

### In This Issue...

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*The sheer volume of promotional media generated by the pharmaceutical industry easily overwhelms the capacity of FDA staff dedicated to their review. What does that mean for those of us watching the ads?*

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*We also look at how pharmaceutical advertising—like advertising for any other consumer product—encourages us to believe that prescription drugs will transform our lives.*

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## Theme: Media Literacy and Pharmaceutical Advertising

Prescription drugs are marketed today like blockbuster Hollywood films. According to a 2003 report by the Kaiser Family Foundation, 6 of the top 10 drugs promoted through direct-to-consumer advertising were among the top 20 drugs in dollar sales and in the number of prescriptions dispensed in 2000 (“Impact of Direct-to-Consumer Advertising on Prescription Drug Spending, p. 5).

Despite its public image as a ‘watchdog’ agency, the federal Food and Drug Administration has relatively little power to correct any inflated claims pharmaceutical companies make for their most popular drugs. User fees from drug companies comprise more than half of the FDA’s funding for review of their products, and the great majority of those funds are used for evaluating and approving new drugs. Little remains for monitoring product marketing, and, typically, the FDA sends enforcement letters for misleading direct-to-consumer advertising months after an advertisement has been published or aired (Angell, *The Truth About the Drug Companies*, 208-210; Roynce and Myers, “Recognizing Consumer Issues,” 71-74). With so many advertisements escaping even the most basic review, media literacy and health literacy skills have become crucial for consumers who want to make reasoned decisions about prescription drugs.

Questions about the effects of ‘blockbuster’ pharmaceutical marketing on the quality of our health care system have become more persistent over the last decade. Since 2000, several heavily promoted drugs were withdrawn from the market due to the adverse effects they caused, including Merck’s pain-relieving drug Vioxx, which was found to have caused heart attacks and other cardiovascular “events” in over 130,000 patients (Lurie, “DTC Advertising Harms Patients,” p.445).

As Howard Brody and Donald Light observe in a March 2011 article in the *American Journal of Public Health*, when drugs have been found to be less effective or safe than originally thought, the pharmaceutical industry often characterizes those events as “unavoidable risks and bad luck.” The authors make a rather pointed counter-argument to these claims: the benefit-to-harm ratio of drugs tends to vary inversely with how aggressively the drugs are marketed (“The Inverse Benefit Law,” p.399).

The inverse benefit argument is based on the need of pharmaceutical companies to expand the markets for their products. The authors argue that the greater chance for benefit from drug treatment is concentrated among those patients with the most severe symptoms or the highest level of risk for disease. At some evidence-based threshold, drug therapy is recommended for the disease or risk state. Because a small group of people is targeted (in comparison to the general population), the number of adverse reactions to the drug will be relatively low. Drug companies, however, have a disincentive to adhere to an evidence-based threshold. Instead, they will market their product to populations at low risk for a disease, and as the drugs are administered, the number of adverse reactions—which may include death—will increase.

This argument might appear to be a simple thought experiment, but the authors refer to articles from periodicals such as *Lancet* and the *Journal of the American Medical Association* which point to financial ties to the pharmaceutical industry among members of expert panels who issue the clinical guidelines which determine the threshold for treatment of conditions and diseases such as diabetes and high cholesterol. As the authors note, the threshold measures for diagnosis and treatment for both conditions have been steadily revised downward.

In this issue of *Connections*, we investigate the role which media originating from the pharmaceutical industry play in our health care system, as well as the role which this industry plays in our society as a whole. There is great educational potential in direct-to-consumer advertisements, yet most do not deliver the kind and quantity of information which audiences need to make health decisions. While it is not the fault of the pharmaceutical industry that we are swimming in a sea of information about the use of drugs for treatment of disease, it can be held responsible for lowering the quality and reliability of information typically accessed by both doctors and patients (Clinical guidelines are just one example). And while it is a valid question whether most of us believe we are too busy or under too much stress to address health challenges through changes in behavior, brand name drugs are consistently marketed and promoted not only as a treatment for disease, but as a legitimate lifestyle choice.

