



**Testimony of Alex Sugerman-Brozan,
Director of the Prescription Access Litigation Project to the
FDA Public Hearing on Direct to Consumer Advertising
November 2, 2005**

The Prescription Access Litigation Project, or PAL, is a coalition of over 115 organizations representing consumers, health care advocates, seniors, labor union members, legal services organizations, and others. PAL is a project of Community Catalyst, a national advocacy organization that builds consumer and community participation in the shaping of our health system to ensure quality, affordable healthcare for all.. The organizations in our coalition have a combined membership of over 13 million people. PAL works to make prescription drugs more affordable for consumers by using class action litigation and public education to bring an end to illegal pharmaceutical price inflation.

We see deceptive marketing by pharmaceutical companies as one of the primary factors driving up the cost and inappropriate use of prescription drugs in the United States. This, in turn, is a major contributor to the health care crisis and health care inflation in this country, driving up premiums and depriving more and more people of medical coverage. Thus, we see the regulation of direct to consumer advertising not as a peripheral issue but one that cuts to the heart of the excessive cost and improper usage of prescription drugs. We recommend a number of changes to the FDA's regulation of DTCA, detailed below, and most importantly, an increase in the oversight and enforcement against deceptive DTCA.

We feel strongly that the net effect of DTCA is negative. Echoing statements by previous speakers, we feel that DTCA :

- Interferes with the doctor-patient relationship
- Creates unrealistic expectations of drug efficacy and downplays the risk and severity of side effects. We refer to this as the “**fields of flowers effect**,” so named after the common images of carefree people frolicking through fields of flowers in drug advertisements, giving the impression that the drug being promoted will make the user just as happy as the people shown in the ads.
- Fosters the misconception of drugs as “consumer goods” rather than medical treatment
- Promotes drug treatment as a panacea while undermining genuine public health messages that promote lifestyle changes such as diet, exercise, nonmedical interventions, and reduction of environmental exposures
- Furthers the misconception that “newer is better,” thus overpromoting expensive brand-name drugs whose real-world long-term side effect profiles are as yet unknown, at the expense of generics whose long-term safety and efficacy is well-documented
- Skews the research priorities of the pharmaceutical industry, by creating a system where higher profits can be gained by introducing “me-too” and “lifestyle” drugs for the so-

called “worried well” than by developing genuinely innovative medicines for smaller populations with more serious medical needs.

All of these effects drive up health care costs, with ripple effects throughout the economy and the health care system. DTCA financially harms consumers and third party payors directly (health insurers, union health and welfare funds and self-insured employers) by inducing consumers to purchase expensive prescription drugs that they may not need, that they might not have purchased if they had received more even-handed information, and that they might have substituted with equally effective cheaper generic drugs or lifestyle modifications. We see DTCA as a major contributing factor to the runaway costs of prescription drugs in the U.S. **It is our conclusion that the current regulatory and enforcement framework is inadequate to prevent deceptive and misleading marketing of prescription drugs that leads to billions of dollars in unnecessary drug spending every year.**

PAL holds an annual event called **the Bitter Pill Awards: Exposing Drug Company Manipulation of Consumers**. Several of our 2005 awardees illustrate what we see as the inherent flaws of DTCA:

- **The Speak No Evil Award: For Concealing Drug Risks and Benefits in the Name of Profits** was awarded to Pfizer and Merck, makers of Celebrex and Vioxx. We all know the devastating results of Merck’s failure to disclose the cardiac risks of Vioxx and the thousands of deaths alleged to be linked to that failure.

But there was also a massive financial effect of the promotion of Vioxx and Celebrex. More than 20 million people took these two drugs. Their only supposed advantage was a lower risk of GI complications. But even the FDA-approved labels for these drugs stated that only 1-2% of patients were at risk of such complications. These drugs were massively promoted – with the Dorothy Hammill ads for Vioxx and the Celebrex ads with the “Celebrate” jingle that 2/3 of the people in this room could probably sing from memory. These promotional campaigns turned drugs that should have been small niche drugs for a very targeted population into two of the most massive blockbusters in the history of modern medicine. The ads created the impression that these were so-called “super-aspirins” that provided much better pain relief – they played into the public misconception that newer is better and that prescription medicines are better than over-the-counter.

In addition to the thousands of unnecessary deaths and hundreds of thousands of unnecessary heart attacks, these drugs sucked money out of the wallets of millions of Americans and from a health care system already reeling from out of control drug costs. It is possible that even in the absence of DTCA, untrammelled promotions to physicians by drug company salespeople would still have resulted in many inappropriate and unnecessary prescriptions for these drugs. But it was the ubiquitous and relentless promotions to consumers that drove millions of Americans to their doctors’ offices, demanding the latest and greatest. The regulatory and enforcement environment would have had to be significantly different to prevent this from happening.

