

**Testimony of Gary Ruskin, Executive Director of Commercial Alert  
Before the U.S. Food and Drug Administration  
Hearings on Direct-to-Consumer Prescription Drug Advertising  
November 2, 2005**

Thank you for inviting me to testify today.

I'd like to start by quoting three letters sent to the Subcommittee on Oversight and Investigations of the U.S. House of Representatives, Committee on Energy and Commerce, some two decades ago.

“Schering-Plough believes there is a fundamental flaw in the concept of advertising prescription pharmaceuticals directly to patients, and that is the inability to provide them complete, meaningful and useful information.”<sup>1</sup>

That quote did not come from a critic of the industry, or some consumer watchdog. It came from Allan S. Kushen, who was then senior vice president for public affairs at Schering-Plough. Most of his peers in the pharmaceutical industry agreed.

“We do not believe that [prescription drug advertising to consumers] is a good idea,” wrote Thomas M. Collins, president of Smith Kline & French Laboratories. “[T]he likelihood that meaningful patient education will occur is small...” It “can inform, but it is not education; and [it] should not be portrayed as a part of the education process.”<sup>2</sup>

“We do not believe that prescription drug advertising to consumers is in the public interest,” wrote Robert A. Schoellhorn, chairman of Abbott Laboratories. “We believe direct advertising to the consumer introduces a very real possibility of causing harm to patients who may respond to advertisements by pressuring physicians to prescribe medications that may not be required.”<sup>3</sup>

Today, I want to explain why these gentlemen are right.

First, a word about why I'm here, and what my expertise is. I am the executive director of Commercial Alert, which is a nonprofit organization that protects children and communities from commercialism. We are a watchdog group for the advertising industry, and my full-time job is to study commercialism and the advertising industry, and to mitigate the damage that they do to the American public.

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<sup>1</sup> Prescription Drug Advertising to Consumers, Staff Report for the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. 98<sup>th</sup> Congress, 2<sup>nd</sup> Session, Committee Print 98-DD, September, 1984, p. 146.

<sup>2</sup> Prescription Drug Advertising to Consumers, pp. 150-151.

<sup>3</sup> Prescription Drug Advertising to Consumers, p. 80. For a useful account of this report, and the circumstances surrounding it, see Greg Critser, *Generation Rx: How Prescription Drugs Are Altering American Lives, Minds and Bodies*. New York: Houghton Mifflin Co., 2005.

I'm going to respond directly to questions you have posed. But at the outset, I want to emphasize that under the prescription drug laws,<sup>4</sup> and the principles that underlie them, there is no basis for allowing direct-to-consumer (DTC) prescription drug advertising. By law, only doctors may prescribe prescription medicine. There is no legitimate purpose in advertising what consumers may not directly purchase. For this reason alone, DTC advertising should be prohibited.

Now I'd like to focus my testimony today on questions #1 and #3 in the Food and Drug Administration's (FDA) notice of public hearing.

Question #1 asks: "Does current DTC promotion present the benefits and risks of using medical products in an accurate, nonmisleading, balanced and understandable way?"

The answer is no. DTC advertising is inherently misleading.

1. Pharmaceutical companies have conflicts-of-interest that keep them from presenting unbiased information about their products.

Pharmaceutical companies exist to make a profit. That is their duty under the law – to yield a maximum return for their shareholders. In order to do that they have to sell drugs. The more drugs they sell, the better their shareholders will do. Every piece of information that the company sends out must be geared to this end.

This is why pharmaceutical companies are not a good source of information about their own prescription medicines. Their financial interests directly conflict with any intention to provide unbiased information about their products. Because of their financial conflicts-of-interest, pharmaceutical companies are perhaps the least trustworthy sources for information about their own drugs. By their very nature, drug companies hype the benefits – or alleged benefits – of their drugs and downplay the negatives. They encourage people to see their problems as diseases that require medication. The result is a public that is increasingly pathologized and drugged.