In our resources section, we also direct you to a small but reliable set of resources about pharmaceuticals and the pharmaceutical industry. And in the MediaLit Moment for this issue, your students will have the chance to identify the Western genre in film, in its many and sometimes fantastic expressions.

## Research Highlights

### The Quality of Information About Prescription Drugs

In 1997, the federal Food and Drug Administration radically revised its standards for advertising of prescription drugs to consumers. Previously, all advertisements in all formats were required to publish a Brief Summary, which provided an often extensive review of the actions, indications (i.e., conditions drugs are intended to treat) and potential adverse effects of the drug advertised. With the new ruling, the FDA allowed direct-to-consumer (DTC) advertisements to refer consumers to websites, print advertisements or toll-free telephone numbers for the Brief Summary information.

Growth in DTC broadcast advertising since the change in policy has been explosive. In 2008, expenditures reached \$4.3 billion, and comprised one of the largest ad categories, second only to automobiles (*USA Today*, “Lawmakers Push to End Drug Ads Targeting Consumers,” August 10, 2009). Most reports also show that DTC advertising is effective. For example, one 2002 analysis found that every \$1,000 in advertising for prescription antilipidemic drugs (to combat high cholesterol) yielded 41 new prescriptions for advertised drugs (as cited in Koch-Laking et al., “Does DTC Advertising Affect Physician Prescribing Habits?”, p.650).

In its guidelines for DTC advertisements, the FDA tends to focus on the “fair balance” of statements of benefits and risk, and this is especially true of the relatively few enforcement actions it takes. Yet this emphasis leaves open a wide range of questions which ads would need to answer for consumers to decide whether they might be suitable candidates for drug treatment. Most give a general description of the condition and describe some of its symptoms. In a literature survey, Frosch et al. find that significantly fewer ads provide information on the prevalence of, risk factors for, or causes of the condition which the drug is supposed to treat. Moreover, only a minority of ads acknowledge any variations in product effectiveness, and fewer than one third of ads provide information about alternative treatments, including changes in behavior (“A Decade of Controversy,” p.24).

With the Brief Summary restrictions removed, the benefits claimed for these products are often stated in ambiguous, emotional terms and elaborated through storytelling devices. Many television advertisements follow a familiar plot structure: a character is depicted who has lost the ability to participate in cherished everyday activities. With the help of the drug, the character is able to regain control, often to the welcome or approval of others around him (Frosch et. al, “Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising”). Moreover, the ambiguity in such advertisements does not represent an unintentional oversight, but rather a conscious strategy for enhancing audience expectations regarding the effectiveness of the drug.

But surely consumers can rely on their physicians for reliable information on prescription drugs? Sadly, this is not always the case. Sales representatives, also known as “detailers,” are often the first source of information for doctors regarding new pharmaceuticals. In 2004,

the industry fielded over 100,000 sales representatives, roughly one for every six practicing physicians (Petersen, *Our Daily Meds*, p.8). In his 2004 book *Powerful Medicines*, Jerry Avorn, a professor at Harvard Medical School, recounts the results of a random sample study he conducted of primary-care physicians in the greater Boston area: fully a fifth of physicians reported that detailers were an important source of influence on their prescribing (p.294).

Over the last decade, attempts to influence physician prescriptions have reached far beyond the realm of detailing and free samples. Experts on medical school faculties, sought out by marketers as “key opinion leaders,” are hired as consultants to write publications and give talks at medical meetings to promote brand name drugs. Annual consulting fees for their services can run in the hundreds of thousands of dollars. For physicians lower down in the chain of influence, companies often pay for post-graduate continuing education courses. A substantial number of “courses” are simply industry-sponsored symposia (Angell, *The Truth About Drug Companies*, chapter 8).

