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**Testimony before the Senate Special Committee on Aging**  
**on The Impact of Direct-to-Consumer Drug Advertising on Seniors'**  
**Health and Health Care Costs**  
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Like all interventions in health care, direct-to-consumer (DTC) advertising should be evaluated by comparing its risks to its benefits, in the context of the available or potentially available alternatives. The objective, of course, is to realize the potential benefits while minimizing the risks. On balance, we believe that the clearly demonstrated adverse effects of DTC advertising outweigh the still-undemonstrated, theoretical benefits of the advertising. Every country in the world has reached this conclusion, except the United States. Only New Zealand has ever permitted DTC advertising, but it imposed a moratorium in December 2004. The European Union considered permitting DTC advertising, but rejected the idea.

**DTC Advertisements Bear Little Relationship to Public Health Needs**

Predictably, DTC advertising has been concentrated on new, expensive drugs for conditions that are bothersome and incurable. Thus, according to the Government Accounting Office (GAO), the top 15 DTC-advertised drugs in 2000 accounted for 54% of all DTC advertising expenditures.<sup>1</sup> Only 14% of sales for the top 50 DTC-advertised drugs is for acute conditions and only one of the top 50 DTC-advertised drugs was an antibiotic, presumably because patients are generally cured and have no need for refills. Most are targeted at seniors. Strikingly, one never encounters advertisements for generic drugs, even though, for example, generic diuretics are the most cost-effective method for preventing heart attacks and stroke.<sup>2</sup> Because patient entreaties are unlikely to induce a physician to initiate or change a prescription for a cancer drug, these are also less likely to be advertised. Of course, DTC advertising shoulders aside non-drug interventions such as behavioral smoking cessation, weight-loss or exercise programs, which can be less costly, safer or more effective. In sum, there is little relationship between our true public health needs and the subjects of DTC advertising.

**Many DTC Advertisements Are Misleading or Dangerous**

In the eight years since the FDA opened the floodgates to broadcast DTC advertising, numerous inappropriate advertisements have appeared. The most widely discussed have been the massive DTC campaigns waged by the manufacturers of the Cox-2 inhibitors. Importantly, these drugs were never proved to be more effective pain relievers than many drugs available over-the-counter. For most patients the purported stomach protection offered by these drugs (a claim that the FDA permitted only for Vioxx, but through industry promotional efforts came to be associated with the other Cox-2 inhibitors as

well) was irrelevant as those patients tolerated conventional pain relievers without stomach upset. Nonetheless, an estimated two-thirds of the growth in Cox-2 use between 1999 and 2000 was among such patients.<sup>3</sup> In 2000, Vioxx was the number one DTC-advertised drug – at \$160 million, larger than the campaigns that year for Pepsi and Budweiser – and retail sales quadrupled.<sup>4</sup> With as many as 140,000 serious cardiovascular events due to Vioxx alone,<sup>5</sup> the dangers of such promotions are now increasingly apparent. Other drugs that have been transformed from pedestrian to blockbuster in part by DTC advertising are Claritin for allergies and Singulair for asthma.

One of the more astounding DTC advertisements we have seen is attached to this testimony and is still running. Produced by Galderma Laboratories, the makers of the prescription acne medication Differin (adapalene), and broadcast both on the Internet<sup>6</sup> and on MTV, the advertisements direct teenage viewers to a portion of the Differin website to receive free music downloads. The advertisements are clearly directed at teenagers: the viewer is exhorted to obtain a Teen Survival Handbook and to take a self-test on acne called Zit 101, a course on offer at Acne High. The advertisement plays to teenage fears (“Remember: There are thousands of pores on your face, which means your skin has the potential to ‘give birth to’ thousands of microcomedones.”) and notions of empowerment (“Fight Acne with Free Music. How Cool is That?”). Realizing that many teens will visit physicians only with their parents, the website has an entire section on “Talking to Parents About Acne.” If you can convince your parent to help you secure a prescription for Differin, the benefits multiply: the “3 levels of cool” are Level 1: sign up (two free music downloads); Level 2: get and fill Differin prescription (seven free downloads); and Level 3: refill Differin prescription (ten free downloads). Bribing physicians to prescribe medications has long been held to be illegal. This advertisement essentially pays teenagers to convince adults to procure this drug for them, with the size of the payment in proportion to the amount of drug prescribed. Incidentally, a previous Differin DTC advertisement has already been the subject of an FDA regulatory letter.<sup>7</sup>