There are so many examples that it is hard to know where to start. But we might kick off the examples with the Cialis TV ad from this year's Super Bowl, which showed a rapid succession of mostly older couples smiling and caressing one other playfully, deep in love. The implication of the ad is that if you use Cialis, you will be loved.<sup>5</sup>

Then there's the recent Sepracor ad for Lunesta, a prescription sleep aid, featuring a worried woman afflicted with a "restless mind," tossing and turning in her bed. But after taking Lunesta, she awakes refreshed, smiling, almost radiant. "Ready to catch a great night's sleep?" the ad's narrator asks, "just climb into bed, and leave the rest to Lunesta." A restless mind is a sick mind, the ad implies, and Lunesta is the proper remedy for night worries.

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<sup>4</sup> Public Law 82-215, 65 Stat. 648.

<sup>5</sup> "Cialis – Be My Baby." Grey Worldwide. <http://hot.adcritic.com/content/cialis-sb05-bemybaby.html>.

2. Advertising agencies also have conflicts-of-interest that keep them from presenting unbiased information about their clients' products.

Ad agencies exist to sell products. That is their function, and reason for being. An ad agency that handles a drug company account is hired to help that company sell more drugs and boost profits. But a persuasive pitch for the severity of a drug's side effects will not sell more drugs. This conflict-of-interest makes advertising agencies institutionally incapable of fairly presenting the risks and benefits of their clients' drugs. Corporations do not pay millions of dollars to these agencies to sell fewer products, whether of drugs or anything else.

This too is an established fact. In a candid moment, two DTC advertising executives at FCB Healthworks wrote: "The ultimate goal of DTC advertising is to stimulate consumers to ask their doctors about the advertised drug and then, hopefully, get the prescription."<sup>6</sup> Please read that sentence over several times. It will answer most of the questions that prompted this hearing.

We also know the strategy works. For example, a study by the Kaiser Family Foundation concluded that "DTC advertising produces a significant return for the pharmaceutical industry: every additional \$1 the industry spent on DTC advertising in 2000 yielded an additional \$4.20 in sales."<sup>7</sup>

There is such a compelling case against DTC advertising that only the U.S. and New Zealand have ever allowed it, and New Zealand is expected to ban it again by the end of the year.<sup>8</sup> The European Parliament's Committee on Environment, Public Health rejected an effort to undo the E.U. ban on DTC advertising, and the Committee's decision was ratified by the entire European Parliament.<sup>9</sup>

3. The techniques used by pharmaceutical companies and advertising agencies are misleading.

(a) Creating a culture of disease and fear

Pharmaceutical companies and their advertising agencies strive to convince people that they are ill, and to invent new classes of illness. For example, in an article titled "The Art of Branding a Condition," Vince Parry, a marketing executive, discusses how pharmaceutical companies are "fostering the creation of a condition and aligning it with a product."<sup>10</sup> An article in *Reuters*

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<sup>6</sup> D. John Loden and Caroline Schooler Ph.D., "How to Make DTC Advertising Work Harder." *Medical Marketing and Media*, April, 1998.

<sup>7</sup> "Impact of Direct-to-Consumer Advertising on Prescription Drug Spending," The Henry J. Kaiser Family Foundation, June, 2003, p. 7.

<http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14378>

<sup>8</sup> "New Zealand to Ban DTC Advertising by '06," *Advertising Age*, September 5, 2005.

<sup>9</sup> Sarah Houlton, "Europe Turns Down DTC Test Run." *Pharmaceutical Executive*, January 1, 2003.

Alan Cassels, "Europe Rejects Pitch for Direct-to-Consumer Drug Ads." *Canadian Medical Association Journal*, January 21, 2003.

<sup>10</sup> Vince Parry, "The Art of Branding a Condition." *Medical Marketing & Media*, May 1, 2003.