Readers may take heart that the Association of American Medical Colleges has drafted a detailed model conflict-of-interest policy which several major academic medical centers have begun to implement. But what can consumers do to raise standards of quality for information on prescription drugs? For readers versed in media literacy skills, you may want to practice both media and health literacy skills by critiquing sample ads. The article titled “A Decade of Controversy,” mentioned above, includes a page of proposed content guidelines for prescription drug advertisements, many of which can be used for that purpose. Some sources of reliable consumer information are available, such as the National Institute for Health’s Medline Plus website, and the health section of the Consumer’s Union site (Please see our Resources section for more). To date, many proposals have been circulated for educating physicians and patients about pharmaceuticals (e.g., forging partnerships between medical and pharmacy schools), but few seem to have generated key legislation or new brick-and-mortar institutions. At this point in time, your active participation as a citizen may be of the greatest value, and you may wish to visit our resources section to find listings of reform organizations which can provide you with information on new initiatives in the field.

### **Blurring the Line Between Dissatisfaction and Disease**

Pre-Menstrual Dysphoric Disorder is one of those conditions which brings the ironies of advertising a disease into sharp relief. PMDD was added to the Diagnostic and Statistical Manual of Mental Disorders (DSM) in 1987 to separate normal pre-menstrual tensions from a severe form of mood disturbance which could be disabling for some women and warrant treatment. But so little was known about its causes or even its treatment that it was also listed in the appendix as a tentative unofficial condition requiring further research. In 1998, Eli Lilly gathered a ‘roundtable’ of experts who were able to convince FDA representatives in attendance that the company’s anti-depressant drug Prozac could be a viable treatment for PMDD, and the drug was approved for that purpose the following year. Months after approval, Lilly aired a television ad which featured a woman attempting—with

increasing exasperation—to disentangle a shopping cart from an interlocked row, followed by the voiceover: “Think it’s PMS? It could be PMDD.” In a single stroke, Lilly condensed a decade of debate into a single image which blurred the line between disease and everyday experience (Moynihan and Cassels, *Selling Sickness*, chapter 6).

Lilly’s ad is hardly unique, however. In terms of structure and theme, most DTC television advertising of drugs jumps between disease and normal functioning. Even if the drug is intended to help patients with a condition as serious as diabetes, the ad is likely to bypass realistic discussion of the drug as a therapy for the condition, and instead show characters regaining the ability to take part in pleasurable everyday activities. The implicit message is that the drug will improve one’s life.

In one chapter of her 2008 book *Our Daily Meds*, Melody Petersen, a reporter for the *New York Times*, visits her home state of Iowa to discover that many of her fellow citizens appear to have received the message that prescription medications can be used for the purpose of self-improvement, if not self-transformation. Particularly striking is her portrait of Patrick Hurley. At 42, distraught after an affair and a divorce, Hurley was diagnosed with adult ADHD. With just one sample of Ritalin, Hurley says, almost every troubling experience from his past made sense in his mind. Now in his early fifties, Hurley has become an informal coach for those with the disorder. At the time of the interview, Hurley’s “clients” included a lawyer, a nurse with a PhD, and three engineers from Rockwell Collins, a military contractor in Cedar Rapids.

Hurley argues that some of the “greatest minds” may have had ADHD, and seems to believe that medication can unmask the latent genius within. Petersen notes that Hurley’s theory is reflected in drug advertising as well. “Does living up to your potential feel like a game that never goes your way?” asks one 2005 ad on a website promoting Strattera, Eli Lilly’s attention deficit disorder drug. The ad featured a bespectacled man, somewhere between ages twenty and thirty, who vaguely resembled Bill Gates. The tag line: “Focus on the possible” (p.82).

Petersen’s book suggests there is no real epidemic of ADHD in the United States. Rather, more Americans are demanding the drugs which treat it. In their book *Selling Sickness*, Ray Moynihan and Alan Cassels cite a 2003 *Reuters Business Insight* report which forecasts the greatest growth in the pharmaceutical industry in sales of ‘lifestyle drugs.’ At one point the report waxes prophetic: “The medicalization of many natural processes is creating markets for . . . drugs for those who want to ‘optimize quality of life’” (p. 179). This is one area in which the pharmaceutical industry clearly distorts the priorities of our health care system. By marketing more and more to the ‘unhappy healthy,’ pharmaceutical companies trivialize the needs and experiences of patient populations who are most likely to benefit most from drug treatment—including the children and adults who need treatment for severe symptoms of ADHD.