An improbable new low in inappropriate DTC advertising was reached in a November 2004 advertisement by AstraZeneca on its website and in print that actually had the audacity to mislead the public by misrepresenting the FDA. In an advertisement for the cholesterol-lowering drug Crestor, a drug associated with muscle and kidney damage, AstraZeneca claimed that “We have been assured today at senior levels in the FDA that there is no concern in relation to CRESTOR’s safety.” Public Citizen wrote to the FDA<sup>8</sup> pointing out that the agency was actually on record stating that “[the Agency] has been very concerned about Crestor since the day it was approved, and we’ve been watching it very carefully.” The agency forced the company to terminate its campaign.<sup>9</sup>

### **Consumers Are Being Misled**

Consumers have many misconceptions about DTC advertising. In one survey, 50% believed that DTC advertisements had to be pre-approved by the government and 43% thought that only “completely safe” drugs were allowed to be advertised.<sup>10</sup> Studies conducted by the FDA itself confirm the dangers of DTC advertising. The agency’s 2002 survey<sup>11</sup> found that 60% of patients thought that the advertisements provide insufficient

information about drug risks and 44% felt similarly about benefits. Fifty-eight percent believed the advertisements made the drugs appear better than they are, and 42% said the advertisements made it seem as if the drug would work for everyone.

Consumer support for these advertisements is actually declining. Compared to a similar FDA survey in 1999, fewer patients responding to the FDA's 2002 survey said that the advertisements had prompted them to talk to a doctor (27% in 1999 vs. 18% in 2002), fewer said that the advertisements provide enough information even to decide whether to consult a physician (70% vs. 58%), fewer felt that the advertisements helped them make better decisions about their own health (47% vs. 32%) and fewer "liked seeing" the advertisements (52% vs. 32%).<sup>11</sup>

### **Doctors Are Being Coerced**

Early defenses of DTC advertising asserted that physicians would not be manipulated by patient demands based on DTC advertisements. Unfortunately, this assertion has proved to be wrong. In an already classic study published in the *Journal of the American Medical Association* in April, Kravitz and colleagues sent "standardized patients" with either depression or adjustment disorder into doctors' offices.<sup>12</sup> The patients either 1) described their symptoms and made no specific request for medication; 2) said they had seen a program on television and wondered about drug treatment; or 3) said they had seen a DTC advertisement for Paxil. Of standardized patients with adjustment disorder, a condition not generally requiring drug treatment, 10% of those making no specific request received a prescription (none for Paxil), compared with 55% of those saying they had seen a Paxil advertisement (67% for Paxil) and 39% of those making a general request (26% for Paxil). Clearly these advertisements can spur unnecessary drug prescribing.

Of course, in principle, doctors could be grateful for patients' prompting. But other empirical research suggests otherwise. In one study, doctors were asked whether they considered drugs they had just prescribed to be only "possible" or "unlikely" choices. Fifty percent answered affirmatively for DTC-advertised drugs that were prescribed at the patient's request, compared to only 12% of new prescriptions not requested by patients.<sup>13</sup> Thus, physicians often accede to patients' DTC-driven requests, but are left feeling uneasy.

### **The Price of Health Care is Being Driven Up**

Predictably, the cost of health care is being driven up, as patients are induced to request newer, more expensive medications instead of equally effective, older, generic alternatives. One report indicated that the top 25 DTC-advertised drugs accounted for 41% of the growth in retail drug spending in 1999.<sup>14</sup> The report did not separate the effects of DTC advertising from those of advertising to physicians, which often go hand-in-hand. The GAO agreed that "DTC advertising appears to increase prescription drug spending and utilization,"<sup>1</sup> primarily because of increased utilization, not increased prices. In a study that did separate out the various forms of advertising, the growth in

DTC advertisements for the 25 largest therapeutic classes accounted for 12% of drug sales growth from 1999 to 2000 and resulted in an additional \$2.6 billion in pharmaceutical expenditures in 2000.<sup>15</sup> The GAO has estimated that a 10% increase in DTC advertising translates into a 1% increase in sales for that class of drugs, an enormous increase given that many drug classes sell in the billions of dollars.<sup>1</sup> One way or another – through insurance premiums, co-payments or taxes – consumers foot the bill for all this.