*Business Insight* explains that drug companies can “create new disease markets” through “the medicalization of many natural processes” which are “worthy of medical intervention.” “Pharmaceutical companies are searching for new disorders,” the article continues, “based on extensive analysis of unexploited market opportunities (whether recognized today or promoted as such tomorrow). The coming years will bear greater witness to the corporate sponsored creation of disease.”<sup>11</sup> This often involves, according to Vince Parry, “elevating the importance of an existing condition,”<sup>12</sup> or “raising the level of awareness about something we don’t even know we have until we began looking at it further.”<sup>13</sup>

For example, GlaxoSmithKline took the notion of shyness and turned it into “social anxiety disorder.”<sup>14</sup> They hired the public relations firm Cohn & Wolfe to help establish “social anxiety disorder” as a way of “cultivating the marketplace” even before the launch of their drug Paxil. The Cohn & Wolfe effort, which involved “aggressive media outreach,” generated “1.1 billion media impressions” in one year, and won an award from the Public Relations Society of America.<sup>15</sup> Later on, GlaxoSmithKline issued a pamphlet claiming that “Social anxiety disorder is a lot more common than you think... 1 out of every 8 Americans suffers from social anxiety disorder. The good news is that it is treatable.”<sup>16</sup> But after a review of the literature, prominent psychiatrists argue that fewer than 1 percent suffer from social phobia.<sup>17</sup>

Another example is the marketing of the “erectile dysfunction” drugs Viagra, Cialis and Levitra, which has turned them into recreational drugs. The *New York Times* reported on “an increasing number of sexually healthy men, many in their 20's, 30's and 40's, who doctors and sex therapists say are using impotence drugs -- Viagra, Levitra and the new Cialis... as psychological palliatives against the mighty expectations of modern romance.”<sup>18</sup>

The advertising industry succeeds insofar as it makes people feel like they want to buy the drug advertised. “Consumers react emotionally,” said another DTC advertising executive, “so you want to know how they feel about your message and what emotional triggers will get them to act.... We want to identify the emotions we can tap into to get that customer to take the desired course of action.”<sup>19</sup> That’s marketing. It is not education.

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<sup>11</sup> J. Coe, “The Lifestyle Drugs Outlook to 2008, Unlocking New Value in Well-Being.” Datamonitor, *Reuters Business Insight*, Healthcare, PLC, 2003, pp. 42-3. Quoted in Ray Moynihan and Alan Cassels, *Selling Sickness: How the World’s Pharmaceutical Companies Are Turning Us Into Patients*. New York: Nation Books, 2005, p. xii and p. 179.

<sup>12</sup> Vince Parry, “The Art of Branding a Condition.” *Medical Marketing & Media*, May 1, 2003.

<sup>13</sup> *Selling Sickness*, p. 71.

<sup>14</sup> See especially *Selling Sickness*, pp. 119-138, and Michelle Cottle, “Selling Shyness,” *The New Republic*, August 2, 1999.

<sup>15</sup> *Selling Sickness*, pp. 121-123. For an excellent reportage on the public relations industry generally, see PR Watch and the Center for Media and Democracy, <http://www.prwatch.org>.

<sup>16</sup> *Selling Sickness*, p. 130.

<sup>17</sup> *Selling Sickness*, p. 130.

<sup>18</sup> Warren St. John, “In an Oversexed Age, More Guys Take a Pill.” *New York Times*, December 14, 2003.

<sup>19</sup> “Why Rubin-Ehrenthal Sticks Exclusively to DTC Accounts.” *Medical Marketing and Media*, September, 1999. Interview conducted by Warren Ross.

Here's how one PR expert at Ogilvy Public Relations explained how drug companies should expand their markets for osteoporosis drugs. The companies needed, she said, to "convince women who were much closer to the age of fifty that osteoporosis was something that they needed to be thinking about then, because there were steps they could be taking in their fifties and in their sixties, to make sure they didn't end up being that little old woman that they saw on the street."<sup>20</sup>

(b) Using visual imagery

Question #3 asks: "Could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers?"