By now, Americans seem to have already grown accustomed to the use and promotion of prescription drugs as a lifestyle choice, and nowhere is this more evident than in the marketing and prescription of drugs for erectile dysfunction. Viagra, for example, was intended for men suffering from impotence, and was initially marketed to older patients. But according to figures released in 2003 by Pfizer, 10 percent of the 16 million prescriptions written for Viagra since its introduction in 1998 had been for men under 39 (St. John, "In an Oversexed Age, More Guys Take a Pill," *New York Times*, December 14, 2003)

In the same *New York Times* article, a Pfizer spokeswoman denied that the company intended to promote the drug to younger men. But consider the following television advertisement produced four years later: a group of healthy-looking 40-something men are jamming together in a roadside bar. The song they're performing sounds familiar—the melody line is from Elvis Presley's "Viva Las Vegas!" But something seems a little out of place when one man belts out, "Cant' wait to go home." The final line in the song? "Viva Viagra!" (Paoletta, "What Would Elvis Think?," *Billboard Magazine*, August 18, 2007).

### ***Internet Protocol with Tish***

<http://www.YouTube.com/IPTish>

*Internet Protocol with Tish*, hosted by Letitia Miele, provides interviews and information on using the internet wisely. CML President Tessa Jolls was a recent guest on the show titled *Parental Controls*. Find the YouTube video posted [here](#).

### **CONSORTIUM for MEDIA LITERACY**

*Uniting for Development*

#### **About Us...**

The Consortium for Media Literacy addresses the role of global media through the advocacy, research and design of media literacy education for youth, educators and parents.

The Consortium focuses on K-12 grade youth and their parents and communities. The research efforts include nutrition and health education, body image/sexuality, safety and responsibility in media by consumers and creators of products. The Consortium is building a body of research, interventions and communication that demonstrate scientifically that media literacy is an effective intervention strategy in addressing critical issues for youth.

[www.consortiumformedia literacy.org](http://www.consortiumformedia literacy.org)

## Resources for Media Literacy

**Teaching Tip:** Create a list of online resources for yourself and the parents of your students. Start by watching the YouTube included in CML News this month. We believe a team approach of teachers, students, and parents is important to media literacy learning.

### Resources: Media Literacy and the Pharmaceutical Industry

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#### Recommended Articles

Groopman, Jerome, and Pamela Hartzband. "Designing a Smarter Patient." *Wall Street Journal* 24 September 2011. <[www.wsj.com](http://www.wsj.com)>

Good exercise in health literacy regarding the benefits of drug treatment and the risk of disease.

Greene, Jeremy A., and David Herzberg. "Hidden in Plain Sight: Marketing Prescription Drugs To Consumers in the Twentieth Century." *American Journal of Public Health* 100.5:792-803.

Discusses the evolution of drug advertising from the 1906 passage of the Pure Food and Drug Act to the present.

Willman, David. "How a New Policy Led to Seven Deadly Drugs." *Los Angeles Times* 20 December 2000. <[www.latimes.com](http://www.latimes.com)>

Pulitzer prize-winning story on the consequences of policy shifts at the FDA towards an expedited drug approval process.

*Pro Publica*, "Dollars for Doctors" series, [www.propublica.org](http://www.propublica.org)

Citizen journalists at Pro Publica have sifted through the public court documents of seven major pharmaceutical firms to compile a database of payments made to physicians, and have written a number of informative articles based on the data. Some academic medical centers have also been utilizing the database to help enforce conflict-of-interest policies.

## Sources for Information and Advocacy

Public Citizen [www.citizen.org](http://www.citizen.org)

Public Citizen has been acknowledged in academic publications for its health policy research. You'll find a substantial amount of material for consumers at the Health Research Group section of the site, including links to important FDA sites and worstpills.org, a sub-site which provides reviews of prescription drugs.

