey results are consistent from 1999 through 2001. First, the possibility that DTC advertising is causing systematic consumer deception, including the inappropriate downplaying of risks and side effects, can be ruled out. Advertising regulation by the FDA is inherently biased toward prohibiting nondeceptive claims rather than risking permitting possibly deceptive claims. Survey results bear this out. The FDA and Prevention surveys address the FDA’s central concern—the balance of risk and benefit information—in many ways. The surveys contained questions that could easily have revealed a strong tendency for DTC advertising to downplay the risks of prescription drugs. The results, however, strongly indicate the absence of a bias against risk information. It is unlikely that widespread consumer deception has escaped detection by the FDA regulators.

Second, surveys supply direct and indirect evidence that DTC advertising provides valuable information to consumers, not just on topics such as potential treatments and dosages but also on risks and side effects. In general, DTC advertising appears to increase the salience of both risks and benefits from drug therapy. This provides a valuable addition to the market in view of the proven difficulties of communicating risk information to patients (reflected in AARP survey results) and the pervasive consumer information deficits about treatable medical conditions. The high levels of awareness about and attention to DTC advertisements also strongly suggest that consumers gained information about the core topics of those advertisements—the symptoms of medical conditions, potential therapies, alternative dosages, and related topics—as a by-product of competitive advertising.

Third, the information in DTC advertising motivates consumers to seek additional information from many sources, especially from physicians and pharmacists. Many of these consumers ask about conditions they had not previously discussed with their doctors. They usually do so, however, in regularly scheduled appointments. Given the overwhelming number of consumers who are aware of DTC advertisements, it is notable that 14% and 27% of them (1999 Prevention and 1999 FDA surveys, respectively, with the 2002 FDA survey at 18%) said DTC advertisements caused them to ask their doctors about a medical condition they had not previously discussed.

Fourth, from the patient’s perspective, DTC advertising causes almost no tension in the doctor’s office. A consistent finding is that few respondents—usually under 5%—encountered resentment or resistance when they brought up what they had seen in advertising or asked about specific drugs, and overwhelming majorities said their physicians treated their questions as an ordinary part of office discussions.

Fifth, consumers like DTC advertising. Large majorities (on the order of 60% to 80%) believe DTC advertisements provide them with useful information and help them in talking to their doctors.

Sixth, DTC advertising appears to yield significant spillover benefits that go to consumers rather than to advertisers. Such benefits range from heightened awareness of the inherently risky nature of prescription drugs to better compliance with drug therapies and even motivation to pursue lifestyle and behavioral changes that may obviate the need to use pharmaceuticals. In particular, advertisements reminded consumers to take their medications and refill their prescriptions. In addition, DTC advertisements appear
to make patients more comfortable with the risks and benefits of the medicines they take and may improve compliance with drug therapy.

Overall, these survey results are strongly supportive of a situation in which consumers are motivated by advertising first to seek additional information—especially from physicians and particularly for previously untreated or inadequately treated conditions—and, second, to work with their doctor to reach a decision about what, if any, prescription drug to use.

Policy Recommendations

The range of feasible policy options for DTC advertising appears narrow. An outright ban on DTC advertising, including broadcast advertising as conducted since August 1997, is probably ruled out by the First Amendment. The Supreme Court has long based its commercial free speech decisions on practical matters. Faced with a growing body of evidence showing substantial benefits and modest costs, the Court would probably provide First Amendment protection to DTC advertisements. However, the comprehensive nature of the FDA’s regulatory mandate (which extends far beyond advertising and promotion) rules out a drastic relaxation of DTC advertising rules. This assumes that the FDA continues to have primary responsibility for regulating DTC advertisements, a topic that is addressed subsequently.

Aside from First Amendment considerations, there is little reason for the FDA to roll back its expansion in the scope of DTC advertising in the late 1990s. Advertising deception and consequent medically inappropriate prescribing appear to be minimal, whereas the benefits of DTC advertisements appear substantial. The possibility that DTC advertising increases drug expenditures and usage is not a charge against the advertising itself. To use restrictions on DTC advertising as a method to improve physician prescribing would be to employ an extremely blunt tool with no assurance that the result would be to improve consumer health. Proposals to tighten regulation (e.g., mandatory preclearance as recommended by Lyles [2002, p. 81]) are unlikely to increase consumer welfare, because they would increase costs and reduce the scope of DTC advertising and therefore limit its benefits.

Conversely, the FDA should consider relaxing some of its rules. The context of FDA regulation virtually ensures that its advertising standards are too stringent and thus deprive the market of useful information. An obvious problem is the quantity of warning information required in broadcast advertisements. This information, which is already modulated according to risks, could be further simplified and shortened, partly by replacing simpler advice to the effect that physicians will have opinions about whether and how to use the drug. One effect would be greater relative prominence for strong warnings in advertisements for the few drugs for which dangers are substantial and consumer vigilance is especially useful. In addition, the FDA could accelerate (with help from manufacturers) its ongoing effort to simplify consumer risk and dosage information, which would allow the substantial proportion of consumers who look at this material in advertisements to make more sense of it (see FDA 2001b).