The answer is no. Broadcast DTC ads are inherently misleading.

To understand why, it is important to examine the nature of television, and what it is good at. Television is great at entertainment. It excels at bringing show business into the homes of millions of Americans each day. It excels at presenting visual images to people. Visual images dance on the screen, and we watch them, and we are amused. That is what television does well.

In particular, it is good at using visual imagery to sell products. This is why advertisers migrated to TV in the early days -- even before most Americans did. To see a smoker taking a deep drag on the cigarette was much more evocative than a jingle on the radio. We want what we see. Television is an excellent selling medium.

Television is great at conveying images of happy tummies and smiling people who are relieved because they no longer suffer from "irritable bowel syndrome." But it is not so good at conveying complex information. The main reason is that television teaches us primarily with images, not words. Images are an inefficient way to convey most information. And while there are some things that you can learn through images, anything that is complicated, or requires conceptual analysis, is typically taught poorly through television. Neil Postman wrote that "it is in the nature of [television] that it must suppress the content of ideas in order to accommodate the requirements of visual interest."<sup>21</sup> We need words and symbols to understand what is complicated. Printed words are far better for teaching what is complicated for many reasons, including that you can easily look at it again, and analyze it, and evaluate it.

Television also encourages us to passively absorb what we see. But real education is active, not passive.

Television is excellent at spreading to millions of people what U.S. Senate Majority Leader Bill Frist called "upbeat fantasyland images."<sup>22</sup> But it is simply incapable of presenting the depth and

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<sup>20</sup> *Selling Sickness*, pp. 141-2.

<sup>21</sup> Neil Postman, *Amusing Ourselves to Death: Public Discourse in the Age of Show Business*. New York: Penguin Books, 1985, p. 92. See Postman's book generally regarding why television is a poor medium for education.

<sup>22</sup> U.S. Senator Bill Frist, "Concerns About Prescription Drug Advertising." July 1, 2005, 109th Congress, 1st Session, 151 Cong. Rec. S 7876.

richness of information that people need about pharmaceuticals, and certainly not in 30- or even 60-second spots.

Much the same is true for radio. The high cost of buying ads on the medium makes it impossible to convey the extensive information that consumers need about prescription drugs. And while radio is better suited for conveying complex information, it is still far inferior to print, because it is harder to repeat and review and review information that has been broadcast.

#### (c) Using actors and celebrity endorsements

The advertising industry employs actors in ways that are plainly deceptive. For example, it uses actors who do not, and have never, used the drug they are advertising. But it does not disclose that these actors are, in fact, deliberately falsifying any improvements in health that they are portraying or implying. This deception is so plain and outrageous that it can only be described as fraudulent.

Celebrity endorsements can be equally deceptive. For example, Wyeth hired the supermodel Lauren Hutton to promote its drug for hormone replacement during menopause. In an article in *Parade* magazine, Hutton said “My No. 1 secret is estrogen.” She continued, “It’s good for your moods, it’s good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I’d take the estrogen.” But there was no mention that she had been hired by Wyeth. Hutton was a hired shill, and her promotion of Wyeth’s drug had nothing to do with education.<sup>23</sup>

At best, paid celebrity endorsements have virtually no educational value. They come from paid shills with an anecdotal story to tell, and one that may have no relation to the relative merits of the endorsed drug.

### 4. DTC advertising harms consumers

#### (a) DTC advertising leads to the over-prescription of drugs

The purpose of DTC advertising is to increase the sale of a particular drug. But many people who see DTC ads could be harmed or even killed if they took the advertised drug. The results can be tragic.