### **Potential Benefits of DTC Advertising**

The principal benefit asserted by supporters of DTC advertising is that patients with undertreated conditions might receive treatment they otherwise would not have received. This claim remains unproven. The only comprehensive review of studies on DTC advertising concluded that “No empirical research has demonstrated better communication [between patients and physicians] and improved health outcomes.”<sup>16</sup> The authors continue: “The onus is on those who might support [DTC advertising] to produce evidence of benefit and, in the absence of this evidence, we must assume that the likely disbenefits (clinical and economic) outweigh the as yet unproven benefits.”

Although the review excluded the recent Kravitz study,<sup>12</sup> the Kravitz study hardly supports DTC advertisements. While it is true that, in the Kravitz study, DTC advertisements led to more prescribing of antidepressants for those standardized patients presenting with depression, general entreaties to physicians were actually more effective than those based on DTC advertisements (76% prescribing rate vs. 53%). (This assumes that prescribing an antidepressant to a depressed patient at his or her first visit is good medicine.) As noted, the study also showed that DTC produced massive overprescribing of antidepressants for those patients with adjustment disorder who have little need for them; the study leaves unanswered whether patients with depression or adjustment disorders are more likely to approach their doctors. Regardless, it seems clear that the purported benefits of DTC advertising can be secured more effectively through non-commercial public-service announcements, without the risk of misleading the public or driving up health-care costs unnecessarily.

### **FDA Enforcement is Lackadaisical**

For years, Public Citizen have tracked FDA’s drug advertising enforcement. The attached figure depicts all Warning Letters and Untitled Letters dating back to 1997. Despite a small increase in enforcement activity this year (and FDA has elsewhere claimed that there has been an increase in enforcement activity for DTC advertising specifically), the broader trend is more important: an 85% decline in enforcement actions between 1998 and 2004, the last year with complete data. Much of this decrease predates the current administration, but there was an added drop in 2002. This drop was due to the policy of then-Chief Counsel Daniel Troy to require all regulatory letters to pass through his office, a departure from previous practice and a change that, according to the GAO, “adversely affected” FDA’s oversight. The GAO concluded in 2002 that “Since the policy change, [the Office of the Chief Counsel’s] reviews of draft regulatory letters

from FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before FDA issued the letters.”<sup>17</sup> According to a report by the Minority Staff of the Committee on Government Reform, in 2003 the average time from initial placement of a prescription drug advertisement and an enforcement action (if any) was 177 days.<sup>17</sup> Recidivism is common; the companies with the largest numbers of advertising-related regulatory letters between 2002 and 2005 were Pfizer (11); Roche, Boehringer Ingelheim and Novartis (five each); and Glaxo (four).<sup>18</sup> The drug advertising division remains greatly understaffed to cope with the continually rising levels of advertising, and DTC advertising in particular.

## **Conclusion**

Even if one were to grant, on a strictly hypothetical basis, that DTC advertisements did, incidentally, convey some useful information to consumers, the real question remains: Are there alternative methods for conveying this information that avoid the risks of DTC advertisements? The answer, as the Kravitz study demonstrates, is an indisputable “yes”: If antidepressants were indeed underprescribed, requests based on general entreaties to physicians led to more prescribing than requests based on DTC advertisements. This unproven benefit weighs poorly against the proven risks of DTC advertising.

## **Recommendations**

In developing an approach to reducing the harms of DTC advertising, three overriding points are worth noting. First, at least under prevailing legal interpretations, DTC advertising is unlikely to be prohibited in the United States. Second, the industry has demonstrated a gross inability to police itself. It is only the public-relations disaster of the Vioxx debacle that has roused PhRMA to develop DTC advertising guidelines.<sup>19</sup> These guidelines are, of course, voluntary, and are designed primarily to stave off more aggressive legislation or regulation. The guidelines recommend that companies should wait “an appropriate amount of time” after launching a new drug before initiating a DTC campaign. (Senator Frist has recommended a two-year waiting period.) Third, the growth of broadcast DTC advertising did not arise magically. Rather, it was the predictable result of FDA’s deregulatory efforts.\* It follows that the genie can, to a large extent, be put back in the bottle.