- **Least Extreme Makeover Award: For Dressing Up an Old Drug with a New Name and a New Price Tag** was given to AstraZeneca, makers of Nexium. Nexium is one of the rawest examples of the tactics used by drug companies to wring profits and market share from consumers and the health care system, with little or no benefit to health or the pharmaceutical armamentarium available to physicians. Nexium is an isomer of Prilosec, AstraZeneca's previous heartburn and reflux blockbuster. Nexium at comparable doses is clinically no more effective than Prilosec, yet is at least seven times more expensive than Prilosec, which is now available over the counter. Some have joked that the main difference is the three yellow stripes on the pill. The trials that AstraZeneca uses to show Nexium's supposed advantage compare a 40 mg dose of Nexium to a 20 mg dose of Prilosec. Even with that difference in dosage, the supposed "advantage" of Nexium is far from overwhelming: two studies showed a slight increase in the numbers of people with sustained resolution of heartburn and erosive esophagitis healing, and one study showed no statistically significant difference at all. When Nexium was put head-to-head against Prilosec at 20 mg dosages, there was no difference.

Business Week estimates that 2005 sales of Nexium will be \$4.6 billion. With five other proton pump inhibitors on the market, as well as numerous H2 antagonists that would suffice for millions of people with just simple heartburn, why would this drug have such massive sales? Two words: Purple Pill. AstraZeneca has poured millions into promoting Nexium.

The drug industry claims that its advertisements educate consumers about medical conditions and available treatments but that is completely absurd. These are advertisements, not public service announcements. As Marcia Angell, author of the Truth About the Drug Companies, said:

“[T]o rely on the drug companies for unbiased evaluations of their products makes about as much sense as relying on beer companies to teach us about alcoholism...

The fact is that marketing is meant to sell drugs, and the less important the drug, the more marketing it takes to sell it. Important new drugs do not need much promotion. Me-too drugs do.”

Any educational benefit is significantly outweighed by the negative effects described above. There are other ways of educating the public about medical conditions and the need for treatment that do not carry the “baggage” of DTCA. The effect of DTCA is to place a profit-driven corporation in between the doctor and the patient, and to substitute the financial interest of that corporation in place of the reasoned judgment of the prescriber. It has no place in our medical system, and that is why every country but the US and New Zealand does not permit it – and even New Zealand is reconsidering whether it ought to remain legal.

That said, the conventional wisdom is that DTCA is here to stay, a product of the 19th century legal fiction that corporations are “persons” and thus entitled to the right of “free speech.” The question then is how best to regulate and monitor DTCA and defang its worst aspects.

PhRMA recently issued its own “guidelines” on DTCA, to much fanfare. The FDA should take no heed of these whatsoever. As Ronald Reagan is reported to have said, “Trust, but Verify.” Voluntary guidelines which do not require compliance, which have no enforcement mechanism

and which carry no penalties for violation are a public relations measure, nothing more. They are intended to allay public anger at the recent scandals involving drug industry deception (Vioxx, Celebrex, Paxil) and to reduce the momentum for Congressional or regulatory action restricting DTCA. The history of public enforcement is littered with the remnants of “self-regulation” by industry, which amounts to little more than the proverbial fox guarding the henhouse.

We strongly urge the FDA to take the following actions:

1. Increase enforcement against specific deceptive advertisements.

FDA enforcement, in the form of untitled and warning letters, has decreased significantly over the past seven years. The number of letters issued in 2005 is approximately 20% of the number issued in 1998. This sends a strong message to the industry that deceptive advertisements are unlikely to be acted upon. It also fosters the understandable public belief that the FDA is more protective of the interests of industry than of the health and safety of the consumer. Although the number and frequency of letters is up in 2005 compared to 2004, ending a seven year downward trend, the level of enforcement is still way too low. This is partially a function of resources. Dr. Rachel Berman, Deputy Director of the Office Medical Policy at the FDA’s Center for Drug Evaluation and Research, in her testimony to the Senate Special Committee on Aging on September 29, 2005 that the FDA has 40 staff to review all drug promotions, including both DTCA and promotions to medical professionals. She reported that there were 52,800 promotional pieces in 2004. This required each and every of the 40 staff to review 1,320 pieces per year, or 5.5 per day.¹ That’s just under 90 minutes per piece. This pace and workload runs strongly counter to the kind of thorough scrutiny that these promotions deserve. Reviewing any promotion, whether directed at consumers or physicians, requires a detailed knowledge of the drug in question and its FDA-approved label, and a detailed review of the claims made in the promotion. This simply can’t be done at the rate currently required. In such an environment, it is inevitable that reviewers err on the side of approval rather than enforcement. The FDA should significantly increase the size of the staff and resources devoted to reviewing all drug promotions, not just DTCA.