Medline Plus [www.nlm.nih.gov/medlineplus/](http://www.nlm.nih.gov/medlineplus/)

MedlinePlus is the National Institute of Health's web site for patients. Produced by the National Library of Medicine, it provides reliable information about diseases, conditions, and wellness issues in language which most consumers can understand. The site also offers information on clinical trials, and links to medical research. Some articles on the site feature illustrations and medical videos as well.

Consumers Reports "Best Buy" Drugs

[www.consumerreports.org/health/best-buy-drugs/index.htm](http://www.consumerreports.org/health/best-buy-drugs/index.htm)

In addition to reporting on the best values in prescription drugs, this section of the Consumer Reports site offers advice on a number of prescription drug issues, such as off-label prescribing by physicians.

The Pew Prescription Project [www.prescriptionproject.org](http://www.prescriptionproject.org)

The Pew Prescription Project is an initiative to promote consumer safety through reforms in the approval, manufacture and marketing of prescription drugs, as well as through initiatives to encourage evidence-based prescribing. The project also conducts research related to federal oversight of drug safety to illuminate problems and potential solutions. Current goals include passage of the Physician Payments Sunshine Act, and the Independent Drug Education and Outreach Act.

## MediaLit Moments

### Just a Little Outpost on the (Animated) Frontier

March saw the release of one of the most offbeat movies of the year. Rapidly spinning off allusions to works and authors as various as “Chinatown” and Carlos Castaneda, “Rango” featured a cast of computer-animated creatures who populate a small Western desert town in desperate need of water. Despite its quiriness, “Rango” remains faithful to the Western genre in many respects, and in this MediaLit Moment, your students will have the chance to discover the significance of the Western genre to American film, and to American society.

#### **Ask students to make a list of elements common to the Western genre**

**AHA!** Wherever and whenever they take place, Westerns all have similar characters facing the same kinds of challenges!

**Key Question #2:** What techniques are used to attract my attention?

**Core Concept #2:** Media messages are constructed using a creative language with its own rules.

**Key Question #4:** What values, lifestyles and points of view are represented in, or omitted from, this message?

**Core Concept #4:** Media have embedded values and points of view.

**Grade Level:** 6-8

**Materials:** Television, DVD player, DVD of “Rango” and possibly another Western film

**Activity:** For students who are unfamiliar with “Rango,” explain its basic premise: A pet gecko who dreams of doing something important is abandoned in the desert, and stumbles into a small Western town full of other creatures. After an act of courage (or is that foolhardiness?), he is made town sheriff, and the people begin to look up to him as the hero who can discover where their water has gone, and find a way to get it back.

Play an excerpt for students in which Rango (voiced by Johnny Depp) enters the town saloon and boasts that he killed the outlaw Jenkins brothers with one bullet. Ask, can you think of any other scenes from Western movies where a hero makes his entrance? What do they have in common? Next, expand the scope of investigation, and ask students to brainstorm a list of things common to most Westerns. This is where the fun really begins, as students discover that they know much more about Westerns than they might have guessed.

If students need any help or prompting, here’s a sampler—

Locations: saloon, bank, jail

Characters: the courageous sheriff, the villainous gunslinger, the corrupt judge, the female

character who refuses to defer to men

Themes: small town threatened by powerful outsiders; frontier justice; cattle rustling, land grabbing and other resource issues

Finally, focus the discussion on the theme of justice, which is common to nearly every Western. How is justice served when government is weak? Is it always accomplished through violence? How do different Western heroes respond when confronted by powerful antagonists? (Rango is definitely not a typical hero in this genre). If you wish, play a clip from a classic Western for comparison. Here are some suggested titles: "High Noon," "Rio Bravo," "The Ox-Bow Incident," "Destry Rides Again."

For more ideas go to: <http://vtropes.org/pmwiki/pmwiki.php/Main/Literature>. This site addresses techniques that are used in storytelling, and one of the categories is Westerns.

The Five Core Concepts and Five Key Questions of media literacy were developed as part of the Center for Media Literacy's MediaLit Kit™ and Questions/TIPS (Q/TIPS)™ framework. Used with permission, © 2002-2011, Center for Media Literacy, <http://www.medialit.com>