For example, Merck & Co. deployed one of the largest DTC ad campaigns ever on behalf of Vioxx. Some of Merck’s ads made extremely broad appeals, such the tagline “for everyday victories,” for arthritis sufferers who wanted to overcome their disabilities.<sup>24</sup> In 2000 and 2001, Merck spent \$160.8 and \$135.4 million on Vioxx ads, the most for any drug during those years,

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<sup>23</sup> *Selling Sickness*, p. 43. Amy Allina and Cynthia Pearson, “The Great Hormone Hoax.” *Multinational Monitor*, July 1, 2002.

<sup>24</sup> Janice Rosenberg, “Head to Head Struggle; Initial Celebrix, Vioxx Ad Spending, Sales Stunning.” *Advertising Age*, April 3, 2000.

and *Advertising Age* named it one of its “Top 100 MegaBrands” for 2000.<sup>25</sup> According to a recent study in *The Lancet*, as many as 140,000 serious cardiovascular events in the United States resulted from the use of Vioxx.<sup>26</sup>

(b) DTC prescription drug marketing harms the doctor-patient relationship

In support of this argument, I’d like to present to you a statement I wrote that was endorsed by 211 professors from U.S. medical schools, calling for an end to DTC advertising. The statement’s endorsers include prominent medical school professors from Harvard, Johns Hopkins, University of Pennsylvania, Columbia, Stanford, Yale, Duke, University of California, San Francisco and other top medical schools, along with two former editors-in-chief of the *New England Journal of Medicine*.

The statement reads:

Direct-to-consumer marketing of prescription drugs should be prohibited.

In 2004, pharmaceutical companies spent more than \$4 billion in an onslaught of advertising to promote prescription drugs. This advertising does not promote public health. It increases the cost of drugs and the number of unnecessary prescriptions, which is expensive to taxpayers, and can be harmful or deadly to patients.

For more than half a century, certain drugs have been available to patients only with a prescription, because all drugs, including those that can heal, can also cause harm. Doctors, nurses and other health professionals have the necessary training and experience to help them decide whether drugs are indicated in particular cases. This is why they make the prescription decision, not patients.

Prescription drug advertising pressures health professionals to prescribe particular medications, and often the ones that may be less effective and more expensive and dangerous. This intrudes in the relationship between medical professionals and patients, and disrupts the therapeutic process. It takes up valuable time to explain to patients why they may have been misled by the drug advertisements they have seen.

Prescription drug advertising is not educational. It is inherently misleading because it features emotive imagery and omits crucial information about drugs and their proper use, as well as about side effects and contraindications that can be found on the full FDA-approved label. Drug companies have an inherent and

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<sup>25</sup> Mark Schumann, “Top 100 MegaBrands.” *Advertising Age*, July 16, 2001. Mark Schuman, “Megabrands.” *Advertising Age*, July 22, 2002.

<sup>26</sup> Graham DJ, Campen D, Hui R, Spence M, Cheetham C, Levy G, Shoor S, Ray WA, “Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-oxygenase 2 Selective and Non-selective Non-steroidal Anti-inflammatory Drugs: Nested Case-control Study.” *Lancet*, 2005 Feb 5-11;365(9458):475-81.

irredeemable financial conflict-of-interest which drives them to exaggerate the positive and minimize the negative qualities of their own products.

At a minimum, direct-to-consumer prescription drug advertising should not exist unless accompanied by the full FDA-approved label. Nor should drug ads be allowed to display imagery that is primarily emotive and not educational. Drug ads on TV and radio should be prohibited because they cannot meet this standard for truthfulness.

5. There is no justification for DTC advertising because consumers cannot obtain prescription medicines without a prescription

What is especially absurd about DTC advertising is that pharmaceutical companies are trying to push drugs at consumers – who cannot buy them, or at least not without a doctor’s prescription. For this reason alone, too, DTC advertising should be prohibited.