2. End the requirement that all untitled and warning letters be reviewed by the FDA’s chief counsel, and reduce the delay for issuance of such letters.

In January 2002, HHS began requiring that the Office of FDA Chief Counsel review all untitled and warning letters prior to issuance. The GAO criticized this policy in its October 2002 report, “FDA Oversight of Direct-to-Consumer Advertising Has Limitations,” saying:

The ability to issue regulatory letters quickly after an advertising violation is identified is a key component of FDA’s oversight of DTC advertising...Prior to the policy change, FDA officials told us that regulatory letters were issued directly by DDMAC within several days of its receipt of an advertisement that it identified as misleading... Since the policy change, OCC’s reviews of draft regulatory letters from FDA have taken so long that misleading advertisements may have completed their broadcast life cycle before

¹ This assumes 239 working days per calendar year – i.e. 52 weeks less 2 weeks vacation and 11 Federal Holidays.

FDA issued the letters... [M]any television DTC advertisements are on the air for only a short time—about one-fifth of them for 1 month, and about one third for 2 months or less.

This policy thus completely undermines the effectiveness of what little enforcement authority the FDA has to police DTCA. Representative Henry Waxman has reported that in 2003, the average delay between the placement of a false and misleading advertisement and any FDA action being taken was 177 days. Thus, it is likely that in most cases, an untitled or warning letter is too little, too late, coming after the promotion in question has stopped running. This calls to mind the saying “closing the barn door after the horse is gone.” It also sends a message to pharmaceutical companies that they will more often than not get able to misleading or deceptive promotions.

An example of this took place earlier this year, when the FDA sent a letter to Lilly concerning a television ad for Strattera. As one media report described:

“In a letter to Lilly dated June 14, the FDA asked the Indianapolis drug maker to stop using the ad or similar Strattera promotional materials. Lilly hasn't aired the ad since May 22 and doesn't plan to again, said company spokeswoman Jennifer Bunselmeyer. The ad, which ran for about two months primarily on cable channels, stopped when Lilly's advertising buy ended.”²

Such delays are attributable in part to the requirement that Chief Counsel review all letters, and in part to the inadequate staff and resources for review of drug promotions. The FDA should end the Chief Counsel review requirement.

3. Require pre-dissemination submission of all DTCA.

Currently, pharmaceutical companies are only required to submit DTCA promotions to the FDA after they have begun running. This creates the problem described above, where ad campaigns have often run their course by the time FDA review is completed. The PhRMA guidelines suggest: “Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.” Of course, since this is merely a suggestion, there is no guarantee that any manufacturer will comply with it, or do so all the time. The FDA should require that not only all TV ads, but all radio, print and online advertisements be submitted prior to ‘broadcast.’ Of course, this requires that the FDA have sufficient staff and resource capacity to review these submissions to avoid the problem described above of completing reviews after promotions have run their course.

4. Seek Congressional authority to impose civil monetary penalties

Currently, there is a huge gap in the FDA’s enforcement authority that renders its untitled and warning letters ineffective. At best, such a letter will prompt the manufacturer to stop running the ad in question. But they are ineffective at fostering compliance generally. This is because manufacturers are aware that the risk of real enforcement is essentially absent. The only tools beyond letters at the FDA’s disposal are injunctions and seizure. These are severe and blunt instruments, and thus the FDA is hesitant to use them. Manufacturers know this, and so that they

² “FDA criticizes content of Lilly television spot,” J.K. Wall, Indianapolis Star, June 17, 2005

know that there is nothing to back up the untitled and warning letters. It is akin to what the comedian Robin Williams has said that unarmed British police shout to fleeing criminals “Stop, or I’ll shout ‘Stop’ again!”