More generally, the FDA should reconsider the notion that all DTC advertisements need to balance information about risks and benefits. Advertising works best as a dynamic medium, filling the most important relevant holes in consumer awareness and emphasizing different product features as dictated by circumstances. This makes information dissemination more efficient, an essential virtue in information-intensive markets such as pharmaceuticals. (Consumers assume that information in advertisements is biased in favor of the advertiser and have recourse to more objective sources.) In addition, advertising is necessarily poorly targeted, and the vast majority of viewers are unlikely to use the advertised product. It makes more sense for detailed risk information to be targeted precisely at users, which would be the natural result of focusing risk dissemination in physician offices and pharmacies. Despite the absence of detailed risk information in advertisements, the ability of consumer advertising to work well in medical markets is apparent for products such as hospitals, clinics, physicians, and dentists.

The FDA has shown considerable energy and courage in opening up DTC advertising, which is prohibited by all other advanced economies except New Zealand. It has also commissioned surveys that could have easily demonstrated harm from its DTC ad policy, a level of self-scrutiny that is rare among regulatory agencies. Nonetheless, there are reasons to believe that the FDA is not the best agency for regulating DTC advertising.

Congress should consider returning responsibility for prescription drug advertising (at least when directed to consumers) to the FTC, which had jurisdiction before the 1962 amendments to the Food, Drug, and Cosmetic Act (see Calfee 1996). This would permit regulation to focus on advertising and communication, unencumbered by pervasive regulatory linkages to other matters such as new drug approvals and manufacturing oversight. Regulation would also be conducted by an agency with superior experience and expertise in assessing advertising. Most important is that the FTC must defend its actions in court against advertisers that are not afraid to challenge the agency and possibly offend its staff. This provides an essential system of checks and balances, which is the only way to ensure that the regulating agency strikes a reasonable balance between the dangers of deceptive advertising and the consumer benefits of a free flow of commercial information. Fortunately, there is little reason to fear that FTC regulation would engender damaging advertising claims for inherently risky products. This is clear from the FTC’s record in regulating advertising for such diverse products as hospitals, clinics, physicians, medical devices, and even automobiles and motorcycles. The FTC could easily augment its staff with a small group of pharmacology experts and consult with outside experts, as it already does on other matters involving health and safety.

In the absence of legislation, the FDA should make advertising regulation more independent from drug approvals and manufacturing regulation. The Division of Drug Marketing, Advertising, and Communications, which regulates DTC advertising, should be transferred out of the Center for Drug Evaluation and Research (CDER), to report directly to the FDA Commissioner. The new division should add staff with
expertise in advertising and its effects and should operate independently from CDER. These changes would substantially reduce manufacturers’ qualms about challenging advertising regulations, which could lead to litigation in which FDA advertising rules would be subject to judicial scrutiny and First Amendment protections for commercial speech.

Finally, the United States should take advantage of the New Zealand experience, described in Hoek and Gendall’s (2002b) article. New Zealand has demonstrated that self-regulation for DTC advertising can work well, providing substantial information to patients with little apparent harm, while also achieving support from the medical community. This is of great significance precisely because the New Zealand experience departs so strongly from both the American system and those in Europe and other developed nations. This experience strongly suggests that many of the protections in the tightly regulated pharmaceutical information regimes of Europe and Canada are both unnecessary and costly to consumers.

Toward New Research

Little is known about the effects of DTC advertising, especially its impact on consumer behavior (as opposed to attitudes and knowledge) and, ultimately, on consumer health. Even elementary knowledge of the nature of the market forces unleashed by the FDA in its August 1997 policy change is lacking. Experience in other markets, such as airlines, has shown that short-term effects of deregulation often differ strongly from long-term effects, which may be very different from those expected by both supporters and opponents of regulatory change (Morrison and Winston 1995). Second-order effects from DTC advertising, such as enhanced consumer participation in health care decisions, improved patient compliance, faster research and development, swifter development and adoption of new uses for older drugs, smaller distribution margins (a typical result of national brand advertising), and increased awareness of non-drug therapies, could dominate short-term effects.

The papers in the USDHHS (2001) conference (Bero and Lipton 2001; Frank et al. 2001; Schommer and Hansen 2001) provide useful suggestions, with considerable attention to consumer research methods. Econometric research is promising, though little has been performed to date. Panel data may prove especially useful for both consumer research and econometric methods. Large sample sizes, rich demographic data, and the ability to employ longitudinal methods to assess the impact of waves of DTC advertising, with lagged effects, offer exceptional opportunities to test many hypotheses regarding compliance, for example, as well as physician visits and prescriptions.33

Finally, physician surveys, with all their expense and difficulty, could also be useful. Two major efforts, one by the FDA and the other by a group at Harvard School of Public Health (with industry funding), should be forthcoming soon.

33To assess the brand-level effects of statin drug advertising, see Wosinska (2001) for a recent analysis of panel data.

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