Only doctors and other medical professionals may diagnose disease and prescribe treatment. For over fifty years, since Congress passed the Durham-Humphrey Amendments, it has been illegal for consumers to obtain prescription medications without a prescription provided by a medical professional.<sup>27</sup> The law exists because many consumers do not have the knowledge, experience or diagnostic equipment to diagnose their own diseases, and some drugs are too toxic, dangerous, new, complicated or habit-forming to use except under the supervision of a physician. There is no way to reconcile DTC ads and the premise behind the laws governing prescription drugs, nor any legitimate justification for advertising drugs to people who cannot directly legally obtain them.

6. The minimum requirements for protecting the public from DTC ads

Under the Federal Food, Drug and Cosmetic Act (“the Act”), the labeling of drugs must not be “false or misleading in any particular.”<sup>28</sup> If the FDA believes that it cannot, at this time, fully prohibit DTC prescription drug advertising, we strongly urge the FDA to expand its interpretation of the term “misleading.”

(a) Any DTC ads should be accompanied by the full FDA-approved label.

At a minimum, direct-to-consumer prescription drug advertising should not exist unless accompanied by the full FDA-approved label. The label is the minimum amount of information needed for pharmaceutical marketing communication to be not misleading. Any marketing communication that presents less than that is misleading, because it is dangerously incomplete.

The FDA should consider the entire label as material information to a consumer’s decision-making process. Any marketing communication that does not include the entire label should be

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<sup>27</sup> Public Law 82-215, 65 Stat. 648.

<sup>28</sup> 21 U.S.C. § 352(a).

deemed misleading because it involves a failure to disclose key information about a drug and its effects.

Regarding the omission of material information, the FDA should consider the Federal Trade Commission's policy statement on deception. It states that "the practice of offering a product for sale creates an implied representation that it is fit for the purposes for which it is sold. Failure to disclose that the product is not fit constitutes a deceptive omission. Omissions may also be deceptive where the representations made are not literally misleading, if those representations create a reasonable expectation or belief among consumers which is misleading, absent the omitted disclosure."<sup>29</sup>

In essence, DTC prescription drug ads make an implied representation that a drug is fit for use by the consumers who view the ads. Such an implied representation is misleading if it is not accompanied by the full FDA-approved label.

(b) Remove the loophole for broadcast ads

DTC prescription drug print ads must include the brief summary,<sup>30</sup> which generally contains the each of the risk concepts from the product's approved labeling. And FDA regulations state that broadcast DTC ads may, instead of the brief summary, make "adequate provision...for dissemination of the approved or permitted package labeling in connection with the broadcast presentation."<sup>31</sup>

Regrettably, in its guidance for industry on consumer-directed broadcast advertisements, the FDA created a devastating loophole by interpreting "adequate provision" to mean that broadcast DTC ads may merely refer to print advertisements, websites or toll-free telephone numbers where consumers may gather this information.

There is no basis for this loophole, which establishes a stronger standard for DTC prescription drug advertising in print and a weaker one for broadcast media. It is not enough merely to tell people viewing a broadcast DTC ad to see the label elsewhere. In essence, this allows the broadcast ad itself to be misleading, with the hope that consumers will be able to seek out and read enough non-misleading information elsewhere. This is completely inadequate, and does not meet the requirement under the Act that DTC ads *themselves* must be non-misleading.

There is no public policy justification for lax standards for broadcast media, merely because the print standards are almost impossible for broadcast media to meet. In fact, this is a compelling reason to prohibit DTC ads on TV and radio, because these media are poorly suited to convey complicated information. At a minimum, there should be a uniform standard for all DTC advertising: the current print standard.

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<sup>29</sup> FTC Deception Policy Statement, appended to Cliffdale Associates, Inc. 103 F.T.C. 110, 175 (1984).

<sup>30</sup> The Act requires DTC ads to contain "information in brief summary relating to side effects, contraindications and effectiveness" 21 U.S.C. § 352(n).

<sup>31</sup> 21 C.F.R. § 202(e)(1).