Even if such civil monetary penalties were seldom used, the risk alone would vastly improve compliance. Without them, the FDA is reduce to being an occasional scold, and one whose verbal reprimands come too late and elicit nothing meaningful in terms of changes in corporate behavior. **The FDA should seek Congressional authority to impose civil monetary penalties on manufacturers that violate the FDA standards on DTCA.**

5. Prohibit “reminder advertisements”

So-called reminder ads are those in which only the name of a drug is mentioned and nothing about the approved indications. The FDA does not require any risk information to be included in such ads because the benefits are not being described either. The logic seems to be that manufacturers must present the “bitter with the sweet” – the absence of any “sweet” (benefits, indications) thus means there needs be no “bitter” (risks, side effects). This logic is flawed and fails to recognize the harm done by reminder ads. A message that says nothing more than “Ask your doctor if Drug X is right for you” does absolutely nothing to educate the consumer. Its only purpose is to increase the name recognition of the drug and bolster those longer ads for the drug that do contain the benefits and risks.

Furthermore, some reminder ads veer dangerously close to description of benefits and indications. The FDA did take action against one such ad in the past year – Pfizer’s “Wild Thing” Viagra ad. This ad clearly crossed the line into describing uses and benefits and the FDA rightly took action. However, while other reminder ads may not come as close to violation as that one, some do suggest the drug’s uses and benefits, even if only subtly, through graphics and visuals. The age and appearance of actors appearing in the ads, for instance, can suggest what the drug is used for and by who.

The PhRMA guidelines purport to put an end to reminder ads. Since these guidelines are voluntary, that is inadequate. **The FDA should issue a regulation or guidance prohibiting reminder ads as a violation of the relevant FDA standards on DTCA. Any advertisement including the name of a drug should be required to disclose the same risk information as an ad describing the drug’s use.**

6. Regulate so-called “disease awareness” ads

There has been much speculation in the past year that the pharmaceutical industry will “tone down” its DTCA in the wake of the Vioxx and Celebrex scandals. Industry press and spokespeople have said that there will be shift to so-called “disease awareness” ads. Such ads merely describe a medical condition, and do not mention a particular medication (although they at times mention that prescription medications are available for that condition). Such ads are supposedly more educational and less promotional than traditional DTCA. This may be true up to a point, in that they do not promote a particular medication, but the same financial motives still underlie their use. As one article on celebrities appearing in such ads put it, “[D]isease awareness

ads work particularly well for a company whose drug is the leader in a category, because it is sure to gain sales from new patients seeking treatment.”³ Not surprisingly, many of these ads are in fact sponsored by the companies whose drugs are the leaders in the therapeutic class treating that condition.

These are not public service announcements. Educating the public about medical conditions is of course extremely valuable, but we should not entrust that education to such self-interested parties as the companies that stand to make billions from increased use of prescription drugs. Instead, such education should be carried out by public health authorities and by non-profit organizations that are not funded by the drug industry (as unfortunately many disease organizations and patient advocacy groups are).

Disease awareness ads are the new “reminder ads.” Usually, they refer viewers to a website or toll-free number set up by the sponsor. These websites and toll-free hotlines frequently tout a particular drug made by that sponsor. An excellent example of this is a Pfizer-sponsored ad about depression featuring Lorraine Bracco, star of “The Sopranos.” In the television ad, she discussed her battle against depression, and no mention is made of any drug. She refers viewers to a website, **depressionhelp.com**. That website is an untrammelled promotion of Pfizer’s SSRI, Zoloft. The link between the original supposedly non-promotional ad, and the website promoting Zoloft belies the claim that disease awareness ads are some benign form of public education.

DEPRESSIONHELP.COM
Why Live with Depression?™

I made a conscious decision after that year of being unhappy - I said, I'm moving forward. I can't stay where I'm at because this is not working for me. And that's when I went to the doctor.

I was diagnosed as clinically depressed by my doctor. He said, I'm going to put you on an anti-depressant and put me on **Zoloft® (sertraline HCl)**. I was also in therapy. Taking these pills changed the quality of my life. And let me tell you something...getting treatment was the best thing I've ever done for myself. I finally moved forward. And I got rid of that "veil" that was covering me.

As an actor, I was afraid that taking medication would affect my acting ability...that I wouldn't have my full range of emotions. But it's not like that. It didn't change my personality. I just felt like a better version of myself.

Do I think I'm brave for talking about depression? I don't think it has anything to do with bravery, I think it's a

LORRAINE BRACCO, ACTOR

The online materials that disease awareness ads refer people to are subject to regulation as DTCA promotions when they promote particular drugs. However, up to now, the referring “disease awareness” have not been. These awareness ads function as “barkers,” steering consumers to promotional materials that do discuss a particular drug’s benefits and risks. **When**

³ “Web Sites New Twist in Celebrity Drug Ads,” Linda A. Johnson, Associated Press, July 17, 2005

there is an explicit link between a “disease awareness” ad and another DTCA source that is subject to regulation, the original ad should be considered part of the same promotional materials to which it links and subject to regulation as well. Thus, if the source to which the awareness ad refers promotes a particular drug, the referring awareness ad should be subject to the same balance and disclosure requirements as any DTCA promotion.