How, then, is the public to be protected from this misleading information? First and foremost, FDA-approved patient information for all prescription drugs is necessary. In 1979, the FDA proposed just this, but opposition from organized medicine, which feared the erosion of its authority, and the pharmaceutical industry ensured that the proposal was withdrawn early in the Reagan administration. In the 1990s, the idea was revisited in the form of FDA-approved Medication Guides, but we estimate that only about 75 drugs of the thousands on the market have such Guides. Instead, the market has been left to the

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\* Until 1997, all DTC advertisements that sought to link a disease with a particular drug had to provide the so-called Brief Summary, an often extensive review of potential adverse effects of the drug being advertised. Since 1997, companies have been permitted to refer consumers to websites, print advertisements or toll-free telephone numbers to obtain this information.

makers of Patient Information Leaflets, which are not FDA-approved and which, as we have shown in three studies,<sup>20,21,22</sup> often omit important safety information. FDA-approved information for patients, rather than self-serving advertising, is the appropriate response to the dearth of patient-appropriate drug information. As Franz Ingelfinger, the editor of the *New England Journal of Medicine* once argued, “advertisements should be overtly recognized for what they are – an unabashed attempt to get someone to buy something, although some useful information may be provided in the process.”<sup>23</sup>

Federal agencies could also be doing more to educate patients. The agencies most able to do this are the FDA itself, the National Institutes of Health and the Agency for Healthcare Research and Quality. The failure of these agencies to step into the information gap and fulfill their educational missions allows the industry to cloak its advertising in the mantle of education. Of course, if the industry truly wished to exhort patients to seek care for undertreated medical conditions, it would avail itself only of “help-seeking” advertisements, which inform patients of the existence of particular diseases without naming a treatment. Such advertisements are regulated by the Federal Trade Commission instead of the FDA, presumably because they have less capacity to mislead.

Even as DTC advertising has mushroomed from a \$791 million industry in 1996<sup>24</sup> to a \$4.1 billion one in 2004,<sup>25</sup> the FDA has yet to publish any regulations regarding DTC advertisements. Some guidances have been promulgated,<sup>26,27,28</sup> but these are voluntary and the agency has little ability to enforce them, in part because the advertising division is so severely understaffed and because regulatory letters have to pass through the Office of the Chief Counsel. At a minimum, regulations should provide for pre-review of television advertising and should not allow celebrity endorsements. More fundamentally, the agency still does not have the ability to levy civil monetary penalties. Instead, the FDA issues (often delayed) Warning Letters and Untitled Letters, which often arrive after the advertisement has completed its run, by which time millions of people have already been exposed to their misleading messages.

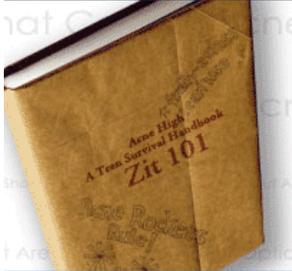
Health-care observers have long noted that health care is unlike other markets in that patients typically do not purchase services directly. Rather, due to the complexity of the decisions involved and the potentially life-threatening nature of poor choices, the physician acts as a “learned intermediary” on the patient’s behalf. DTC advertising is nothing less than an end-run around the doctor-patient relationship – an attempt to turn patients into the agents of pharmaceutical companies as they pressure physicians for medications they may not need.

**Differin®**  
(adapalene cream) CREAM, 0.1%



Select a picture from above to navigate sections.