(c) Non-educational imagery in DTC prescription drug ads should be prohibited

The pharmaceutical industry depends on emotional imagery to promote the sale of its products. The overwhelming majority of DTC ads feature imagery which is primarily emotive not educational. In this respect, it closely resembles advertising for consumer goods such as soap and cereal. There is no legitimate purpose for such non-educational imagery in DTC ads. All imagery that does not directly and precisely convey facts about a drug's action, indications, contraindications and side effects should be deemed misleading and should be prohibited.

(d) Governments, non-profits and news organizations that have no conflicts-of-interest are infinitely better qualified than drug companies to educate the public about drugs

Consumers need and deserve reliable sources of education about pharmaceuticals. Such education can only be provided by those who have no financial conflicts-of-interest regarding prescription drugs. The public may properly place its trust in entities that receive no money (other than taxes) from the pharmaceutical or advertising industries, and in persons within these entities who have no financial ties to the pharmaceutical industry.

7. Congressional failure to investigate DTC advertising

While the FDA deserves praise for re-considering the regulatory framework for DTC advertising, and for soliciting public comments about it, it is outrageous that the FDA is merely receiving testimony from the pharmaceutical and advertising industries about the worthy questions it asks in its notice of public hearing. Unfortunately, Congress has not granted the FDA administrative subpoena power.<sup>32</sup> In order to obtain definitive answers to the FDA's questions, Congress must either give the FDA administrative subpoena power, or must conduct a thorough investigation itself, which involves, at a minimum, issuing subpoenas for documents from pharmaceutical companies and their advertising agencies. In either case, the public deserves to read what these companies say to themselves in private about DTC advertising, and especially regarding whether their ads are misleading. It is an abject failure of the public trust that the Congress has not done so during the eight years since the FDA issued its draft guidance regarding consumer-directed broadcast advertisements.<sup>33</sup> Congress has put its head in the sand for the last eight years. It is time for this to end.

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<sup>32</sup> "The...power that is involved here is the power to get information from those who best can give it and who are the most interested in not doing so." *United States v. Morton Salt Co.*, 338 U.S. 632, 642 (1950).

<sup>33</sup> 62 FR 43171.

## **Appendix A**

### **Statement on Direct-to-Consumer Marketing of Prescription Drugs**

Direct-to-consumer marketing of prescription drugs should be prohibited.

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Prescription drug advertising pressures health professionals to prescribe particular medications, and often the ones that may be less effective and more expensive and dangerous. This intrudes in the relationship between medical professionals and patients, and disrupts the therapeutic process. It takes up valuable time to explain to patients why they may have been misled by the drug advertisements they have seen.

Prescription drug advertising is not educational. It is inherently misleading because it features emotive imagery and omits crucial information about drugs and their proper use, as well as about side effects and contraindications that can be found on the full FDA-approved label. Drug companies have an inherent and irredeemable financial conflict-of-interest which drives them to exaggerate the positive and minimize the negative qualities of their own products.

At a minimum, direct-to-consumer prescription drug advertising should not exist unless accompanied by the full FDA-approved label. Nor should drug ads be allowed to display imagery that is primarily emotive and not educational. Drug ads on TV and radio should be prohibited because they cannot meet this standard for truthfulness.

Prominent endorsers include:

1. Amy P. Abernethy, MD, Assistant Professor of Medicine, School of Medicine, Duke University
2. John Abramson MD, Clinical Instructor, Ambulatory Care and Prevention, Harvard Medical School; author, *Overdosed America*
3. Maria T. Abreu, MD, Associate Professor of Medicine, Mount Sinai Hospital, Director, Inflammatory Bowel Disease Center
4. Lisa V. Adams, MD, Assistant Professor, Department of Medicine and Community and Family Medicine, Dartmouth Medical School
5. Qais Al-Awqati, MB, ChB, Robert F. Loeb Professor of Medicine, College of Physicians and Surgeons, Columbia University
6. Elizabeth Alexander, MD, MS, Professor and University Physician, Department of Family Practice, Michigan State University
7. Murray D. Altose, MD, Professor of Medicine, School of Medicine, Case Western Reserve University
8. Bradley D. Anawalt, MD, Associate Professor of Medicine, School of Medicine, University of Washington
9. Barbara Anderson, MD, Professor of Pediatrics, Baylor College of Medicine
10. Marcia Angell, MD, Senior Lecturer, Department of Social Medicine, Harvard Medical School; former Editor-in-Chief, *New England Journal of Medicine*; author, *The Truth About the Drug Companies*
11. Cynthia Aranow, MD, Assistant Professor of Medicine, College of Physicians and Surgeons, Columbia University