7. Regulate ads to children

There is a disturbing trend towards targeting drug ads to children, particularly for acne medications. Such advertisements use the same tactics of psychological manipulation that marketers have honed to a science to market junk food, toys, music and movies to children. For those products, it is reprehensible, but for prescription drugs, it is obscene. Children and teenagers are not able to fully appreciate and balance the risks and benefits of a prescription drug. Furthermore, the age at which children are most targeted by acne medication ads is a time when they often feel significant lack of self-confidence, peer pressure, and a desire to fit in. These ads exploit these normal features of adolescence and encourage teens to pressure their parents and physicians for prescriptions. Worse yet, a number of these create completely inappropriate incentives for teens. A promotion for Differin offers teens a certain number of free music downloads for every prescription filled. Such linked promotions, if not already illegal, certainly should be.

**Get Free Music.
Fight Acne.
Stay cool.**

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.

Do you need to print your proof of purchase form? [Do it here.](#)

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

tell a friend

The FDA should promulgate regulations or a guidance prohibiting DTCA directed at children (as shown by the apparent age of models and actors, the appearance of such ads during children’s programming or in children’s publications, etc). The FDA should also prohibit promotions that offer free or discounted goods for filling a prescription that are unrelated to the prescription itself.

8. Prohibit coupons

A common tool used by drug companies is the coupon. Coupons are the consumer counterpart to the samples pushed on doctors by pharmaceutical detailers. But coupons are much more nefarious. Although such coupons are not usable unless and until a doctor writes a prescription for the drug in question, they multiply the consumer’s incentive to ask for a particular drug. DTCA already improperly influences consumers to ask their doctors for particular prescriptions. Adding a coupon, and the irresistible allure of saving money, to the equation ramps up the consumer’s desire for that drug and the pressure placed on the doctor. This moves the decision even further away from medical value that it has already become in the wake of DTCA. It adds further irony that for many drugs offering coupons, much cheaper and equally effective generic and over the counter options are available for the vast majority of patients. Thus, even with a coupon, many consumers are still paying more than they need to.

Consumer-directed coupons for prescription drugs are a completely inappropriate form of DTCA and should be flatly prohibited. The FDA should promulgate regulations to this effect.

9. Return to pre-1997 requirements

Finally, none of the recommendations above cut to the heart of the worst problems of broadcast DTCA. In a 30-second or 1-minute TV or radio ad, there is simply no way to give enough information to consumers, in an understandable way, to enable them to adequately and appropriately reach a conclusion about a particular drug. Only a full disclosure the risks, benefits and side effects of a drug, in a manner and format that is understandable by the majority of the population, is adequate to reach this goal. Prior to 1997, the FDA required this level of information in broadcast DTCA. The shift to requiring only the “major statement” coupled with a reference to an outside source for more information unleashed the tidal wave of DTCA over the past eight years, with all the negative effects described previously. The examples above of the effects of DTCA on the inappropriate usage of Vioxx and Nexium give ample evidence of the insufficiency of the current requirements for DTCA.

The FDA should return to the pre-1997 requirements of full disclosure of risks and benefits. Only this will adequately protect consumers and ensure that drug ads do not overpromise and undereducate. The drug industry will no doubt complain that this will undermine the “educational value” of DTCA, but in truth it will further that supposed educational goal by ensuring consumers are given full information. If that information can’t be included in an understandable television or radio ad, then there should be no television or radio ad for that drug. Such a change would no doubt greatly reduce the number of broadcast drug ads, paring it down to only those that can be adequately described in that format.

Conclusion

In sum, we feel strongly that DTCA has had a very negative effect on the use of prescription drugs in the U.S. It has convinced consumers that drugs of little benefit over their predecessors are “wonder drugs.” It has pushed expensive brand-names over cheaper generics of equal efficacy. It has undermined the doctor-patient relationship so essential to effective treatment. It has distorted the research priorities of the industry. The list of negative effects goes on and vastly outweighs any educational value offered by such ads (which is questionable at best).

The FDA’s enforcement over the past seven years has been on a consistent downward trend, with a slight uptick only in the past year. Much greater enforcement and oversight is needed. The FDA needs to dedicate adequate staff and resources to policing all forms of drug promotions, including DTCA. The changes we propose above will help alleviate some of the negative effects of runaway drug promotions, but are only a start. We appreciate the opportunity to offer our testimony today.