**Acne Basics**   **True or False?**   **Talking to Parents**  
**Ask Your Doctor**   **Skin Care**   **The Right Routine for You**



Make sure you pass  
**Zit 101.**  
Get your  
**Teen Survival Handbook.**

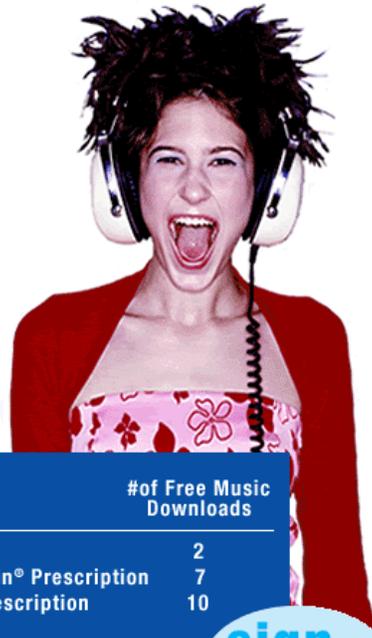
# Get Free Music. Fight Acne. Stay cool.

tell a friend

Get free music downloads from Differin® and RealPlayer Music Store — every time you fight acne with Differin®. RealPlayer Music Store has all the hit music you love, from rock to rap, from country to pop. It's ready and waiting.

So rock harder. And rock acne free. [Sign up now](#) — so you can download free music and receive tips and ideas for keeping your skin looking great.

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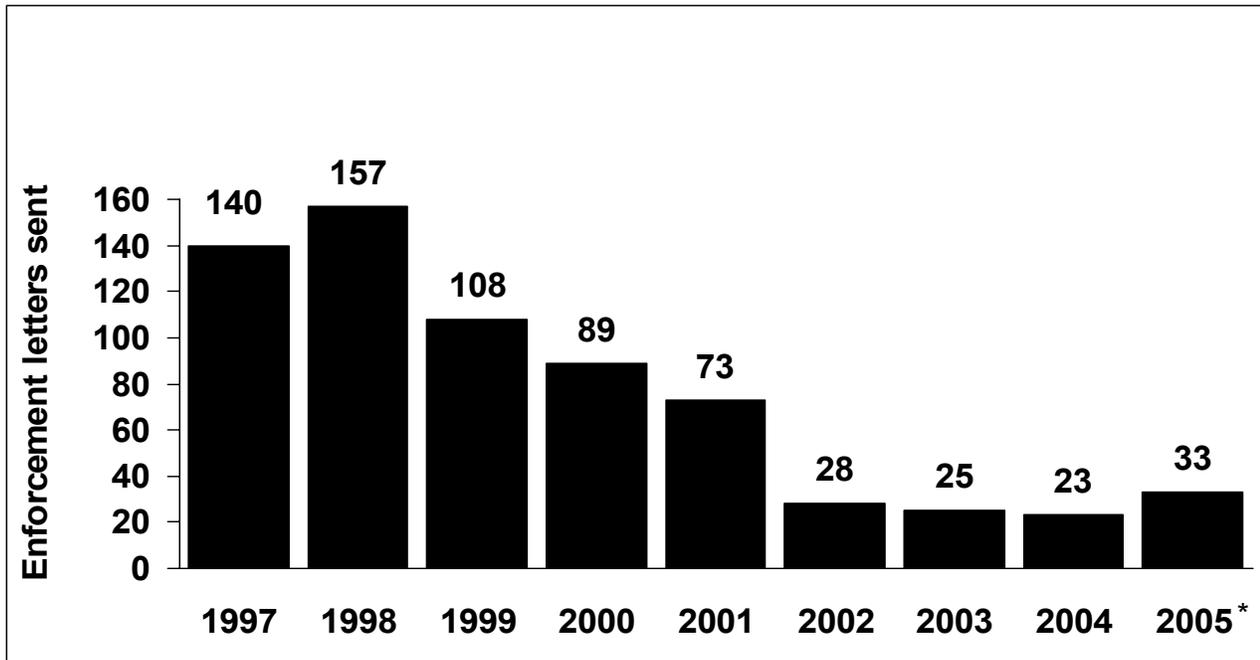


## the 3 levels of cool

| Level | Requirement                         | # of Free Music Downloads |
|-------|-------------------------------------|---------------------------|
| 1     | Sign Up                             | 2                         |
| 2     | Get and Fill Differin® Prescription | 7                         |
| 3     | Refill Differin® Prescription       | 10                        |

sign up

# FDA Warning and Untitled Letters to Drug Companies, 1997-2004



\*Projected from data through August

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