12. David C. Aron, MD, MS, Professor of Medicine, School of Medicine, Case Western Reserve University Joseph Avruch, MD, Professor of Medicine, Harvard Medical School, Chief, Diabetes Unit, Massachusetts General Hospital
13. Thomas Aversano, MD, Associate Professor of Medicine, Cardiology, Johns Hopkins School of Medicine
14. Thomas C. Bailey, MD, Associate Professor of Medicine, Division of Infectious Diseases, Director, Medical Informatics, School of Medicine, Washington University in St. Louis
15. Robert Baltimore, MD, Professor of Pediatrics and Epidemiology, School of Medicine, Yale University
16. Barbara Barnett, MD, Assistant Professor, Departments of Internal Medicine and Emergency Medicine, Albert Einstein College of Medicine, Yeshiva University
17. Ellen Jo Baron, PhD, D(ABMM), Professor of Pathology and Medicine, Stanford University Medical College
18. Henry C. Barry, MD, MS, Associate Professor and Associate Chair for Research, Department of Family Practice, Michigan State University Medical School
19. Thomas M. Bashore, MD, FACC, FSCAI, Professor of Medicine, School of Medicine, Duke University
20. Carl Baum, MD, FAAP, FACMT, Associate Professor of Pediatrics, School of Medicine, Yale University
21. Tomas Berl, MD, Professor of Medicine, School of Medicine, University of Colorado, President, American Society of Nephrology
22. Robert Berger, MD, Professor of Medicine, Director of Medical Informatics, School of Medicine, University of North Carolina at Chapel Hill
23. John E. Billi, MD, Professor of Internal Medicine, School of Medicine, University of Michigan
24. Stanley J. Birge, MD, Associate Professor of Medicine, School of Medicine, Washington University in St. Louis
25. Mark Bogner, MD, FACEP, Associate Professor of Emergency Medicine, Residency Program Director, School of Medicine, University of Wisconsin
26. Scott R. Bolster, PharmD, Clinical Professor of Pharmacy, College of Pharmacy, University of Texas
27. Elizabeth A. Boyd, PhD, Assistant Adjunct Professor of Clinical Pharmacy, School of Pharmacy, University of California, San Francisco
28. Edward Boyko, MD, Professor of Medicine, School of Medicine, University of Washington
29. Daniel Brauner, MD, Associate Professor of Medicine, Pritzker School of Medicine, The University of Chicago
30. Arthur E. Broadus, MD, PhD, Ensign Professor of Medicine, Chief, Section of Endocrinology, Department of Internal Medicine, School of Medicine, Yale University
31. Philip Bromberg, MD, Distinguished Professor of Medicine, School of Medicine, University of North Carolina at Chapel Hill, University of North Carolina Hospitals
32. Alain Broccard, MD, Associate Professor of Medicine, Pulmonary and Critical Care Division, University of Minnesota Medical School
33. John M. Bruza, MD, Assistant Professor of Medicine, School of Medicine, University of Pennsylvania
34. Anne Burke MB, BCh, BAO, Assistant Professor of Medicine, School of Medicine, University of Pennsylvania
35. Deborah Burnet, MD, Associate Professor of Medicine, Pritzker School of Medicine, The University of Chicago
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